UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

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FOR	M 10-Q
(Mark One) Z QUARTERLY REPORT PURSUANT TO SECTION 1934	13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF
For the quarterly per	riod ended June 30, 2016
	OR
☐ TRANSITION REPORT PURSUANT TO SECTION 1 1934	13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF
Commission file	number 001-36014
	CEUTICALS, INC. nt as Specified in Its Charter)
Delaware (State or Other Jurisdiction of Incorporation or Organization)	26-0662915 (I.R.S. Employer Identification No.)
88 Sidney Street, Cambridge, Massachusetts (Address of Principal Executive Offices)	02139 (Zip Code)
` '	649-8600 lumber, Including Area Code)
(Former Name, Former Address and Form	ner Fiscal Year, if Changed Since Last Report)
	equired to be filed by Section 13 or 15(d) of the Securities Exchange Act of strant was required to file such reports), and (2) has been subject to such filing
	ally and posted on its corporate Web site, if any, every Interactive Data File (§232.405 of this chapter) during the preceding 12 months (or for such shorter No \square
Indicate by check mark whether the registrant is a large accelerated file See the definitions of "large accelerated filer," "accelerated filer" and "smalle	r, an accelerated filer, a non-accelerated filer, or a smaller reporting company. er reporting company" in Rule 12b-2 of the Exchange Act. (Check one):
Large accelerated filer 🗵	Accelerated filer □
Non-accelerated filer	Smaller reporting company □
Indicate by check mark whether the registrant is a shell company (as de-	rfined in Rule 12b-2 of the Exchange Act). Yes □ No ⊠
Number of shares of the registrant's Common Stock, \$0.001 par value,	outstanding on August 5, 2016: 38,046,368

Signatures

AGIOS PHARMACEUTICALS, INC.

FORM 10-Q

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited).

AGIOS PHARMACEUTICALS, INC.

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

	June 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	\$ 234,048	\$ 71,764
Marketable securities	231,321	245,238
Collaboration receivable – related party	7,853	8,225
Tenant improvement and other receivables	2,014	3,374
Prepaid expenses and other current assets	8,923	8,728
Total current assets	484,159	337,329
Marketable securities	46,926	58,905
Property and equipment, net	25,134	23,220
Other assets	1,382	611
Total assets	\$ 557,601	\$ 420,065
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 18,448	\$ 14,748
Accrued expenses	14,414	15,996
Deferred revenue – related party	31,469	19,665
Deferred rent	2,933	2,479
Total current liabilities	67,264	52,888
Deferred revenue, net of current portion – related party	183,540	4,699
Deferred rent, net of current portion	17,719	17,360
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 25,000,000 shares authorized; no shares issued or outstanding at June 30, 2016 and December 31, 2015		
Common stock, \$0.001 par value; 125,000,000 shares authorized; 38,029,510 and 37,696,502 shares issued and	_	_
outstanding at June 30, 2016 and December 31, 2015, respectively	38	38
Additional paid-in capital	652,574	630,078
Accumulated other comprehensive income (loss)	297	(318)
Accumulated deficit	(363,831)	(284,680)
Total stockholders' equity	289,078	345,118
Total liabilities and stockholders' equity	\$ 557,601	\$ 420,065

AGIOS PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Operations (in thousands, except share and per share data) (Unaudited)

	Three Months Ended June 30, 2016 2015		Six Months E 2016		s Ended June 30, 2015			
Collaboration revenue – related party	\$	6,978	\$	13,219	\$	38,259	\$	47,421
Operating expenses:								
Research and development (net of \$5,922 and \$4,546 of cost reimbursement from related party for the three months ended June 30, 2016 and 2015, respectively, and \$14,716 and \$8,912 for the six months								
ended June 30, 2016 and 2015, respectively)		50,804		36,423		94,842		68,866
General and administrative		12,644		8,929		23,481		15,883
Total operating expenses		63,448		45,352		118,323		84,749
Loss from operations		(56,470)		(32,133)		(80,064)		(37,328)
Interest income		517		236		913		474
Net loss	\$	(55,953)	\$	(31,897)	\$	(79,151)	\$	(36,854)
Net loss per share – basic and diluted	\$	(1.47)	\$	(0.85)	\$	(2.09)	\$	(0.99)
Weighted-average number of common shares used in net loss per share – basic and diluted	3′	7,956,383	3	7,329,220	3′	7,910,233	3	7,272,300

AGIOS PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Comprehensive Loss (in thousands) (Unaudited)

	Three Moi June	oths Ended	nded Six Months Ende June 30,		
	2016	2015	2016	2015	
Net loss	\$(55,953)	\$(31,897)	\$(79,151)	\$(36,854)	
Other comprehensive income:					
Unrealized gain on available-for-sale securities	208	31	615	279	
Comprehensive loss	\$(55,745)	\$(31,866)	\$(78,536)	\$(36,575)	

AGIOS PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Cash Flows (in thousands) (Unaudited)

	Six Montl June	
	2016	2015
Operating activities		
Net loss	\$ (79,151)	\$ (36,854)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	2,550	1,150
Stock-based compensation expense	20,103	13,237
Net amortization of premium and discounts on investments	330	319
Changes in operating assets and liabilities:	272	(2,002)
Collaboration receivable – related party	372	(3,982)
Tenant improvement and other receivables	1,360	(2,948)
Prepaid expenses and other assets Accounts payable	(1,129) 3,755	(1,210)
Accounts payable Accrued expenses and other liabilities	(833)	(2,558)
Deferred rent	813	13,689
Refundable income taxes and income taxes payable	013	3,841
Deferred revenue – related party	190,645	(6,414)
Net cash provided by (used in) operating activities	138,815	(21,605)
	130,013	(21,003)
Investing activities Purchases of marketable securities	(22 (200)	(106.205)
Proceeds from maturities and sales of marketable securities	(226,289) 252,468	(106,205)
Purchases of property and equipment	(5,267)	198,078 (14,679)
Net cash provided by investing activities	20,912	77,194
Financing activities		
Payment of public offering costs		(207)
Net proceeds from stock option exercises and employee stock purchase plan	2,557	3,120
Net cash provided by financing activities	2,557	2,913
Net increase in cash and cash equivalents	162,284	58,502
Cash and cash equivalents at beginning of the period	71,764	14,031
Cash and cash equivalents at end of the period	\$ 234,048	\$ 72,533
Supplemental disclosure of non-cash investing and financing transactions		
Additions to property, plant and equipment in accounts payable and accrued expenses	\$ 1,360	\$ 1,531
Vesting of restricted stock	<u> </u>	\$ (4)
Proceeds from stock option exercises in other current assets	\$ 23	\$ 3

Agios Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Unaudited)

1. Overview and Basis of Presentation

Overview

Agios Pharmaceuticals, Inc. ("Agios" or the "Company") is a biopharmaceutical company committed to the fundamental transformation of patients' lives through scientific leadership in the field of cancer and rare genetic metabolic disorders. The Company has built a unique set of core capabilities in the field of cellular metabolism, with the goal of making transformative, first or best in class medicines. Agios' therapeutic areas of focus are cancer and rare genetic metabolic disorders, which are a broad group of more than 600 rare genetic diseases caused by mutations, or defects, of single metabolic genes. In both of these areas, the Company is seeking to unlock the biology of cellular metabolism to create transformative therapies. The Company is located in Cambridge, Massachusetts.

Basis of presentation

The condensed consolidated interim balance sheet as of June 30, 2016, the condensed consolidated interim statements of operations and comprehensive loss for the three and six months ended June 30, 2016 and 2015 and cash flows for the six months ended June 30, 2016 and 2015, are unaudited. The unaudited condensed consolidated interim financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly the Company's condensed consolidated financial position as of June 30, 2016, its results of operations for the three and six months ended June 30, 2016 and June 30, 2015 and cash flows for the six months ended June 30, 2016 and 2015. The financial data and the other financial information disclosed in these notes to the condensed consolidated interim financial statements related to the three-month and six-month periods are also unaudited. The results of operations for the three and six months ended June 30, 2016 are not necessarily indicative of the results to be expected for the year ending December 31, 2016 or for any other future annual or interim period. The condensed consolidated interim financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2015 that was filed with the Securities and Exchange Commission (the "SEC") on February 26, 2016.

The Company's consolidated financial statements include the Company's accounts and the accounts of the Company's wholly owned subsidiaries, Agios Securities Corporation and Agios International Sarl. All intercompany transactions have been eliminated in consolidation. The consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles.

2. Summary of Significant Accounting Policies and Recent Accounting Pronouncements

Significant accounting policies

There have been no material changes to the significant accounting policies previously disclosed in the Annual Report on Form 10-K for the year ended December 31, 2015.

Recent accounting pronouncements

In May 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients ("ASU 2016-12"), which addresses implementation issues and is intended to reduce the cost and complexity of applying the new revenue standard in ASU 2014-09, discussed below. ASU 2016-12 has the same effective date as the new revenue standard, ASU 2014-09, (as amended by the one-year deferral and the early adoption provisions in ASU 2015-14). In addition, entities are required to adopt the ASU by using the same transition method they used to adopt the new revenue standard. The Company is currently in the process of evaluating the impact of the guidance on its consolidated financial statements.

In April 2016, the FASB issued ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing ("ASU 2016-10"), which clarifies identifying performance obligation and licensing implementation guidance and illustrations in the ASU 2014-09, discussed below. ASU 2016-10 has the same effective date as the new revenue standard, ASU 2014-09, (as amended by the one-year deferral and the early adoption provisions in ASU 2015-14). In addition, entities are required to adopt the ASU by using the same transition method they used to adopt the new revenue standard. The Company is currently in the process of evaluating the impact of the guidance on its consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting ("ASU 2016-09"), which simplifies several aspects of the accounting for employee share-based payment transactions, including income taxes consequences, classification of awards as either equity or liabilities, and classification in the statement of cash flows. ASU 2016-09 is effective for annual reporting periods beginning after December 15, 2016, including interim periods within those annual reporting periods. The Company is currently in the process of evaluating the impact of the guidance on its consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net) ("ASU 2016-08"), which amends the principal-versus-agent implementation guidance and illustrations in the ASU 2014-09, discussed below. ASU 2016-08 has the same effective date as the new revenue standard, ASU 2014-09, (as amended by the one-year deferral and the early adoption provisions in ASU 2015-14). In addition, entities are required to adopt the ASU by using the same transition method they used to adopt the new revenue standard. The Company is currently in the process of evaluating the impact of the guidance on its consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"), which establishes principles that lessees and lessors shall apply to report useful information to users of financial statements about the amount, timing and uncertainty of cash flows arising from a lease. ASU 2016-02 is effective for annual periods beginning after December 15, 2018 and interim periods therein, with early adoption permitted. The Company is currently in the process of evaluating the impact of the guidance on its consolidated financial statements.

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

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606). The ASU provides for a single comprehensive model for use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance. The accounting standard is effective for interim and annual periods beginning after December 15, 2016 with no early adoption permitted. In April 2015, the FASB proposed a one year deferral of the effective date of this accounting update to annual periods beginning after December 15, 2017, along with an option to permit early adoption. The Company is required to adopt the amendments in the ASU using one of two acceptable methods. The Company is currently in the process of determining which adoption method it will apply and evaluating the impact of the guidance on its consolidated financial statements.

Other accounting standards that have been issued by the FASB or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on the Company's financial statements upon adoption.

3. Fair Value Measurements

The Company records cash equivalents and marketable securities at fair value. Accounting Standards Codification ("ASC") 820, Fair Value Measurements and Disclosures, establishes a fair value hierarchy for those instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). The hierarchy consists of three levels:

- Level 1 Unadjusted quoted prices in active markets for identical assets or liabilities.
- Level 2 Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, directly or indirectly, for substantially the full term of the asset or liability.
- Level 3 Unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the asset or liability in which there is little, if any, market activity for the asset or liability at the measurement date.

The following table summarizes the cash equivalents and marketable securities measured at fair value on a recurring basis as of June 30, 2016 (in thousands):

	Level 1	Level 2	Level 3	Total
Cash equivalents	\$225,564	<u> </u>	\$ —	\$225,564
Marketable securities:				
Certificates of deposit	-	15,790	_	15,790
Government securities	169,179	_	_	169,179
Corporate debt securities	-	93,278	_	93,278
	\$394,743	\$109,068	\$ —	\$503,811

The following table summarizes the cash equivalents and marketable securities measured at fair value on a recurring basis as of December 31, 2015 (in thousands):

	Level 1	Level 2	Level 3	Total
Cash equivalents	\$ 59,332	<u> </u>	\$ —	\$ 59,332
Marketable securities:				
Certificates of deposit	-	11,243	_	11,243
Government securities	292,900			292,900
	\$352,232	\$11,243	<u>\$</u> —	\$363,475

Cash equivalents and marketable securities have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, utilizing third-party pricing services or other market observable data. The pricing services utilize industry standard valuation models, including both income and market based approaches and observable market inputs to determine value. After completing its validation procedures, the Company did not adjust or override any fair value measurements provided by the pricing services as of June 30, 2016 or December 31, 2015.

The carrying amounts reflected in the condensed consolidated balance sheets for cash, collaboration receivable – related party, tenant improvement and other receivables, prepaid expenses and other current assets, other assets, accounts payable, and accrued expenses approximate their fair values at June 30, 2016 and December 31, 2015, due to their short-term nature.

There have been no changes to the valuation methods during the three and six months ended June 30, 2016 or 2015. The Company evaluates transfers between levels at the end of each reporting period. There were no transfers of assets or liabilities between Level 1 and Level 2 during the three and six months ended June 30, 2016 and 2015. The Company had no financial assets or liabilities that were classified as Level 3 at any point during the three and six months ended June 30, 2016 or the year ended December 31, 2015.

4. Marketable Securities

Marketable securities at June 30, 2016 and December 31, 2015 consisted primarily of investments in certificates of deposit, government securities and corporate debt securities. Management determines the appropriate classification of the securities at the time they are acquired and evaluates the appropriateness of such classifications at each balance sheet date. The Company classifies its marketable securities as available-for-sale pursuant to ASC 320, Investments – Debt and Equity Securities. Marketable securities are recorded at fair value, with unrealized gains and losses included as a component of accumulated other comprehensive loss in stockholders' equity and a component of total comprehensive loss in the condensed consolidated interim statements of comprehensive loss, until realized. Realized gains and losses are included in investment income on a specific-identification basis. There were no realized gains or losses on marketable securities for the six months ended June 30, 2016 and, as a result, the Company did not reclassify any amounts out of accumulated other comprehensive income for the periods. There were immaterial realized gains on marketable securities for the three and six months ended June 30, 2015.

Marketable securities at June 30, 2016 consist of the following (in thousands):

	Amo	rtized Cost	ealized ains	ealized osses	Fair Value
Current:			 	 	
Certificates of deposit	\$	5,040	\$ 2	\$ _	\$ 5,042
Government securities		158,571	91	(1)	158,661
Corporate debt securities		67,586	38	(6)	67,618
Non-current:					
Certificates of deposit		10,720	31	(3)	10,748
Government securities		10,511	7	_	10,518
Corporate debt securities		25,522	 138	 	25,660
	\$	277,950	\$ 307	\$ (10)	\$278,247

Marketable securities at December 31, 2015 consist of the following (in thousands):

	Amo	ortized Cost	ealized ains	ealized osses	Fair Value
Current:					
Certificates of deposit	\$	11,248	\$ _	\$ (5)	\$ 11,243
Government securities		234,130	10	(145)	233,995
Non-current:					
Government securities		59,083	_	(178)	58,905
	\$	304,461	\$ 10	\$ (328)	\$304,143

At June 30, 2016 and December 31, 2015, the Company held both current and non-current investments. Investments classified as current have maturities of less than one year. Investments classified as non-current are those that (i) have a maturity of one to two years and (ii) management does not intend to liquidate within the next twelve months, although these funds are available for use and therefore classified as available-for-sale.

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

At June 30, 2016 and December 31, 2015, the Company held 13 and 74 debt securities that were in an unrealized loss position for less than one year, respectively. The aggregate fair value of debt securities in an unrealized loss position at June 30, 2016 and December 31, 2015 was \$20.3 million and \$207.4 million, respectively. There were no individual securities that were in a significant unrealized loss position as of June 30, 2016 and December 31, 2015. The Company evaluated its securities for other-than-temporary impairment and considered the decline in market value for the securities to be primarily attributable to current economic and market conditions. It is not more likely than not that the Company will be required to sell the securities, and the Company does not intend to do so prior to the recovery of the amortized cost basis. Based on this analysis, these marketable securities were not considered to be other-than-temporarily impaired as of June 30, 2016 and December 31, 2015.

5. Collaboration Agreements

2010 Agreement and amendments

In April 2010, the Company entered into a collaboration agreement focused on cancer metabolism with Celgene Corporation and related subsidiaries ("Celgene"), a related party through ownership of the Company's common stock. The agreement was amended in October 2011 and July 2014 (the agreement together with the amendments, the "2010 Agreement"). The goal of the collaboration is to discover, develop and commercialize disease-altering therapies in oncology based on the Company's cancer metabolism research platform. The Company will initially lead discovery, preclinical and early clinical development for all cancer metabolism programs under the collaboration. The discovery phase of the 2010 Agreement expired in April 2016.

The July 2014 amendment of the 2010 Agreement allowed for more flexibility in the design and conduct of phase 1 clinical trials and additional nonclinical and/or clinical activities that the Company agreed to perform at Celgene's request. This amendment further modified the mechanism and timing for payments to be made with respect to such development activities.

Under the 2010 Agreement, the Company is eligible to receive up to \$120.0 million in potential milestone payments for the AG-221 program. The potential milestone payments are comprised of: (i) a \$25.0 million milestone payment upon achievement of a specified clinical development milestone event, (ii) up to \$70.0 million in milestone payments upon achievement of specified regulatory milestone events, and (iii) a \$25.0 million milestone payment upon achievement of a specified commercial milestone event. In January 2016, the Company determined that a substantive clinical development milestone related to the AG-221 program was achieved and received a milestone payment of \$25.0 million.

Under the 2010 Agreement, the Company may also receive royalties at tiered, low- to mid-teen percentage rates on net sales. The royalty payments will be recognized as revenue in the period in which they are earned. To date, the Company has not earned any royalty payments under the 2010 Agreement.

Unless terminated earlier by either party, the term of the 2010 Agreement will continue until the expiration of the last-to-expire of all royalty terms with respect to all royalty-bearing products. Celgene may terminate this agreement for convenience in its entirety or with respect to one or more programs upon ninety days written notice to the Company. If either party is in material breach and fails to cure such breach within the specified cure period, the other party may terminate the 2010 Agreement in its entirety or with respect to one or more programs; however, if such breach relates solely to a specific program, the non-breaching party may only terminate the agreement with respect to such program. Either the Company or Celgene may terminate the agreement in the event of specified insolvency events involving the other party.

AG-881 Agreements

On April 27, 2015, the Company entered into a joint worldwide development and profit share collaboration and license agreement with Celgene and the Company's wholly owned subsidiary, Agios International Sarl, entered into a collaboration and license agreement with Celgene International II Sarl (collectively, the "AG-881 Agreements"). The AG-881 Agreements establish a worldwide collaboration focused on the development and commercialization of AG-881 products. Under the terms of the AG-881 Agreements, the Company received an initial payment of \$10.0 million in May 2015 and is eligible to receive milestone-based payments described below. The Company and Celgene will equally split all worldwide development costs, subject to specified exceptions, as well as any profits from any net sales of, or commercialization losses related to, licensed AG-881 products.

The Company is eligible to receive up to \$70.0 million in potential milestone payments related to AG-881 under the AG-881 Agreements. The potential milestone payments are comprised of: (i) a \$15.0 million milestone payment for filing of first NDA in a major market and (ii) up to \$55.0 million in milestone payments upon achievement of specified regulatory milestone events. The Company may also receive royalties at tiered, low- to mid-teen percentage rates on net sales if it elects to not participate in the development and commercialization of AG-881.

2016 Agreement

On May 17, 2016, Agios entered into a master research and collaboration agreement (the "2016 Agreement") with Celgene and Celgene RIVOT Ltd. The 2016 Agreement establishes a new global collaboration focused on the research and development of immunotherapies against certain metabolic targets that exert their antitumor efficacy primarily via the immune system. In addition to new programs identified under the 2016 Agreement, Agios and Celgene have also agreed that all future development and commercialization of two programs that were conducted under the 2010 Agreement will now be governed by the 2016 Agreement.

During the research term of the 2016 Agreement, the Company plans to conduct research programs focused on discovering compounds that are active against metabolic targets in the immuno-oncology, or IO, field. The initial four-year research term will expire on May 17, 2020. Celgene may extend the research term for up to two, or in specified cases, up to four, additional one-year terms.

For each program under the 2016 Agreement, Agios may nominate compounds that meet specified criteria as development candidates, and, in limited circumstances, Celgene may also nominate compounds as development candidates for each such program. Celgene may designate the applicable program for further development following any such nomination, after which the Company may conduct, at the Company's expense, additional pre-clinical and clinical development for such program through completion of an initial phase 1 dose escalation study.

At the end of the research term, Celgene may designate for continued development up to three research programs for which development candidates have yet to be nominated, which are referred to as continuation programs. Agios may conduct further research and pre-clinical and clinical development activities on any continuation program, at the Company's expense, through completion of an initial phase 1 dose escalation study.

The Company has granted Celgene the right to obtain exclusive options to development and commercialization rights for each program that Celgene has designated for further development and for each continuation program. Celgene may exercise each such option beginning on the designation of a development candidate for such program (or on the designation of such program as a continuation program) and ending on the earlier of the end of a specified period after Celgene is furnished with specified information about the initial phase 1 dose escalation study for such program, or January 1, 2030. Research programs that have applications in the inflammation or autoimmune, or I&I, field that may result from the 2016 Agreement will also be subject to the exclusive options described above.

Agios will retain rights to any program that Celgene does not designate for further development or as to which Celgene does not exercise its option.

Under the terms of the 2016 Agreement, following Celgene's exercise of its option with respect to a program, Agios or its affiliates and Celgene will enter into either a co-development and co-commercialization agreement if such program is in the IO field, or a license agreement if such program is in the I&I field. Under each co-development and co-commercial agreement, the Company and Celgene will co-develop and co-commercialize licensed products worldwide. Either Agios or Celgene will lead development and commercialization of licensed products for the United States and Celgene will lead development and commercialization of licensed products outside of the United States. Depending on the country, the Company and Celgene will each have the right to provide a portion of field-based marketing activities. Under each license agreement, Celgene will have the sole right to develop and commercialize licensed products worldwide.

Co-development and co-commercialization agreements

Under each co-development and co-commercialization agreement entered into under the 2016 Agreement, Agios and Celgene will split all post-option-exercise worldwide development costs, subject to specified exceptions, as well as any profits from any net sales of, or commercialization losses related to, licensed products. Celgene has the option to designate one program in the IO field as the 65/35 program, for which Celgene will be the lead party for the United States and will have a 65% profit or loss share. For programs in the IO field other than the 65/35 program, the Company and Celgene will alternate, on a program-by-program basis, being the lead party for the United States, with Agios having the right to be the lead party for the first such program, and Agios and Celgene will each have a 50% profit or loss share. The lead party for the United States will book commercial sales of licensed products, if any, in the United States, and Celgene will book commercial sales of licensed products, if any, outside of the United States.

License agreements

Under each license agreement under the 2016 Agreement, Celgene will be responsible for all post-option-exercise worldwide development and associated costs, subject to specified exceptions, as well as worldwide commercialization and associated costs, for licensed products.

Financial terms

Under the terms of the 2016 Agreement, Celgene made an initial upfront payment in the amount of \$200 million. Celgene has specified rights to extend the research term for up to two, or in specified cases, up to four, additional years by paying a \$40 million per-year extension fee. Celgene will pay an \$8 million designation fee for each program that Celgene designates for further development and for each continuation program. For each program as to which Celgene exercises its option to develop and commercialize, subject to antitrust clearance, Celgene will pay an option exercise fee of at least \$30 million for any designated development program and at least \$35 million for any continuation programs. In certain cases, Celgene may exercise its option to develop and commercialize two early-stage I&I programs, prior to Celgene designating the program for further development, by paying an option exercise fee of \$10 million.

For the co-development and co-commercialization program Celgene designates the 65/35 program in the IO field, the Company is eligible to receive up to \$209 million in potential milestone-based payments. The potential milestone-based payments for that program are comprised of: (i) a \$25 million milestone-based payment upon achievement of a specified clinical development event and (ii) up to \$184 million in milestone-based payments upon achievement of specified regulatory milestone events. For each co-development and co-commercialization program in the IO field other than the 65/35 program, Agios is eligible to receive up to \$169 million in potential milestone-based payments payable for each program selected by Celgene. The potential milestone-based payments for such programs are comprised of: (i) a \$20 million milestone-based payment upon achievement of a specified clinical development event and (ii) up to \$149 million in milestone-based payments upon achievement of specified regulatory milestone events.

For each licensed program in the I&I field, Agios is eligible to receive royalties at tiered, low double-digit percentage rates on Celgene's net sales, if any, of the applicable licensed products and up to \$386 million in potential milestone-based payments. The potential milestone-based payments for such programs are comprised of: (i) a \$25 million milestone-based payment upon achievement of a specified clinical development event, (ii) up to \$236 million in milestone-based payments upon achievement of specified regulatory milestone events, and (iii) up to \$125 million in milestone-based payments upon achievement of specified commercial milestone events.

Opt-out right

Under the 2016 Agreement, the Company may elect to opt out of the cost and profit share under any co-development and co-commercialization agreement, subject to specified exceptions. Upon opting out, Celgene will have the sole right to develop, manufacture and commercialize the applicable licensed products throughout the world, at its cost, and the Company will undertake

transitional activities reasonably necessary to transfer the development, manufacture and commercialization of such licensed products to Celgene, at the Company's expense. Further, in lieu of the profit or loss sharing described above, Agios would be eligible to receive royalties at tiered, low double-digit percentage rates on Celgene's net sales, if any, of the applicable licensed products. However, the Company would continue to be eligible to receive the developmental and regulatory milestone-based payments described above.

Term

The term of the 2016 Agreement commenced on May 17, 2016 and, if not terminated earlier, will expire upon later of the last-to-expire of the research term and all option exercise periods, or, if an option is exercised by Celgene for one or more programs in the collaboration, upon the termination or expiration of the last-to-exist co-development and co-commercialization agreement or license agreement, as applicable, for any such program.

Termination

Subject to specified exceptions, Celgene may terminate the 2016 Agreement in its entirety for any reason by providing Agios with prior written notice if there are no active co-development and co-commercialization agreements or license agreements in place or on a program-by-program basis if there are no active co-development and co-commercialization agreements or license agreements in place for the terminated program(s). Either party may terminate the 2016 Agreement for the insolvency of the other party. On a program-by-program basis, prior to the exercise of an option, either party may terminate the 2016 Agreement either in its entirety or with respect to one or more programs on prior written notice to the other party in the case of an uncured material breach by the other party that frustrates the fundamental purpose of the 2016 Agreement. Following the exercise of an option for a program, either party may terminate the 2016 Agreement with respect to such program if such party terminates the co-development and co-commercialization agreement or license agreement for an uncured material breach by the other party that frustrates the fundamental purpose of such agreement. Either party may terminate a co-development and co-commercialization agreement or a license agreement upon the bankruptcy or insolvency of the other party. Either party also has the right to terminate the co-development and co-commercialization agreement or license agreement if the other party or any of its affiliates challenges the validity, scope or enforceability of or otherwise opposes, any patent included within the intellectual property rights licensed to the other party under such agreement.

Exclusivity

While any of Celgene's options remain available under the 2016 Agreement, subject to specified exceptions, the Company may not directly develop, manufacture or commercialize, outside of the 2016 Agreement, any therapeutic modality in the IO field or the I&I field with specified activity against a metabolic target.

During the term of each co-development and co-commercialization agreement and license agreement, subject to specified exceptions, neither the Company nor Celgene may directly or indirectly develop, manufacture or commercialize outside of such agreement any therapeutic modality in any field with specified activity against the metabolic target that is the focus of the program licensed under such agreement.

AG-120 letter agreement

On May 17, 2016, Agios entered into a letter agreement with Celgene regarding AG-120 (the "AG-120 Letter Agreement"). Under the AG-120 Letter Agreement, Celgene and the Company have agreed to terminate the 2010 Agreement, effective as of August 15, 2016, as to the program directed to the IDH1 target, for which AG-120 is the lead development candidate. Under the 2010 Agreement, Celgene Corporation had held development and commercialization rights to the IDH1 program outside of the United States, and Agios holds such rights inside the United States. As a result of the AG-120 Letter Agreement, the Company will obtain global rights to AG-120 and the IDH1 program. Neither party will have any financial obligation, including royalties or milestone payments, to the other concerning AG-120 or the IDH1 program after final reconciliation of specified shared development costs. Under the AG-120 Letter Agreement, the parties have also agreed to conduct specified transitional activities in connection with the termination. In addition, pursuant to the AG-120 Letter Agreement, the parties are released from their exclusivity obligations under the 2010 Agreement with respect to the IDH1 program. The AG-120 Letter Agreement does not alter the global collaboration with Celgene Corporation pursuant to the collaboration and license agreements entered into with Celgene Corporation and Celgene International II Sarl on April 27, 2015 concerning AG-881, which is directed to both the IDH1 target and the IDH2 target.

Accounting analysis and revenue recognition - collaboration revenue

Pre-July 2014

Prior to the July 2014 amendment of the 2010 Agreement, the Company concluded that none of the identified deliverables had stand-alone value and, therefore, accounted for the deliverables as a single unit of accounting. The Company further concluded it was unable to estimate the fair value of the undelivered items within the 2010 Agreement. All considerations were recognized on a straight-line basis through the period over which the Company expected to fulfill its performance obligations (the performance period), which was initially determined to be six years.

July 2014 - April 2015

The July 2014 amendment of the 2010 Agreement was determined to be a material modification of the 2010 Agreement due to the change in the total potential consideration that was more than insignificant and significant changes to certain of the deliverables in the arrangement. Upon concluding that the 2010 Agreement had been materially modified in July 2014, the Company identified the remaining deliverables under the arrangement and determined its best estimates of selling price for the undelivered elements as of the modification date as vendor specific objective evidence and third-party evidence were not available. The Company then allocated the total arrangement consideration, which included the remaining deferred revenue balance at the modification date and other consideration that was deemed to be determinable at the modification date, to each unit of accounting based on its best estimate of selling price. The difference between the total arrangement consideration and the best estimate of selling price of the undelivered items was recognized as revenue at the modification date.

The undelivered items from the July 2014 modification, the related best estimate of selling price, the method of recognizing the allocated consideration, and the revenue recognized related to each unit of account through April 27, 2015, the effective date of the AG-881 Agreements was as follows:

- License for the split licensed program AG-120: The Company developed the best estimate of selling price of the license by probability weighting multiple cash flow scenarios using the income approach. There were significant judgments and estimates inherent in the determination of the best estimate of selling price of this unit of accounting. Should different reasonable assumptions be utilized, the best estimate of selling price and the associated revenue recognized would be different. The Company allocated \$21.2 million to the license which was delivered in January 2015. During the period April 1, 2015 through April 27, 2015 and for the period January 1, 2015 through April 27, 2015, the Company recognized the non-contingent consideration allocated to this unit of accounting of \$0.1 million and \$15.8 million, respectively, as collaboration revenue.
- Development services for five separate on-going phase 1 clinical trials (each of which is a separate unit of accounting): The Company developed the best estimate of selling price of the on-going phase 1 clinical trial development services of \$50.8 million for all five studies using management's best estimate of the cost of obtaining these services at arm's length from a third-party provider, as well as internal full time equivalent costs to support the development services. The amount allocated to these units of accounting is recognized as revenue on a proportional performance basis as services are provided. As committed to on the date of the July 2014 amendment, the Company has completed services for three of the on-going phase 1 clinical trials and expected services for the remaining two on-going phase 1 clinical trials are expected to be performed through the second quarter of 2016. As additional consideration is earned and allocated to the three fully delivered units of accounting it is recognized immediately. During the period April 1, 2015 through April 27, 2015 and for the period January 1, 2015 through April 27, 2015, the Company recognized the non-contingent consideration allocated to this unit of accounting of \$0.4 million and \$14.7 million, respectively, as collaboration revenue.
- On-going research and development: The Company developed the best estimate of selling price of the research and development services of \$13.6 million using management's best estimate of the cost of obtaining these services at arm's length from a third-party provider. The amount allocated to this unit of accounting was recognized as revenue ratably over the performance period. During the period April 1, 2015 through April 27, 2015 and for the period January 1, 2015 through April 27, 2015, the Company recognized the non-contingent consideration allocated to this unit of accounting of \$1.0 million and \$5.0 million, respectively, as collaboration revenue.
- Committee participation: The Company developed the best estimate of selling price of the committee participation services of \$0.2 million using management's best estimate of the anticipated participation hours multiplied by a market rate for comparable participants. The amount allocated to this unit of accounting was recognized as revenue ratably over the performance period. During the period April 1, 2015 through April 27, 2015 and for the period January 1, 2015 through April 27, 2015, the Company recognized the non-contingent consideration allocated to this unit of accounting of \$0.1 million as collaboration revenue.

In December 2014, Celgene elected to extend the term of the discovery period over which the Company was providing on-going research and development services from five to six years, to April 2016. As a result of the extension, the Company received a \$20.0

million extension payment from Celgene in May 2015. The Company evaluated the extension and concluded that upon exercise it is obligated to provide its committee participation and research and development services for a period of one year from April 2015 through April 2016, and as such revenue should be recognized ratably over the performance period of April 2015 to April 2016 as services are rendered. The Company recognized revenue of \$0.7 million related to this substantive option during the period April 16, 2015 through April 27, 2015.

Beginning in the first quarter of 2015, the Company and Celgene agreed to plans to advance AG-221 into later stage development studies. Pursuant to the terms of the 2010 Agreement, the parties agreed to transition primary development responsibilities for AG-221 to Celgene for later stage development at which point Celgene became the lead development party for AG-221. During the transition, the Company continued to manage certain arrangements with third-party service providers whose contracts were assigned to Celgene. The Company determined it is no longer the primary obligor of these arrangements and, when considering the other factors included within ASC 605-45, *Revenue Recognition – Principal Agent Considerations*, determined reimbursement of amounts incurred under third-party contracts should be reported on a net basis within research and development expense. The Company re-assessed its estimate of the total level of effort required to perform the development services related to AG-221 as a result of the contract assignments and recorded a change in estimate during the three months ended March 31, 2015. This change in estimate resulted in the recognition of an additional \$5.1 million of revenue, which is included within revenue related to development services for five separate on-going phase 1 clinical trials discussed earlier within this footnote. Including the \$3.8 million presented as a reduction of research and development expenditures, the change in estimate reduced the Company's net loss by \$8.9 million and caused a decrease in net loss per share of \$0.24 during the three months ended March 31, 2015.

During the period January 1, 2015 through April 27, 2015, the execution date of the AG-881 Agreements, the Company performed planning services on behalf of Celgene related to an expanded phase 1 clinical trial of AG-221. The Company determined the work represented a substantive option under the 2010 Agreement. The Company also determined it is not the primary obligor of the underlying third-party contracts and determined that reimbursements of amounts incurred under the contracts should be reported on a net basis in research and development expense. Reimbursements of services performed directly by the Company are presented on a gross basis as collaboration revenue. During the period April 1, 2015 through April 27, 2015 and for the period January 1, 2015 through April 27, 2015, the Company recognized \$0.3 million and \$0.4 million, respectively, in revenues and recorded \$0.3 million and \$0.9 million, respectively, as a reduction in research and development costs related to these services. Costs reimbursed for services performed directly by the Company are presented as collaboration revenues.

April 2015 - May 2016

The AG-881 Agreements, executed on April 27, 2015, were determined to be a modification of the 2010 Agreement due to the AG-881 Agreements including a compound originally identified within the 2010 Agreement. As a result of the modification the Company identified the remaining deliverables under the 2010 Agreement and the AG-881 Agreements with Celgene and determined the best estimate of selling price for the undelivered elements as of the modification date. The Company then allocated the total arrangement consideration, which included the remaining deferred revenue balance at the modification date, the initial payment of \$10.0 million under the AG-881 Agreements and other consideration under the 2010 Agreement and the AG-881 Agreements that was deemed to be determinable at the modification date, to each unit of accounting relative to its best estimate of selling price. The undelivered items, which are each considered by the Company to have stand-alone value and therefore are separate units of accounting, the related best estimate of selling price at April 27, 2015, and the method of recognizing the allocated consideration, for each unit of accounting are as follows:

- Licenses for the AG-881 program: The Company developed the best estimate of selling price of the U.S. license and the rest of world license by probability weighting multiple cash flow scenarios using the income approach. Management estimates within the models include the expected, probability-weighted net profits from estimated future sales, an estimate of the direct cost incurred to generate future cash flows, a discount rate and other business forecast factors. There are significant judgments and estimates inherent in the determination of the best estimate of selling price of these units of accounting. These judgments and estimates include assumptions regarding future operating performance, the timelines of the clinical trials and regulatory approvals and the estimated patient populations. Should different reasonable assumptions be utilized, the best estimate of selling price and the associated revenue recognized would be different. The Company developed a best estimate of selling price of the licenses of \$33.2 million. The Company recognizes the non-contingent consideration allocated to these units of accounting upon delivery of the licenses to Celgene which occurred immediately upon the execution of the AG-881 Agreements. During the period April 1, 2016 through May 17, 2016, the effective date of the 2016 Agreement, and for the period January 1, 2016 through May 17, 2016, the Company recognized the non-contingent consideration allocated to this unit of accounting of \$0.5 million and \$1.4 million, respectively, as collaboration revenue. For the period April 27, 2015 through June 30, 2015, the Company recognized the non-contingent consideration allocated to this unit of accounting of \$8.8 million as collaboration revenue.
- Four separate on-going development services for which the Company determined it is acting as the principal of all development activities (each of which is a separate unit of accounting): The Company developed the best estimate of

selling price for all four of the on-going development services of \$12.7 million using management's best estimate of the cost of obtaining these services at arm's length from a third-party provider, as well as internal full time equivalent costs to support the development services. The estimated costs were determined to represent management's best estimate of the price these services could be sold for separately. The amount allocated to these units of accounting is being recognized as revenue on a proportional performance basis as services are provided. The Company expects the services to be performed through 2017. When considering the factors included within ASC 605-45, the Company determined it is the principal of all development activities and is required to present reimbursement of amounts incurred for these services as revenue. During the period April 1, 2016 through May 17, 2016 and for the period January 1, 2016 through May 17, 2016, the Company recognized the non-contingent consideration allocated to these units of accounting of \$0.6 million and \$1.7 million, respectively, as collaboration revenue. For the period April 27, 2015 through June 30, 2015, the Company recognized the non-contingent consideration allocated to these units of accounting of \$0.6 million as collaboration revenue.

- Four separate on-going development services for which the Company determined it is not acting as the principal of all development activities (each of which is a separate unit of accounting): The Company developed the best estimate of selling price for all four of the on-going development services of \$97.3 million using management's best estimate of the cost of obtaining these services at arm's length from a third-party provider, as well as internal full time equivalent costs to support the development services. The estimated costs were determined to represent management's best estimate of the price these services could be sold for separately. The amount allocated to these units of accounting is being recognized on a proportional performance basis as services are provided. The Company expects the services to be performed through 2017. When considering the factors included within ASC 605-45, the Company determined it is not the principal of all development activities and is required to present reimbursement of amounts incurred for these services on a net basis as a reduction of research and development expenses. During the period April 1, 2016 through May 17, 2016 and for the period January 1, 2016 through May 17, 2016, the Company recognized the non-contingent consideration allocated to these units of accounting of \$2.6 million and \$7.5 million, respectively, as a reduction of research and development costs related to these services. For the period April 27, 2015 through June 30, 2015, the Company recognized the non-contingent consideration allocated to these units of accounting of \$3.4 million as a reduction of research and development costs related to these services.
- On-going research and development: The Company developed the best estimate of selling price of the research and development services of \$30.5 million using management's best estimate of the cost of obtaining these services at arm's length from a third-party provider. The amount allocated to this unit of accounting is being recognized as revenue ratably over the performance period through April 2016. During the period April 1, 2016 through May 17, 2016 and for the period January 1, 2016 through May 17, 2016, the Company recognized the non-contingent consideration allocated to this unit of accounting of \$1.0 million and \$4.6 million, respectively, as collaboration revenue. For the period April 27, 2015 through June 30, 2015, the Company recognized the non-contingent consideration allocated to this unit of accounting of \$1.4 million as collaboration revenue.
- Committee participations under the 2010 Agreement and AG-881 Agreements: The Company developed the best estimate of selling price of the committee participation services of \$0.8 million using management's best estimate of the anticipated participation hours multiplied by a market rate for comparable participants. The amount allocated to this unit of accounting is being recognized as revenue ratably over the performance period, through the fourth quarter of 2016. During the period April 1, 2016 through May 17, 2016 and for the period January 1, 2016 through May 17, 2016, the Company recognized the non-contingent consideration allocated to this unit of accounting \$32 thousand and \$89 thousand, respectively, as collaboration revenue. For the period April 27, 2015 through June 30, 2015, the Company recognized the non-contingent consideration allocated to this unit of accounting of \$22 thousand as collaboration revenue.

The total estimated arrangement consideration, as well as the expected timing of revenue recognition, is adjusted based on changes in estimated arrangement consideration as a result of changes in estimates for on-going development services. The allocable consideration will increase as the Company performs certain services for which it is eligible to receive additional consideration. These amounts will be recognized on a cumulative catch-up basis for any inprocess units of accounting or immediately for any fully delivered units of accounting. The estimated arrangement consideration may decrease if the Company receives less reimbursement than initially estimated.

As a result of Celgene assuming the primary development responsibilities for AG-221 in the first quarter of 2015, the Company recorded \$0.4 million and \$0.9 million of third-party costs incurred on behalf of Celgene during period April 1, 2016 through May 17, 2016 and for the period January 1, 2016 through May 17, 2016, respectively, as a reduction of research and development costs.

Beginning in the third quarter of 2015, the Company initiated a phase 1b frontline combination clinical trial of AG-221 and AG-120 for which it will receive reimbursement from Celgene. The new combination trial was determined to be a substantive option under the 2010 Agreement. When considering the factors included within ASC 605-45, management determined that the Company is the

principal for the efforts related to the AG-221 arm of the combination trial but is acting in the role of an agent for the efforts related to the AG-120 arm of the combination trial. Accordingly, consideration earned related to the AG-221 arm of the combination trial is recognized as collaboration revenue in the period earned and consideration earned related to the AG-120 arm of the combination trial is reported as a reduction of research and development expense in the period earned. During the period April 1, 2016 through May 17, 2016, the effective date of the 2016 Agreement, and for the period January 1, 2016 through May 17, 2016, the Company recognized \$0.5 million and \$1.2 million, respectively, in collaboration revenue and recorded \$0.2 million and 0.3 million, respectively, as a reduction of research and development costs related to the combination trial.

During the period April 1, 2016 through May 17, 2016 and for the period January 1, 2016 through May 17, 2016, the Company incurred an additional \$1.1 million and \$4.4 million, respectively, in reimbursable development expenses related to the AG-120 and AG-881 programs that were not contemplated as of the April 2015 modification. The amounts are recorded as a reduction of research and development costs of each respective program.

Post-May 2016

The 2016 Agreement, executed on May 17, 2016, was determined to be a modification of the 2010 Agreement and the AG-881 Agreements because it includes compounds originally identified within the 2010 Agreement. As a result of the modification the Company identified the undelivered elements under the 2010 Agreement, the AG-881 Agreements and 2016 Agreements with Celgene (collectively, the "Celgene Agreements") and determined the best estimate of selling price for the undelivered elements as of the modification date. The Company then allocated the total arrangement consideration, which included the remaining deferred revenue balance at the modification date, the upfront payment of \$200.0 million under the 2016 Agreement and other consideration under the Celgene Agreements that were deemed to be determinable at the modification date, to each unit of accounting relative to its best estimate of selling price. The undelivered items, which are each considered by the Company to have stand-alone value and therefore are separate units of accounting, the related best estimate of selling price at May 17, 2016, and the method of recognizing the allocated consideration, for each unit of accounting are as follows:

- Three separate development services for which the Company determined it is acting as the principal of all development activities (each of which is a separate unit of accounting): The Company developed the best estimate of selling price for all three of the development services of \$67.8 million using management's best estimate of the cost of obtaining these services at arm's length from a third-party provider, as well as internal full time equivalent costs to support the development services. The estimated costs were determined to represent management's best estimate of the price these services could be sold for separately. The amount allocated to these units of accounting is being recognized as revenue on a proportional performance basis as services are provided. The Company expects the services to be performed through 2019. When considering the factors included within ASC 605-45, the Company determined it is the principal of all development activities and is required to present reimbursement of amounts incurred for these services as revenue. For the period May 17, 2016 through June 30, 2016, the Company recognized the non-contingent consideration allocated to these units of accounting of \$1.7 million as collaboration revenue.
- Three separate on-going development services for which the Company determined it is not acting as the principal of all development activities (each of which is a separate unit of accounting): The Company developed the best estimate of selling price for all three development services of \$22.4 million using management's best estimate of the cost of obtaining these services at arm's length from a third-party provider, as well as internal full time equivalent costs to support the development services. The estimated costs were determined to represent management's best estimate of the price these services could be sold for separately. The amount allocated to these units of accounting is being recognized on a proportional performance basis as services are provided. The Company expects the services to be performed through 2019. When considering the factors included within ASC 605-45, the Company determined it is not the principal of all development activities and is required to present reimbursement of amounts incurred for these services on a net basis as a reduction of research and development expenses. For the period May 17, 2016 through June 30, 2016, the Company recognized the non-contingent consideration allocated to these units of accounting of \$1.3 million as a reduction of research and development costs related to these services.
- On-going research and development: The Company developed the best estimate of selling price of the research and development services of \$207 million using management's best estimate of the cost of obtaining these services at arm's length from a third-party provider. The amount allocated to this unit of accounting is being recognized as revenue ratably through May 2022, the expected performance period. For the period May 17, 2016 through June 30, 2016, the Company recognized the non-contingent consideration allocated to this unit of accounting of \$2.7 million as collaboration revenue.
- Committee participations under the 2010 Agreement, AG-881 Agreements and 2016 Agreement: The Company developed the best estimate of selling price of the committee participation services of \$1.5 million using management's best estimate of the anticipated participation hours multiplied by a market rate for comparable participants. The amount allocated to this unit of accounting is being recognized as revenue ratably over the expected performance period, December 2022. For the period May 17, 2016 through June 30, 2016, the Company recognized the non-contingent consideration allocated to this unit of accounting of \$17 thousand as collaboration revenue.

• Additional development activities for which the Company determined it is acting as the principal of all development activities: The Company developed the best estimate of selling price of the development service of \$48.7 million using management's best estimate of the cost of obtaining these services at arm's length from a third-party provider, as well as internal full time equivalent costs to support the development services. The estimated costs were determined to represent management's best estimate of the price these services could be sold for separately. The activities under this unit of accounting are not expected to begin until 2020. When considering the factors included within ASC 605-45, the Company determined it is the principal of all development activities and is required to present reimbursement of amounts incurred for these services as revenue. For the period May 17, 2016 through June 30, 2016, the Company has not recognized any revenue associated with this unit of account.

The total estimated arrangement consideration, as well as the expected timing of revenue recognition, is adjusted based on changes in estimated arrangement consideration as a result of changes in estimates for on-going development services. The allocable consideration will increase as the Company performs certain services for which it is eligible to receive additional consideration. These amounts will be recognized on a cumulative catch-up basis for any in-process units of accounting or immediately for any fully delivered units of accounting. The estimated arrangement consideration may decrease if the Company receives less reimbursement than initially estimated.

As a result of Celgene assuming the primary development responsibilities for AG-221 in the first quarter of 2015, the Company recorded \$0.4 million of third-party costs incurred on behalf of Celgene for the period May 17, 2016 through June 30, 2016 as a reduction of research and development costs.

During the three months ended June 30, 2016 and 2015, the Company recognized a total of \$7.0 million and \$13.2 million, respectively, as collaboration revenue and recognized \$5.9 million and \$4.5 million, respectively, as a reduction of research and development expenses. During the six months ended June 30, 2016 and 2015, the Company recognized a total of \$13.3 million and \$47.4 million, respectively, as collaboration revenue and recognized \$14.7 million and \$8.9 million, respectively, as a reduction of research and development expenses.

In determining the current and noncurrent classification of deferred revenue, the Company considers the total consideration expected to be earned in the next twelve months for services to be performed under certain units of accounting and the estimated proportional performance and timing of delivery of certain deliverables to determine the deferred revenue balance that will remain twelve months from the balance sheet date. As of June 30, 2016 and December 31, 2015, the Company has recorded a collaboration receivable of \$7.9 million and \$8.2 million, respectively, related to reimbursable development costs.

Accounting analysis and revenue recognition - milestone revenue

The Company concluded that certain of the clinical development and regulatory milestone payments that may be received under the 2010 Agreement, the AG-881 Agreements and the 2016 Agreement, if the Company is involved in future product development and commercialization, are substantive. Factors considered in the evaluation of the milestones included the degree of risk associated with performance of the milestone, the level of effort and investment required, whether the milestone consideration was reasonable relative to the deliverables and whether the milestone was earned at least in part based on the Company's performance. Revenue from substantive milestones, if they are nonrefundable, is recognized as revenue upon successful accomplishment of the milestones. Clinical and regulatory milestones are deemed non-substantive if they are based solely on the collaborator's performance. Non-substantive milestones will be recognized when achieved to the extent the Company has no remaining performance obligations under the arrangement. Milestone payments earned upon achievement of commercial milestone events will be recognized when earned.

In January 2016, the Company determined that a substantive clinical development milestone related to the AG-221 program under the 2010 Agreement was achieved and received a milestone payment of \$25.0 million, which was recognized as revenue during the three months ended March 31, 2016. No other milestones were earned during the six months ended June 30, 2016 or for the year ended December 31, 2015. There are no milestones that are expected to be achieved in the near term.

6. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	June 30, 2016	Dec	ember 31, 2015
Accrued compensation	\$ 6,352	\$	7,005
Accrued contracted research and development costs	6,214		7,449
Accrued professional fees	1,641		228
Accrued other	207		1,314
Total	\$14,414	\$	15,996

7. Share-Based Payments

2013 Stock Incentive Plan

In June 2013, the Company's Board of Directors adopted and, in July 2013, the Company's stockholders approved the 2013 Stock Incentive Plan (the "2013 Plan"). The 2013 Plan became effective upon the closing of the Company's Initial Public Offering, or IPO, and provides for the grant of incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards. Following the adoption of the 2013 Plan, the Company granted no further stock options or other awards under the 2007 Stock Incentive Plan, or 2007 Plan. Any options or awards outstanding under the 2007 Plan at the time of adoption of the 2013 Plan remain outstanding and effective. As of June 30, 2016, the total number of shares reserved under the 2007 Plan and the 2013 Plan are 6,546,275 and the Company had 981,516 shares available for future issuance under such plans. The 2013 Plan provides for an annual increase, to be added on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2014 and continuing until the expiration of the 2013 Plan, equal to the lesser of (i) 2,000,000 shares of common stock, (ii) 4% of the outstanding shares of common stock on such date or (iii) an amount determined by the Company's Board of Directors. On January 1, 2016 and 2015, the annual increase for the 2013 Plan resulted in an additional 1,507,860 shares and 1,484,020 shares, respectively, authorized for issuance.

The following table summarizes all stock option activity for the six months ended June 30, 2016:

	Number of Stock Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2015	4,618,697	\$ 44.45	7.49	\$ 153,573
Granted	1,155,940	42.61		
Exercised	(313,183)	6.36		
Forfeited/expired	(78,265)	73.33		
Outstanding at June 30, 2016	5,383,189	\$ 45.85	7.63	\$ 73,370
Exercisable at June 30, 2016	2,452,292	\$ 30.04	6.26	\$ 58,983
Vested and expected to vest at June 30, 2016	5,037,783	\$ 46.38	7.60	\$ 67,811

The weighted-average grant date fair value of options granted was \$31.89, \$64.19, \$27.17 and \$67.57 during the three months ended June 30, 2016 and 2015 and six months ended June 30, 2016 and 2015, respectively. The total intrinsic value of options exercised was \$5.3 million and \$11.3 million during the three months ended June 30, 2016 and 2015, respectively, and \$15.3 million and \$29.4 million during the six months ended June 30, 2016 and 2015, respectively.

At June 30, 2016, the total unrecognized compensation expense related to unvested stock option awards, including estimated forfeitures, was \$95.4 million, which the Company expects to recognize over a weighted-average period of approximately 2.70 years. The Company also has unrecognized stock-based compensation expense of \$8.2 million related to stock options and performance-based stock units both with performance-based vesting criteria that are not considered probable of achievement as of June 30, 2016.

Restricted stock units

The Company may grant awards of restricted stock units ("RSUs") to non-employee directors, members of the management team and employees on a discretionary basis pursuant to the 2013 Plan. Each RSU entitles the holder to receive, at the end of each vesting period, a specified number of shares of the Company's common stock.

During the three months ended March 31, 2016, the Company granted 58,800 RSUs to various employees; no RSUs were granted during the three months ended June 30, 2016. The Company granted 15,000 RSUs during the three and six months ended June 30, 2015. The Company recorded stock-based compensation expense related to RSUs of \$0.5 million and \$0.2 million for the three months ended June 30, 2016 and 2015, respectively, and stock-based compensation expenses of \$0.9 million and \$0.3 million for the six months ended June 30, 2016 and 2015, respectively. These amounts are included in the total stock-based compensation expense disclosed below. As of June 30, 2016, there was approximately \$2.6 million of total unrecognized compensation expense related to RSUs, which is expected to be recognized over a weighted-average period of 1.5 years.

The following table presents RSU activity for the six months ended June 30, 2016:

	Number of Stock Units	 ited-average late fair value
Unvested shares at December 31, 2015	15,000	\$ 122.22
Granted	58,800	39.76
Vested	(7,500)	 122.22
Unvested shares at June 30, 2016	66,300	\$ 49.09

Performance-based stock options

During the three and six months ended June 30, 2016 and 2015, no options to purchase shares of common stock that contain performance-based or a combination of performance-based and service-based vesting criteria were granted by the Company. However, certain performance-based stock options issued in prior periods were still outstanding as of June 30, 2016. Performance-based vesting criteria for options primarily relate to milestone events specific to the Company's corporate goals, including but not limited to certain preclinical, clinical and regulatory development milestones related to the Company's product candidates. Stock-based compensation expense associated with these performance-based stock options is recognized if the performance condition is considered probable of achievement using management's best estimates. As of June 30, 2016, certain of the performance-based milestones had been achieved. The achievements of certain other milestones have been deemed probable and therefore the related expense either has been fully recognized or is being recognized over the remaining service period. The achievement of the remaining milestones was deemed to be not probable as of June 30, 2016 and, therefore, no expense has been recognized related to these awards. During the three and six months ended June 30, 2015, the Company recognized stock-based compensation expense of \$0.1 million and \$0.3 million, respectively, related to stock options with performance-based vesting criteria. During the three and six months ended June 30, 2016, the Company did not recognize any stock-based compensation expense related to stock options with performance-based vesting criteria.

Performance-based stock units

In December 2015, pursuant to the 2013 Plan, the Company granted 100,270 performance stock units ("PSUs") to certain employees and, in February 2016, the Company granted 15,000 PSUs to one employee. Each PSU entitles the holder to receive, at the achievement of the performance-based and service-based criteria, a specified number of shares of the Company's stock. Performance-based vesting criteria primarily relate to milestone events specific to the Company's corporate goals, specifically regulatory development milestones related to the Company's product candidates. Stock-based compensation expense associated with these PSUs is recognized if the performance condition is considered probable of achievement using management's best estimates. As of June 30, 2016, these milestones were not probable and, therefore, no expense has been recognized related to these awards. No such awards were granted during the six months ended June 30, 2015.

2013 Employee Stock Purchase Plan

In June 2013, the Company's Board of Directors adopted, and in July 2013 the Company's stockholders approved, the 2013 Employee Stock Purchase Plan (the "2013 ESPP"). The 2013 ESPP is administered by the Company's Board of Directors or by a committee appointed by the Company's Board of Directors. Under the 2013 ESPP, each offering period is six months, at the end of which employees may purchase shares of common stock through payroll deductions made over the term of the offering period. The per-share purchase price at the end of each offering period is equal to 85% of the closing price of one share of the Company's common stock at the beginning or end of the offering period, whichever is lower, subject to Internal Revenue Service limits. The Company issued 12,327 shares and 10,664 shares during the six months ended June 30, 2016 and 2015, respectively, under the 2013 ESPP. The Company did not issue any shares during the three months ended June 30, 2016 and 2015. The 2013 ESPP provides participating employees with the opportunity to purchase up to an aggregate of 327,272 shares of the Company's common stock. As of June 30, 2016, the Company had 297,795 shares available for future issuance under the 2013 ESPP.

The Company recorded \$0.2 million and \$0.1 million of stock-based compensation expense for the three months ended June 30, 2016 and 2015, respectively, and \$0.3 million and \$0.2 million of stock-based compensation expense for the six months ended June 30, 2016 and 2015, respectively, related to the 2013 ESPP.

Stock-based compensation expense

During the three and six months ended June 30, 2016 and 2015, the Company recorded stock-based compensation expense for employee and non-employee stock options, restricted stock units, restricted stock, performance-based stock options, performance-based stock units and the employee stock purchase plan shares. Expenses related to these equity-based awards were allocated as follows in the condensed consolidated interim statements of operations (in thousands):

		Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015	
Research and development expense	\$ 6,561	\$ 4,569	\$12,089	\$ 7,180	
General and administrative expense	4,435	3,608	8,014	6,057	
	\$ 10,996	\$ 8,177	\$20,103	\$13,237	

The fair value of each stock option granted to employees is estimated on the date of grant using the Black-Scholes option-pricing model. For non-employees, the fair value of each stock option is estimated on each vesting and reporting date using the Black-Scholes option-pricing model. The following table summarizes the weighted average assumptions used in calculating the grant date fair value of the awards:

		Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015	
Risk-free interest rate	1.38%	1.71%	1.41%	1.71%	
Expected dividend yield	_	_	_	_	
Expected term (in years)	5.89	5.88	6.04	6.03	
Expected volatility	72.53%	68.93%	71.72%	70.02%	

8. Income Taxes

In January 2014, the Company paid \$6.0 million as payment in full of its U.S. federal income tax liability related to the year ended December 31, 2011, including \$1.5 million of interest and penalties accrued. The Company filed a carryback claim to apply the net losses incurred during the year ended December 31, 2013 against the previous taxable income. The amount to be refunded by the Internal Revenue Service ("IRS") was recorded as refundable income taxes as of December 31, 2014. During the three months ended March 31, 2015, the Company received the balance of the refundable income tax. There was no (benefit) provision for income taxes during the three and six months ended June 30, 2016 and 2015.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. The Company evaluated whether any uncertain tax positions arise from commencing operations of its wholly owned subsidiary, Agios International Sarl, and determined no uncertain tax positions existed. As of June 30, 2016 and December 31, 2015, the Company did not have any uncertain tax positions.

9. Loss per Share

Basic net loss per share is calculated by dividing net loss by the weighted average shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method. For purposes of the dilutive net loss per share calculation, stock options, restricted stock units, unvested restricted stock and employee stock purchase plan options are considered to be common stock equivalents but are excluded from the calculation of diluted net loss per share as their effect would be anti-dilutive; therefore, basic and diluted net loss per share were the same for all periods presented.

The following common stock equivalents were excluded from the calculation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect:

	Three and Six Mo	Three and Six Months Ended June 30,		
	2016	2015		
Stock options	5,383,189	4,687,805		
Restricted stock units	66,300	25,000		
Unvested restricted stock	_	2,841		
Employee stock purchase plan options	15,917	3,941		
	5,465,406	4,719,587		

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

Forward-looking Information

The following discussion of our financial condition and results of operations should be read with our unaudited condensed consolidated interim financial statements as of June 30, 2016 and for the three and six months ended June 30, 2016 and 2015 and related notes included in Part I. Item 1 of this Quarterly Report on Form 10-Q, as well as the audited consolidated financial statements and notes and Management's Discussion and Analysis of Financial Condition and Results of Operations and Risk Factors, included in our Annual Report on Form 10-K for the year ended December 31, 2015 filed with the Securities and Exchange Commission, or the SEC, on February 26, 2016. This Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on current expectations, estimates, forecasts, and projections and the beliefs and assumptions of our management and include, without limitation, statements with respect to our expectations regarding our research, development and commercialization plans and prospects, results of operations, general and administrative expenses, research and development expenses, and the sufficiency of our cash for future operations. Words such as "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar statements or variation of these terms or the negative of those terms and similar expressions are intended to identify these forward-looking statements. Readers are cautioned that these forward-looking statements are predictions and are subject to risks, uncertainties, and assumptions that are difficult to predict. Therefore, actual results may differ materially and adversely from those expressed in any forward-looking statements. Among the important factors that could cause actual results to differ materially from those indicated by our forward-looking statements are those discussed under the heading "Risk Factors" in Part II, Item 1A and elsewhere in this report. We undertake no obligation to revise the forward-looking statements contained herein to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

Overview

We are a biopharmaceutical company committed to applying our scientific leadership in the field of cellular metabolism to transform the lives of patients with cancer and rare genetic metabolic disorders, or RGDs, which are a subset of orphan genetic metabolic diseases. Metabolism is a complex biological process involving the uptake and assimilation of nutrients in cells to produce energy and facilitate many of the processes required for cellular division and growth. We focus our efforts on using cellular metabolism, an unexploited area of biological research with disruptive potential, as a platform for developing potentially transformative small molecule medicines. Our most advanced cancer product candidates are AG-221 and AG-120, which target mutated isocitrate dehydrogenase 2 and 1, or IDH2 and IDH1, respectively, and AG-881, which targets both mutated IDH1 and mutated IDH2. These mutations are found in a wide range of hematological malignancies and solid tumors. The lead product candidate in our RGD programs, AG-348, targets pyruvate kinase-R for the treatment of pyruvate kinase deficiency. Pyruvate kinase deficiency is a rare disorder that often results in severe hemolytic anemia due to inherited mutations in the pyruvate kinase enzyme within red blood cells.

In April 2010, we entered into a discovery and development collaboration and license agreement, or the 2010 Agreement, with Celgene Corporation, or Celgene, focused on targeting cancer metabolism. The goal of the collaboration under the 2010 Agreement was to discover, develop and commercialize disease-altering therapies in oncology arising out of our cancer metabolism research platform that have achieved development candidate status. The discovery phase of the collaboration under the 2010 Agreement expired in April 2016.

Under the terms of the 2010 Agreement, we led research, preclinical and early development efforts through phase 1, while Celgene received an option to obtain exclusive rights either upon Investigational New Drug application, or IND, acceptance or at the end of phase 1 to further develop and commercialize medicines emerging from our cancer metabolism research. Celgene led and funded global development and commercialization of development candidates for which it exercised its option to obtain a co-commercialization license, and we retained development and commercialization rights in the United States for development candidates for which we exercised our option to retain a split license. On all programs under the 2010 Agreement for which Celgene exercised its option, we are eligible to receive up to \$120.0 million in milestone-based payments as well as royalties on any sales.

We nominated AG-221 and AG-120 during the discovery phase of the collaboration under the 2010 Agreement. In June 2014, Celgene exercised its exclusive option to license worldwide development and commercialization rights for AG-221. In addition to contributing our scientific and translational expertise, we continue to conduct certain clinical development and regulatory activities within the AG-221 development program while transitioning responsibilities to Celgene, which will lead later development activities. Celgene exercised its exclusive option under the 2010 Agreement to license development and commercialization rights to AG-120 outside the United States during the three months ended March 31, 2015. Following Celgene's exercise of this option, we retained development and commercialization rights for AG-120 in the United States.

During April 2015, we selected a third novel IDH mutant inhibitor, AG-881, for clinical development. On April 27, 2015, we entered into a joint worldwide development and profit share collaboration and license agreement with Celgene and our wholly owned subsidiary, Agios International Sarl, which was organized in Switzerland in April 2015, entered into a collaboration and license agreement with Celgene International II Sarl. We refer to these agreements collectively as the AG-881 Agreements. The AG-881 Agreements establish a worldwide collaboration focused on the development and commercialization of AG-881 products. Under the terms of the AG-881 Agreements, we received initial upfront payments totaling \$10.0 million in May 2015 and are eligible to receive up to \$70.0 million in milestone-based payments. We and Celgene will equally split all worldwide development costs, subject to specified exceptions, as well as any profits from any net sales of, or commercialization losses related to, licensed AG-881 products.

In May 2016, we entered into a master research and collaboration agreement, or the 2016 Agreement, with Celgene and Celgene RIVOT Ltd., a wholly owned subsidiary of Celgene. The 2016 Agreement establishes a new global collaboration focused on the research and development of immunotherapies against certain metabolic targets that exert their antitumor efficacy primarily via the immune system. In addition to new programs identified under the 2016 Agreement, Celgene and we have also agreed that all future development and commercialization of two programs that were conducted under the 2010 Agreement will now be governed by the 2016 Agreement.

During the research term of the 2016 Agreement, we plan to conduct research programs focused on discovering compounds that are active against metabolic targets in the immuno-oncology, or IO, field. The initial four-year research term will expire on May 17, 2020. Celgene may extend the research term for up to two, or in specified cases, up to four, additional one-year terms.

For each program under the 2016 Agreement, we may nominate compounds that meet specified criteria as development candidates, and, in limited circumstances, Celgene may also nominate compounds as development candidates for each such program. Celgene may designate the applicable program for further development following any such nomination, after which we may conduct, at our expense, additional pre-clinical and clinical development for such program through completion of an initial phase 1 dose escalation study.

At the end of the research term, Celgene may designate for continued development up to three research programs for which development candidates have yet to be nominated, which we refer to as continuation programs. We may conduct further research and pre-clinical and clinical development activities on any continuation program, at our expense, through completion of an initial phase 1 dose escalation study.

We have granted Celgene the right to obtain exclusive options to development and commercialization rights for each program that Celgene has designated for further development, and for each continuation program. Celgene may exercise each such option beginning upon the designation of a development candidate for such program (or upon the designation of such program as a continuation program) and ending on the earlier of (i) the end of a specified period after we have furnished Celgene with specified information about the initial phase 1 dose escalation study for such program, or (ii) January 1, 2030. Research programs that have applications in the inflammation or autoimmune, or I&I, field that may result from the 2016 Agreement will also be subject to the exclusive options described above.

We will retain rights to any program that Celgene does not designate for further development or as to which Celgene does not exercise its option.

Under the terms of the 2016 Agreement, following Celgene's exercise of its option with respect to a program, we and Celgene will enter into either a co-development and co-commercialization agreement if such program is in the IO field, or a license agreement if such program is in the I&I field. Under each co-development and co-commercial agreement, we and Celgene will co-develop and co-commercialize licensed products worldwide. Either we or Celgene will lead development and commercialization of licensed products for the United States and Celgene will lead development and commercialization of licensed products outside of the United States. Depending on the country, we and Celgene will each have the right to provide a portion of field-based marketing activities. Under each license agreement, Celgene will have the sole right to develop and commercialize licensed products worldwide. We will retain rights to any program that Celgene does not designate for further development or as to which Celgene does not exercise its option.

Subsequent to the execution of the 2016 Agreement, Celgene and we agreed to terminate the 2010 Agreement, effective as of August 15, 2016, as to the program directed to the IDH1 target, for which AG-120 is the lead development candidate. Under the 2010 Agreement, Celgene had held development and commercialization rights to the IDH1 program outside of the United States, and we held such rights inside the United States. As a result of the termination, we will obtain global rights to AG-120 and the IDH1 program. Neither party will have any financial obligation, including royalties or milestone payments, to the other concerning

AG-120 or the IDH1 program after final reconciliation of specified shared development costs. Under the terms of the termination, the parties are released from their exclusivity obligations under the 2010 Agreement with respect to the IDH1 program. The AG-120 termination does not alter our global collaboration with Celgene pursuant to the AG-881 Agreements concerning AG-881, which is directed at both the IDH1 target and the IDH2 target.

Since inception, our operations have focused on organizing and staffing our company, business planning, raising capital, assembling our core capabilities in cellular metabolism, identifying potential product candidates, undertaking preclinical studies and conducting clinical trials. To date, we have financed our operations primarily through funding received from the 2010 Agreement, the AG-881 Agreements, the 2016 Agreement, private placements of our preferred stock, our initial public offering of our common stock and concurrent private placement of common stock to an affiliate of Celgene and our follow-on public offerings. Substantially all of our revenue to date has been collaboration revenue received from Celgene.

Since inception, we have incurred significant operating losses. Our net loss was \$56.0 million and \$31.9 million, for the three months ended June 30, 2016 and 2015, respectively, and \$79.2 million and \$36.9 million for the six months ended June 30, 2016 and 2015, respectively. As of June 30, 2016, we had an accumulated deficit of \$363.8 million. We expect to continue to incur significant expenses and operating losses over the next several years. Our net losses may fluctuate significantly from year to year. We anticipate that our expenses will increase significantly as we continue to advance and expand clinical development activities for our lead programs, AG-221, AG-120, AG-881 and AG-348, as well as AG-519 our second product candidate that is a potent activator of the PKR enzyme; continue to discover and validate novel targets and drug product candidates; expand and protect our intellectual property portfolio; and hire additional commercial, development and scientific personnel.

Financial Operations Overview

Revenue

Through June 30, 2016, we have not generated any revenue from product sales and do not expect to generate any revenue from product sales in the near future. Primarily all of our revenue to date has been derived from our collaborations with Celgene. In the future, we will seek to generate revenue from a combination of product sales and upfront payments, cost reimbursements, milestone payments, and royalties on future product sales.

Collaboration and license revenue

Arrangement consideration is allocated to each separately identified unit of accounting based on the relative selling price, using our best estimate of selling price of each deliverable. The provisions of the Financial Accounting Standards Board's Accounting Standards Codification (ASC) 605-25, *Multiple-Element Arrangements* are then applied to each unit of accounting to determine the appropriate revenue recognition. In the event that a deliverable of a multiple element arrangement does not represent a separate unit of accounting, we recognize revenue from the combined units of accounting over the term of the related contract or as undelivered items are delivered, as appropriate.

Revenue is recognized under the proportional performance method for certain units of accounting. The amount recognized is determined based on the consideration allocated to each unit of accounting based on the ratio of the level of effort incurred to date compared to the total estimated level of effort required to complete our performance obligations under the unit of accounting. Determining the total estimated level of effort required to complete all performance obligations requires management judgment and estimation, including assumptions regarding future operating performance, the timelines of the clinical trial approvals and the estimated patient populations.

Reimbursement of research and development costs by Celgene is recognized as revenue, provided we have determined that we are acting primarily as a principal in the transaction according to the provisions outlined in ASC 605-45, Revenue Recognition – Principal Agent Considerations, the amounts are determinable and collection of the related receivable is reasonably assured.

Milestone revenue

We recognize revenue contingent upon the achievement of a milestone in its entirety in the period in which the milestone is achieved, only if the milestone meets all the criteria within the guidance to be considered substantive. At the inception of each arrangement that includes milestone payments, we evaluate each contingent payment on an individual basis to determine whether they are considered substantive milestones, specifically reviewing factors such as the degree of certainty in achieving the milestone, the research and development risk and other risks that must be overcome to achieve the milestone, as well as the level of effort and investment required and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement. This evaluation includes an assessment of whether (a) the consideration is commensurate with either (1) the entity's performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, (b) the consideration relates solely to past performance and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement.

Revenue from milestones, if they are nonrefundable and deemed substantive, are recognized upon achievement of the milestones. We recognize revenue associated with the non-substantive milestones upon achievement of the milestone if there are no undelivered elements and we have no remaining performance obligations.

Research and development expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our drug discovery efforts, and the development of our product candidates, which include:

- · employee-related expenses including salaries, benefits and stock-based compensation expense;
- expenses incurred under agreements with third parties, including contract research organizations, or CROs, that conduct research and development and both preclinical and clinical activities on our behalf and the cost of consultants;
- · the cost of lab supplies and acquiring, developing and manufacturing preclinical and clinical study materials; and
- facilities, depreciation, and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other operating costs.

Research and development costs are expensed as incurred. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are performed. Reimbursements received from Celgene for certain third-party costs for which we are not the principal in the transaction according to the provisions of ASC 605-45 are recorded as a reduction to research and development expense.

The following summarizes our most advanced current research and development programs.

AG-221: lead IDH2 program

AG-221 is an orally available, selective, potent inhibitor of the mutated IDH2 protein, making it a highly targeted therapeutic candidate for the treatment of patients with cancers that harbor IDH2 mutations, including those with acute myeloid leukemia, or AML, who have a historically poor prognosis. On June 16, 2014, the U.S. Food and Drug Administration, or FDA, granted us orphan drug designation for AG-221 for treatment of patients with AML. On August 13, 2014, we announced that the FDA granted fast track designation to AG-221 for treatment of patients with AML that harbor an IDH2 mutation. In April 2016, we and Celgene received European Medicines Agency, or EMA, Orphan Drug Designation for AG-221 for the treatment of AML. We have been evaluating AG-221 in several phase 1 dose-escalation clinical trials evaluating both hematological and solid tumor cancers with IDH2 mutations. To date, all clinical data reported by us in hematological cancers highlights that the mechanism of response is consistent with preclinical studies, including substantial reduction of plasma 2-hydroxygluturate, or 2HG, levels, as well as evidence of cellular differentiation and normalization of cell counts in the bone marrow and blood. This differentiation effect is distinct from that seen with traditional chemotherapeutics commonly used to treat AML.

In September 2013, we initiated our first phase 1 multicenter, open-label, dose-escalation clinical trial to assess the safety, clinical activity, and tolerability of AG-221 in patients with advanced hematologic malignancies with an IDH2 mutation. In June 2014, Celgene exercised its option to an exclusive global license for development and commercialization of AG-221 under a collaboration agreement between us and Celgene, which focuses on cancer metabolism, or the 2010 Agreement. Under the 2010 Agreement, Celgene is responsible for all development costs for AG-221. We are eligible to receive up to \$120.0 million in milestone payments and a tiered royalty on any net sales of products containing AG-221. In January 2016, in conjunction with the initiation of AG-221 phase 3 trials we received a milestone payment of \$25.0 million. We also have the right to conduct a portion of any commercialization activities for AG-221 in the United States. In addition to contributing our scientific and translational expertise, we will continue to conduct some clinical development and regulatory activities within the AG-221 development program in collaboration with Celgene.

In October 2014, we initiated four expansion cohorts in our ongoing phase 1 clinical trial of AG-221 in patients with IDH2 mutant-positive hematologic malignancies to assess the safety and tolerability of AG-221 at 100 mg once daily oral dose in approximately 100 patients with IDH2 mutant-positive hematologic malignancies, including AML. In the expansion cohorts, we evaluated relapsed or refractory AML patients 60 years of age and older, relapsed or refractory AML patients under age 60, untreated AML patients who decline standard of care chemotherapy and patients with other IDH2 mutant-positive advanced hematologic malignancies.

In May 2015, we announced that our ongoing phase 1 clinical trial of AG-221 had been expanded to add an additional more homogenous cohort of 125 patients with IDH2 mutant-positive AML who are in second or later relapse, are refractory to second-line

induction or reinduction treatment, or have relapsed after allogeneic transplantation. Consistent with the previous expansion cohorts, AG-221 is administered at a dose of 100 mg once daily. The primary objectives of the trial are to confirm the safety and clinical activity of AG-221 in a select, highly resistant AML population. Enrollment of the expansion cohorts has been completed.

In October 2015, Celgene, in collaboration with us, initiated IDHENTIFY, an international phase 3, multi-center, open-label, randomized clinical trial designed to compare the efficacy and safety of AG-221 versus conventional care regimens in patients 60 years or older with IDH2 mutant-positive AML that is refractory to or relapsed after second- or third-line therapy.

In December 2015, we reported additional clinical data, as of September 1, 2015, from the dose escalation phase and expansion cohorts of the ongoing phase 1 clinical trial, which was transitioned to a phase 1/2 trial in May 2015, evaluating single agent AG-221, which included 209 response-evaluable enrolled patients with IDH2 mutant-positive AML. The new data were presented at the 2015 American Society of Hematology (ASH) Annual Meeting and Exposition in Orlando, Florida and showed investigator-assessed objective responses in 79 out of 209 response-evaluable patients. Of the 79 patients who achieved an objective response, there were 37 complete remissions (CR), three complete remissions with incomplete platelet recovery (CRp), 14 marrow complete remissions (mCR), three complete remissions with incomplete hematologic recovery (CRi) and 22 partial remissions (PR). A CR is determined by using wellestablished criteria, which requires no evidence of leukemia in the bone marrow and blood accompanied by full restoration of all blood counts to normal ranges. A CRp means all the criteria for CR are met except that platelet counts are outside of the normal range. Platelets are one of the three major types of blood cells. A mCR means that there is no evidence for leukemia in the marrow but the blood counts have not fully restored. A CRi means there is no evidence for leukemia in the marrow but the neutrophils, a subset of white blood cells responsible for fighting bacterial infections, are outside the normal range. A partial response means all the criteria for CR are met except that the immature defective blood cells, or leukemia, in the bone marrow are in the 5% to 25% range and have been decreased by at least 50% over pretreatment. Of the 159 patients with relapsed or refractory AML, 59 achieved an objective response, including 29 CRs, one CRp, nine mCRs, three CRis and 17 PRs. Of the 24 patients with AML who declined standard of care chemotherapy, 10 achieved an objective response, including four CRs, one CRp, one mCR and four PRs. Of the 14 patients with MDS, seven achieved an objective response, including three CRs, one CRp and three mCRs. Responding relapsed or refractory AML patients were on the trial for up to 18 months with a median duration of treatment of 6.8 months, ranging from 1.8 to 18 months. Responses were durable, with median response duration of 6.9 months in patients with relapsed or refractory AML. A safety analysis was conducted for all 231 treated patients. The majority of adverse events, or AEs, reported by investigators were mild to moderate, with the most common being nausea, diarrhea, fatigue and febrile neutropenia. The serious adverse events, or SAEs, observed during the trial were mainly disease related. Twenty-three percent of patients had treatment-related SAEs, including notably differentiation syndrome (4 percent), leukocytosis (4 percent) and nausea (2 percent). Drug-related Grade 5 SAEs included atrial flutter (one patient), cardiac tamponade (one patient), pericardial effusion (one patient) and respiratory failure (one patient). Dose escalation has been completed and a maximum tolerated dose, or MTD, has not been reached. AG-221 continued to show favorable drug exposure and pharmacokinetics at all doses tested with substantial reductions in plasma levels of 2HG, which is produced by the mutated IDH2 and IDH1 proteins, to the level observed in healthy volunteers. In 2016, Celgene, in collaboration with us, intends to initiate an expansion arm of our phase 1/2 clinical trial, evaluating AG-221 in high-risk MDS patients.

Also in December 2015, we announced the initiation of a phase 1b, multicenter, international, open-label clinical trial to evaluate the safety and clinical activity of AG-221 or AG-120 in combination with induction and consolidation therapy in patients with newly diagnosed AML with an IDH2 or IDH2 mutation who are eligible for intensive chemotherapy. The trial will evaluate continuous dosing for up to one year with AG-221 administered at an initial oral dose of 100 mg once daily in patients with an IDH2 mutation or AG-120 administered at an initial oral dose of 500 mg once daily in patients with an IDH1 mutation. AG-221 or AG-120 will be administered with two types of AML induction therapies (cytarabine with either daunorubicin or idarubicin) and two types of AML consolidation therapies (mitoxantrone with etoposide [ME] or cytarabine).

In March 2016, Celgene, in collaboration with us, initiated a phase 1/2 frontline combination clinical trial, to be conducted by Celgene, of either AG-221 or AG-120 in combination with VIDAZA® (azacitidine) in newly diagnosed AML patients not eligible for intensive chemotherapy, with a phase 1 component to determine the safety of the combinations, followed by a phase 2 randomized component evaluating the safety and clinical activity of each investigational combination versus single-agent VIDAZA® using a primary endpoint of overall response rate.

Celgene maintains worldwide development and commercial rights to AG-221 and Celgene will fund the future development and commercialization costs related to this program.

AG-120: lead IDH1 program

AG-120 is an orally available, selective, potent inhibitor of the mutated IDH1 protein, making it a highly targeted therapeutic candidate for the treatment of patients with cancers that harbor IDH1 mutations. Mutations in IDH1 have been identified in difficult to treat hematologic and solid tumor cancers, including AML, chondrosarcoma and cholangiocarcinoma where both the treatment options and prognosis for patients are poor. In March 2014, we initiated two phase 1, multicenter, open-label, dose-escalation and expansion clinical trials for AG-120, one designed to assess the safety, clinical activity and tolerability of AG-120 as a single agent in patients with advanced hematologic malignancies and the second designed to evaluate the safety, clinical activity and tolerability of AG-120 in patients with advanced solid tumors. Both trials are only enrolling patients that carry an IDH1 mutation. On May 18, 2015, we announced that the FDA granted fast track designation to AG-120 for treatment of patients with AML that harbor an IDH1 mutation. On June 10, 2015, the FDA granted us orphan drug designation for AG-120 for treatment of patients with AML.

Four expansion cohorts have been added to the ongoing phase 1 clinical trial of AG-120 in patients with advanced hematologic malignancies. These four expansion cohorts will evaluate AG-120 in 200 patients with IDH1 mutant-positive advanced hematologic malignancies. The first cohort will evaluate a more homogenous population of 125 AML patients who are in second or later relapse, are refractory to second-line induction or reinduction treatment, or have relapsed after allogeneic transplantation. The second cohort will evaluate 25 untreated AML patients. The third cohort will evaluate 25 patients with other non-AML IDH1 mutant-positive relapsed or refractory advanced hematologic malignancies. The fourth cohort will evaluate patients with relapsed IDH1 mutant-positive AML not eligible for the first arm or standard of care chemotherapy. AG-120 is administered at a 500 mg once daily oral dose, in 28-day cycles. The trial's primary objectives are to confirm the safety and clinical activity of AG-120.

In November 2015, we reported clinical data from the dose-escalation portion of our ongoing phase 1 clinical trial evaluating AG-120 in patients with IDH1 mutant-positive advanced solid tumors, including glioma, intrahepatic cholangiocarcinoma, or IHCC, and chondrosarcomas who received AG-210 administered from 200 mg to 1200 mg total daily doses. The data were presented at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics in Boston. As of the September 3, 2015 data cut-off, 62 patients had been treated with single agent AG-120, of which 55 were response-evaluable. Seven of the 11 response-evaluable patients with IDH1 mutant-positive chondrosarcoma had stable disease, with five of these patients maintaining stable disease for six months or more. One of the 20 patients with IDH1 mutant-positive IHCC had a partial response and 11 patients had stable disease, with six such patients maintaining stable disease for six months or more. Ten of the 20 patients with IDH1 mutant-positive glioma had stable disease, with four of these patients maintaining stable disease for six months or more. One of the four patients with other IDH1 mutant-positive solid tumors had stable disease. Treatment with AG-120 showed substantial reduction of 2HG in plasma and tumor tissue, and imaging results suggest that AG-120 can lower 2HG levels in the brain. AG-120 was well tolerated, with the majority of AEs reported by investigators being mild to moderate. The most common investigator-reported AEs were nausea, diarrhea, vomiting, anemia and QT prolongation. The majority of reported SAEs were disease related. A MTD has not been reached. We are currently enrolling four expansion cohorts of 25 patients each in (i) low grade glioma with at least six months of prior scans to assess volumetric changes, (ii) second-line cholangiocarcinoma, (iii) high grade, or metastatic, chondrosarcoma, and (iv) other solid tumors with an IDH1 mutation, who will receive the recommended dose of 500 mg of AG-120 once daily.

In December 2015, we reported new data, as of October 1, 2015, from the ongoing phase 1 clinical trial evaluating single agent AG-120, which included 87 enrolled patients with IDH1 mutant-positive advanced hematologic malignancies, of which 78 were from the dose-escalation phase and nine were from the expansion phase. The data were presented at the 2015 ASH Annual Meeting and Exposition in Orlando, Florida and showed investigator-assessed objective responses in 27 out of 78 response-evaluable patients on AG-120. Of the 27 patients who achieved an objective response, there were 12 CRs, seven CRps, six mCRs, one CRi and one PR. Patients were on the trial treatment for up to 14.1 months, with a median duration of treatment of 2.9 months, ranging from 0.1 to 14.1 months. Data continued to show durable clinical activity for AG-120, with responses maintained for up to 12.5 months and a median duration of response of 5.6 months. AG-120 continued to show favorable drug exposure and pharmacokinetics at all doses tested and also substantially reduced plasma levels of 2HG to the level observed in healthy volunteers. The mechanism of response is consistent with differentiation, as evidenced by the maturation of the leukemic cells into infection fighting white blood cells, or neutrophils. The majority of AEs reported by investigators were mild to moderate, with the most common being fatigue, diarrhea, pyrexia and nausea. A MTD has not been reached, and dose escalation is now complete.

As described above, in December 2015, we announced the initiation of a phase 1b, multicenter, international, open-label clinical trial of AG-221 or AG-120 in combination with induction and consolidation therapy in patients with newly diagnosed AML with an isocitrate dehydrogenase (IDH) mutation who are eligible for intensive chemotherapy. Also as described above, in the March 2016, Celgene, in collaboration with us, initiated a phase 1/2 frontline combination clinical trial, to be conducted by Celgene, of either AG-221 or AG-120 in combination with VIDAZA® (azacitidine) in newly diagnosed AML patients not eligible for intensive chemotherapy, with a phase 1 component to determine the safety of the combinations, followed by a phase 2 randomized component evaluating the safety and clinical activity of each investigational combination versus single-agent VIDAZA® using a primary endpoint of overall response rate.

We intend to initiate a global registration-enabling phase 3 clinical trial in frontline AML patients who harbor an IDH1 mutation in the first half of 2017. In addition, we intend to initiate a randomized phase 2 clinical trial of AG-120 in patients with IDH1 mutant-positive cholangiocarcinoma in the second half of 2016

As described above, Celgene and we agreed to terminate the 2010 Agreement, effective as of August 15, 2016, as to the program directed to the IDH1 target, for which AG-120 is the lead development candidate. Under the 2010 Agreement, Celgene had held development and commercialization rights to the IDH1 program outside of the United States, and we held such rights inside the United States. As a result of the termination, we will obtain global rights to AG-120 and the IDH1 program and expect to fund the future development and commercialization costs related to the program. Neither party will have any financial obligation, including royalties or milestone payments, to the other concerning AG-120 or the IDH1 program after final reconciliation of specified shared development costs.

AG-881: pan-IDH program

AG-881 is an orally available, selective, brain-penetrant, pan-IDH mutant inhibitor, which provides added flexibility to our current portfolio of IDH mutant inhibitors. AG-881 successfully completed IND-enabling studies in April 2015. We and Celgene are jointly collaborating on a worldwide development program, wherein we share worldwide development costs and profits and Celgene would book any worldwide commercial sales. We will lead commercialization in the United States with both companies sharing equally in field-based commercial activities, and Celgene will lead commercialization outside of the United States with us providing one third of field-based commercial activities in the major EU markets.

We are conducting phase 1 multi-center, open-label clinical trials of AG-881, one in patients with advanced IDH1 or IDH2 mutant-positive solid tumors, including glioma, and the other in patients with advanced IDH1 or IDH2 mutant-positive hematologic malignancies whose cancer has progressed on a prior IDH inhibitor therapy. The goal of these trials is to evaluate the safety, pharmacokinetics, pharmacodynamics and clinical activity of AG-881 in advanced solid tumors and hematologic malignancies, respectively. In each trial, AG-881 will be administered continuously as a single agent dosed orally in a 28-day cycle. The first portion of each trial includes a dose-escalation phase in which cohorts of patients will receive ascending oral doses of AG-881 to determine the maximum tolerated dose and/or the recommended phase 2 dose based on safety and tolerability. The second portion of each trial is a dose expansion phase where patients will receive AG-881 to further evaluate the safety, tolerability and clinical activity of the recommended phase 2 dose.

AG-348: lead pyruvate kinase deficiency program

AG-348 is an orally available small molecule and a potent activator of the wild-type (normal) and mutated PKR enzyme, which has resulted in restoration of ATP levels and a decrease in 2,3-DPG (2,3-diphosphoglycerate) levels in blood sampled from patients with PK deficiency in nonclinical studies. The wild-type PKR activity of AG-348 allowed the study of enzyme activation in healthy volunteers, providing an opportunity to understand the safety, dosing and pharmacodynamic activity of AG-348 prior to entering a proof-of-concept study in patients. On March 24, 2015, the FDA granted us orphan drug designation for AG-348 for treatment of patients with PK deficiency.

In June 2015, we initiated DRIVE PK, a global phase 2, first-in-patient, open-label safety and efficacy clinical trial of AG-348 in adult, transfusion-independent patients with PK deficiency. The multi-center, randomized trial includes two arms with 25 patients each. The patients in the first arm receive 50 mg twice daily, and the patients in the second arm receive 300 mg twice daily. The trial includes a six-month dosing period with the opportunity for continued treatment beyond six months based on safety and clinical activity.

In June 2016, we reported the first clinical data from DRIVE PK at the 21st Congress of the European Hematology Association (EHA) in Copenhagen, Denmark. These data established proof of concept for AG-348 as a novel, first-in-class, oral activator of both wild-type and mutated PKR enzymes. Results presented were as of the March 27, 2016 data cut-off and were from 18 transfusion independent patients treated with twice-daily dosing for up to six months. The data showed that AG-348 was well tolerated, and no patients discontinued treatment early. The majority of AEs were mild to moderate and transient. One patient received a dose reduction due to rapidly increasing hemoglobin. This patient was dose-reduced from 300 mg to 50 mg and remained on study. One Grade 2 AE of osteoporosis was reported after the cut-off date. This patient had osteopenia at baseline assessment. Sex steroids were assessed at baseline, week 12 and week 24. Free testosterone and estradiol were available for four and five male patients, respectively. An upward trend in free testosterone and a downward trend in estradiol were observed in these patients. Due to the small number of female patients with hormone data, only data from male patients were reported. Additional data and longer follow up are needed to determine if hormonal changes are clinically significant. In the study, nine of 18 patients, including nine of 13 patients with at least one missense

mutation, demonstrated robust, rapid and sustained increases in hemoglobin as evidenced by an increase in hemoglobin of greater than 1.0 g/dL. Both doses of AG-348 demonstrated clinical activity, with four patients in the 50 mg group and five patients in the 300 mg group experiencing increases of greater than 1.0 g/dL. In patients who had hemoglobin increases of greater than 1.0 g/dL, the mean maximum hemoglobin increase was 3.4 g/dL (range 2.3–4.9 g/dL). The median time to a hemoglobin increase of >1.0 g/dL was 1.9 weeks (range 1.1–9.1 weeks). None of the five patients with two non-missense mutations showed increases in hemoglobin of greater than 1.0 g/dL. Further data are needed to obtain a greater understanding of the relationship between genotype and response. Additionally, pharmacokinetics was favorable and consistent with those observed in healthy volunteers. Pharmacodynamics data did not demonstrate a correlation with hemoglobin increases and ATP elevation. More data are needed to clarify if any correlation exists between 2,3-DPG (2,3-diphosphoglycerate) decreases and Hb increases of greater than 1.0 g/dL. Enrollment for this trial is ongoing.

We have worldwide development and commercial rights to AG-348 and expect to fund the future development and commercialization costs related to this program.

AG-519: a second novel PKR activator

AG-519 is an orally available small molecule and our second product candidate that is a potent activator of the PKR enzyme. We initiated a placebo-controlled phase 1 clinical trial of AG-519 in healthy volunteers in the first quarter of 2016. This trial is an integrated single ascending dose, or SAD, and multiple ascending dose, or MAD, trial.

In June 2016, we reported the first clinical data from this trial at EHA in Copenhagen. These results provided proof-of-mechanism for AG-519, a potent, oral, selective PKR activator. In the SAD portion of the trial, four cohorts with doses of AG-519 ranging from 50 mg to 1250 mg were tested against placebo in 32 healthy volunteers and demonstrated a favorable safety profile in all doses tested. There were no SAEs reported, and all AEs were mild to moderate, with the most common being headache. In addition, there were no early discontinuations due to AG-519 and the maximum tolerated dose was not reached. Mean decreases in blood 2,3-DPG levels, up to 43 percent from baseline were observed in the SAD cohorts, reaching minimum levels after 24 hours. As expected, ATP levels did not change after a single dose of AG-519, consistent with phase 1 SAD findings from AG-348. Healthy volunteers receiving placebo showed no changes in 2,3-DPG or ATP levels. In the MAD portion of the trial, the first two cohorts reported data from 16 healthy volunteers dosed twice daily with 125 mg or 375 mg of AG-519 or placebo for 14 days. There were no SAEs reported, with all AEs being mild to moderate, and the most common being headache. One subject receiving AG-519 at the 375 mg dose experienced a low blood platelet count (Grade 2 thrombocytopenia) on Day 14. Platelet levels started to recover within five days of the last dose and returned to normal levels seven days after the last dose. Since the EHA data presentation, three additional cohorts of healthy volunteers have been dosed with AG-519 in the MAD portion of the trial, in which there have been no additional reported cases of low blood platelet count. Pharmacodynamic data from these MAD cohorts showed a mean decrease of up to 62 percent in blood 2,3-DPG levels and a mean increase of up to 62 percent in blood ATP levels from baseline. In contrast, healthy volunteers receiving placebo showed no changes in 2,3-DPG levels and a mean increase of up to 62 percent in blood ATP levels from

We have worldwide development and commercial rights to AG-519 and expect to fund the future development and commercialization costs related to this program.

Other research and platform programs

Other research and platform programs include activities related to exploratory efforts, target validation and lead optimization for our discovery and follow-on programs and our proprietary metabolomics platform.

We use our employee and infrastructure resources across multiple research and development programs, and we allocate internal employee-related and infrastructure costs, as well as certain third-party costs, net of reimbursements from Celgene, to each of these programs based on the personnel resources allocated to such program. Our research and development expenses, by major program, are outlined in the table below:

		nths Ended		hs Ended	
	Jun	June 30,		June 30,	
(in thousands)	2016	2015	2016	2015	
IDH2 inhibitor (AG-221)	\$ 2,079	\$ 2,258	\$ 4,277	\$ 5,587	
IDH1 inhibitor (AG-120)	20,572	12,444	33,699	22,861	
Pan IDH inhibitor (AG-881)	3,129	3,441	6,131	7,314	
PKR activator (AG-348)	5,099	4,607	10,191	9,678	
PKR activator (AG-519)	4,737	2,074	9,542	2,687	
Other research and platform programs	15,188	11,599	31,002	20,739	
Total research and development expenses, net	\$50,804	\$36,423	\$94,842	\$68,866	

Research and development expenses for AG-221 for the three months ended June 30, 2016 and 2015 are net of \$0.7 million and \$1.1 million, respectively, and the six months ended June 30, 2016 and 2015 are net of \$1.2 million and \$5.5 million, respectively, in reimbursement of certain third-party costs under the 2010 Agreement, as amended, which are classified as a reduction of research and development expense.

Research and development expenses for AG-120 for the three and six months ended June 30, 2016 are net of \$3.3 million and \$9.9 million, respectively and for the three and six months ended June 30, 2015 are net of \$2.6 million in reimbursement of certain third-party and internal costs under the 2010 Agreement, as amended, which are classified as a reduction of research and development expense.

Research and development expenses for AG-881 for the three and six months ended June 30, 2016 are net of \$1.9 million and \$3.6 million, respectively and for the three and six months ended June 30, 2015, are net of \$0.8 million in reimbursement of certain third-party and internal costs under the AG-881 Agreements, which are classified as a reduction of research and development expense.

The successful development of our product candidates is highly uncertain. As such, at this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the remainder of the development of these product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from AG-221, AG-120, AG-881, AG-348, AG-519 or any of our other product candidates. This is due to the numerous risks and uncertainties associated with developing medicines, including the uncertainty of:

- establishing an appropriate safety profile with IND and/or NDA enabling toxicology studies;
- successful enrollment in, and completion of, clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- · obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- · launching commercial sales of the products, if and when approved, whether alone or in collaboration with others; and
- maintaining an acceptable safety profile of the products following approval.

A change in the outcome of any of these variables with respect to the development of any of our product candidates would significantly change the costs and timing associated with the development of that product candidate.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect research and development costs to increase significantly for the foreseeable future as our product candidate development programs progress. However, we do not believe that it is possible at this time to accurately project total program-specific expenses through commercialization. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will impact our clinical development programs and plans.

General and administrative expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in executive, finance, accounting, business development, legal and human resources functions. Other significant costs include facility costs not otherwise included in research and development expenses, legal fees relating to patent and corporate matters and fees for accounting and consulting services.

We anticipate that our general and administrative expenses will increase in the future to support continued research and development activities and potential commercialization of our product candidates. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside consultants, lawyers and accountants, among other expenses.

Critical Accounting Policies and Estimates

Our critical accounting policies are those policies which require the most significant judgments and estimates in the preparation of our consolidated financial statements. Management has determined that our most critical accounting policies are those relating to revenue recognition, accrued research and development expenses and stock-based compensation. There have been no significant changes to our critical accounting policies discussed in the Annual Report on Form 10-K for the year ended December 31, 2015.

Results of Operations

Comparison of three months ended June 30, 2016 and 2015

The following table summarizes our results of operations for the three months ended June 30, 2016 and 2015, together with the changes in those items in dollars and as a percentage:

	Three Mor June			
(in thousands)	2016	2015	Dollar Change	% Change
Collaboration revenue – related party	\$ 6,978	\$ 13,219	\$ (6,241)	(47)%
Operating expenses:				
Research and development (net of \$5,922 and \$4,546 of cost reimbursement from				
related party for the three months ended June 30, 2016 and 2015, respectively)	50,804	36,423	14,381	39
General and administrative	12,644	8,929	3,715	42
Loss from operations	(56,470)	(32,133)	(24,337)	76
Interest income	517	236	281	119
Net loss	\$(55,953)	\$(31,897)	\$ (24,056)	75%

Revenue. In April 2015, we entered into the AG-881 Agreements with Celgene upon which we received additional consideration and were required to evaluate the 2010 Agreement and AG-881 Agreements under the current revenue recognition accounting guidance resulting in additional revenue being recognized. For the three months ended June 30, 2015, we recognized \$13.2 million in revenue under the new accounting guidance, which includes the recognition of \$8.8 million related to the delivery of U.S and ex-U.S. licenses for AG-881.

In May 2016, we entered into the 2016 Agreement with Celgene upon which we received a \$200.0 million upfront payment and which required us to reevaluate the 2010 Agreement, AG-881 Agreements and the 2016 Agreement under the current revenue recognition accounting guidance. In addition, in May 2016, Celgene and we agreed to terminate the 2010 Agreement as to the AG-120 program. For the three months ended June 30, 2016, we recognized \$7.0 million in revenue under the new accounting guidance, which includes \$3.9 million related to new deliverables identified under the 2016 Agreement and does not include any revenue associated with the AG-120 program after the 2016 amendment date.

Research and Development Expense. The increase in research and development expenses was primarily attributable to net increases of \$6.9 million in external services and \$7.5 million in internal expenses; both of these increases are inclusive of \$5.9 million in reimbursement of certain costs related to AG-221, AG-120 and AG-881, which are recorded as a reduction of research and development expenses. During the three months ended June 30, 2016 and 2015, we recognized certain cost reimbursements related to our on-going development activities under our IDH programs for which we are no longer acting as the principal in the transaction as a reduction of research and development expenses.

The increase in external services in 2016 was attributable to the following:

- increases of approximately \$0.8 million and \$2.9 million for external clinical studies and manufacturing activities for our lead product candidates AG-221 and AG-120, respectively, offset by decreases of approximately \$0.2 million and \$0.8 million for external clinical studies and manufacturing activities for our lead product candidates AG-348 and AG-881, respectively;
- an increase of approximately \$0.9 million for preclinical and clinical studies for our product candidate AG-519; and
- an increase of approximately \$3.3 million for costs related to other early research and platform programs.

We incurred approximately \$7.5 million of additional internal research and development expenses related to the following:

- an increase of \$6.4 million in personnel costs related to an increase in our internal headcount of 46%, which includes an increase of \$2.0 million in stock-based compensation expense; and
- an increase of approximately \$1.1 million for facilities and other related expenses.

General and Administrative Expense. The increase in general and administrative expenses was primarily attributable to the following:

- an increase of \$2.1 million in personnel costs related to an increase in our internal headcount of 42% which includes an increase of \$0.8 million for stock-based compensation expense;
- an increase of \$1.3 million in professional service costs and insurance costs; and
- an increase of \$0.3 million in certain operating expenses, including consulting and facility costs.

Interest Income. The increase is attributable to a more diversified investment portfolio, resulting in higher interest earned on investments.

Provision for Income Tax. We did not have a provision for income taxes during the three months ended June 30, 2016 or 2015 due to our net loss.

Comparison of six months ended June 30, 2016 and 2015

The following table summarizes our results of operations for the six months ended June 30, 2016 and 2015, together with the changes in those items in dollars and as a percentage:

	Six Mont June			
(in thousands)	2016	2015	Dollar Change	% Change
Collaboration revenue – related party	\$ 38,259	\$ 47,421	\$ (9,162)	(19)%
Operating expenses:				
Research and development (net of \$14,716 and \$8,912 of cost reimbursement from				
related party for the six months ended June 30, 2016 and 2015, respectively)	94,842	68,866	25,976	38
General and administrative	23,481	15,883	7,598	48
Loss from operations	(80,064)	(37,328)	(42,736)	114
Interest income	913	474	439	93
Net loss	\$(79,151)	\$(36,854)	\$ (42,297)	115%

Revenue. In April 2015, we entered into the AG-881 Agreements with Celgene upon which we received additional consideration and were required to evaluate the 2010 Agreement and AG-881 Agreements under the current revenue recognition accounting guidance resulting in additional revenue being recognized. For the six months ended June 30, 2015, we recognized \$47.4 million in revenue under the new accounting guidance, which includes approximately \$4.8 million related to the delivery of certain AG-120 studies, \$8.8 million related to the delivery of an ex. U.S. licenses for AG-881 and \$15.8 million related to the delivery of an ex. U.S. license for AG-120.

In May 2016, we entered into the 2016 Agreement with Celgene upon which we received a \$200.0 million upfront payment and required us to reevaluate the 2010 Agreement, AG-881 Agreements and the 2016 Agreement under the current revenue recognition accounting guidance. In addition, in May 2016, the Celgene and we agreed to terminate the 2010 Agreement as to the AG-120 program. For the six months ended June 30, 2016, we recognized \$38.3 million in revenue under the new accounting guidance, which includes \$3.9 million related to new deliverables identified under the 2016 Agreement and does not include any revenue associated with the AG-120 program after the 2016 amendment date. In addition, during the three months ended March 31, 2016, we recognized a \$25.0 million milestone payment related to a substantial clinical development milestone achieved.

Research and Development Expense. The increase in research and development expenses was primarily attributable to net increases of \$8.4 million in external services and \$17.6 million in internal expenses; both of these increases are inclusive of \$14.7 million in reimbursement of certain costs related to AG-221, AG-120 and AG-881, which are recorded as a reduction of research and development expenses. During the six months ended June 30, 2016 and 2015, we recognized certain cost reimbursements related to our on-going development activities under our IDH programs for which we are no longer acting as the principal in the transaction as a reduction of research and development expenses.

The increase in external services in 2016 was attributable to the following:

- an increase of approximately \$0.7 million for external clinical studies and manufacturing activities for our lead product candidate AG-120, offset by decreases of approximately \$0.2 million, \$2.0 million and \$1.2 million for our lead product candidates AG-221, AG-881 and AG-348, respectively;
- an increase of approximately \$3.6 million for preclinical and clinical studies for our product candidate AG-519; and
- an increase of approximately \$7.5 million for costs related to other early research and platform programs.

We incurred approximately \$17.6 million of additional internal research and development expenses related to the following:

- an increase of \$13.8 million in personnel costs related to an increase in our internal headcount of 46%, which includes an increase of \$4.9 million in stock-based compensation expense; and
- an increase of approximately \$3.8 million for facilities and other related expenses.

General and Administrative Expense. The increase in general and administrative expenses was primarily attributable to the following:

- an increase of \$4.9 million in personnel costs related to an increase in our internal headcount of 42% which includes an increase of \$1.9 million for stock-based compensation expense; and
- an increase of \$2.7 million in professional service costs and insurance costs.

Interest Income. The increase is attributable to a more diversified investment portfolio, resulting in higher interest earned on investments.

Provision for Income Tax. We did not have a provision for income taxes during the six months ended June 30, 2016 or 2015 due to our net loss.

Liquidity and Capital Resources

Sources of liquidity

Since our inception, and through June 30, 2016, we have funded our operations through upfront, extension and cost reimbursement payments related to our collaboration agreements with Celgene, proceeds received from our issuance of preferred stock, our IPO and our follow-on public offerings, including private placement of common stock to an affiliate of Celgene, which was completed concurrently with our IPO.

In addition to our existing cash, cash equivalents and marketable securities, we are eligible to earn a significant amount of milestone payments, designation fees, license option fees, extension fees and are entitled to cost reimbursements under our collaboration agreements with Celgene. Our ability to earn the milestone payments and cost reimbursements and the timing of earning these amounts are dependent upon the timing and outcome of our development, regulatory and commercial activities and are uncertain at this time. Our right to payments under our collaboration agreements is our only committed potential external source of funds.

Cash flows

The following table provides information regarding our cash flows for the six months ended June 30, 2016 and 2015:

		Six Months Ended June 30,	
(in thousands)	2016	2015	
Net cash provided by (used in) operating activities	\$138,815	\$(21,605)	
Net cash provided by investing activities	20,912	77,194	
Net cash provided by financing activities	2,557	2,913	
Net increase in cash and cash equivalents	<u>\$162,284</u>	\$ 58,502	

Net cash provided by (used in) operating activities. During the six months ended June 30, 2016, we received a \$200.0 million upfront payment from Celgene related to our 2016 Agreement, \$18.5 million in cost reimbursements related to our collaboration agreements, including a \$25.0 million milestone payment in conjunction with the achievement of a substantive development milestone, and \$3.4 million as reimbursement of tenant improvements. These amounts were offset by increased operating expenses which relate to increases in clinical study costs due to advancements in our lead product candidates, expanded facilities and increased staffing needs due to our expanding operations.

During the six months ended June 30, 2015, we received \$13.3 million in cost reimbursements related to the 2010 Agreement, \$20.0 million related to Celgene's December 2014 election to extend the discovery phase of the 2010 Agreement and \$10.0 million related to our AG-881 Agreements. We received \$3.8 million of refundable income taxes during the six months ended June 30, 2015, related to a previously filed carryback claim.

Net cash provided by investing activities. The cash provided by investing activities for the six months ended June 30, 2016 and 2015 was primarily the result of higher proceeds from maturities and sales of marketable securities offset by \$5.3 million and \$14.7 million in purchases of property and equipment, respectively.

Net cash provided by financing activities. The cash provided by financing activities for the six months ended June 30, 2016 and 2015 was the result of proceeds received from stock option exercises and proceeds received from stock purchases made pursuant to our employee stock purchase plan.

Funding requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research, development and clinical trials of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution to the extent that such sales, marketing and distribution are not the responsibility of Celgene or other collaborators. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

We expect that our existing cash, cash equivalents and marketable securities as of June 30, 2016, together with anticipated interest income, and anticipated expense reimbursements under our collaboration agreements with Celgene will enable us to fund our operating expenses and capital expenditure requirements through mid-2018. Our future capital requirements will depend on many factors, including:

- · the scope, progress, results and costs of drug discovery, preclinical development, laboratory testing and clinical trials for our product candidates;
- the success of our collaborations with Celgene;
- the extent to which we acquire or in-license other medicines and technologies;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- · our ability to establish and maintain additional collaborations on favorable terms, if at all.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenue, if any, will be derived from sales of medicines that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds, other than our collaborations with Celgene. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Off-balance Sheet Arrangements

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

Contractual obligations

During the six months ended June 30, 2016, we entered into agreements in the normal course of business with CROs for clinical trials and clinical supply manufacturing and with vendors for preclinical research studies and other services and products for operating purposes. These contractual obligations are cancelable at any time by us, generally upon 30 days' prior written notice to the vendor. Under these agreements, as of June 30, 2016 we are obligated to pay up to \$66.0 million to these vendors.

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. As of June 30, 2016 and December 31, 2015, we had cash, cash equivalents and marketable securities of \$512.3 million and \$375.9 million, respectively, consisting primarily of investments in certificates of deposit, government securities and corporate debt securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term marketable securities. Our marketable securities are subject to interest rate risk and could fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, we do not believe an immediate 10% change in interest rates would have a material effect on the fair market value of our investment portfolio. We have the ability to hold our marketable securities 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 are also exposed to market risk related to changes in foreign currency exchange rates. We have contracts with CROs that are located in Asia and Europe that are denominated in foreign currencies. We are subject to fluctuations in foreign currency rates in connection with these agreements. We do not currently hedge our foreign currency exchange rate risk. As of June 30, 2016 and December 31, 2015, we had minimal or no liabilities denominated in foreign currencies.

Item 4. Controls and Procedures.

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures. Based on that evaluation of our disclosure controls and procedures as of June 30, 2016, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date are effective at the reasonable assurance level. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act are recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

No change in our internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, occurred during the fiscal quarter ended June 30, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1A. Risk Factors

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained herein, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements expressed or implied by the forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. You should read this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect. The risks described are not the only risks facing our company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. These risk factors restate and supersede the risk factors set forth under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2015.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

Since inception, we have incurred significant operating losses. Our net losses were \$117.7 million, \$53.5 million and \$39.4 million for the years ended December 31, 2015, 2014 and 2013, respectively, and \$79.2 million for the six months ended June 30, 2016. As of June 30, 2016, we had an accumulated deficit of \$363.8 million. We have never generated any revenue from product sales, have not completed the development of any product candidate and may never have a product candidate approved for commercialization. We have financed our operations primarily through private placements of our preferred stock, our initial public offering and the concurrent private placement, our follow-on public offerings and our collaboration agreements with Celgene Corporate, or Celgene, focused on cancer metabolism. We have devoted substantially all of our efforts to research and development. We are in clinical development stages of our product candidates and expect that it will be many years, if ever, before we have a product candidate ready for commercialization. Although we may from time to time report profitable results, we expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter. We anticipate that our expenses will increase substantially if and as we:

- initiate and continue clinical trials for our product candidates, including our most advanced product candidates AG-221, AG-120, AG-881, AG-348 and AG-519;
- · continue our research and preclinical development of our product candidates;
- seek to identify additional product candidates;
- seek marketing approvals for our product candidates that successfully complete clinical trials;
- · establish a sales, marketing and distribution infrastructure to commercialize any medicines for which we may obtain marketing approval;
- require the manufacture of larger quantities of product candidates for clinical development and, potentially, commercialization;
- · maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, quality control and scientific personnel;
- add additional personnel to support our product development and planned future commercialization efforts and our operations;
- · add equipment and physical infrastructure to support our research and development; and
- acquire or in-license other medicines and technologies.

To become and remain profitable, we must develop and eventually commercialize a medicine or medicines with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing and selling those medicines for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in these activities and, even if we do, may never generate revenue that are significant or large enough to achieve profitability. We are currently in clinical testing stages for our most advanced product candidates. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company could also cause our stockholders to lose all or part of their investment.

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

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, initiate and continue clinical trials of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of Celgene or other collaborators. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

We expect that our existing cash, cash equivalents and marketable securities as of June 30, 2016, together with anticipated interest income, and the anticipated expense reimbursements under our collaboration agreements with Celgene will fund our operating and capital expenditure requirements through mid-2018. Our estimate as to how long we expect our existing cash and cash equivalents, to be able to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of drug discovery, preclinical development, laboratory testing and clinical trials for our product candidates;
- · the success of, and developments regarding, our collaborations with Celgene;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- · our ability to establish and maintain additional collaborations on favorable terms, if at all; and
- the extent to which we acquire or in-license other medicines and technologies.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenue, if any, will be derived from sales of medicines that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds, other than our collaborations with Celgene, which are limited in scope and duration. For example, the discovery phase under our 2010 collaboration agreement with Celgene, or the 2010 Agreement, expired in April 2016 and we will no longer receive payments from Celgene with respect to extensions of the discovery phase under the 2010 Agreement. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. In addition, securing financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our product candidates.

If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us.

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

We are a clinical-stage company. We were founded in the second half of 2007 and commenced operations in late 2008. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, acquiring and developing our technology, identifying potential product candidates, undertaking preclinical and clinical studies of our product candidates, and establishing a commercial infrastructure. All of our product candidates are still in preclinical and clinical development. We have not yet demonstrated our ability to successfully complete any large-scale or pivotal clinical trials, obtain marketing approvals, manufacture a commercial scale medicine, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Typically, it takes about 10 to 15 years to develop one new medicine from the time it is discovered to when it is available for treating patients, assuming that it successfully completes all stages of research and development and achieves marketing approval, all of which is highly uncertain. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

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

We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

Risks Related to the Discovery, Development, and Commercialization of our Product Candidates

We do not know whether we will be able to develop any medicines of commercial value, based on our approach to the discovery and development of product candidates that target cellular metabolism.

Our scientific approach focuses on using our proprietary technology to identify key metabolic enzymes in cancer, RGDs or other diseased cells in the laboratory and then using these key enzymes to screen for and identify product candidates targeting cellular metabolism. In addition, in May 2016 we entered into a new collaboration agreement with Celgene, or the 2016 Agreement, focused on metabolic immuno-oncology. Metabolic immuno-oncology is an emerging field of cancer research focused on altering the metabolic state of immune cells to enhance the body's immune response to cancer.

Any medicines that we develop may not effectively correct metabolic pathways or affect the metabolic state of immune cells. Even if we are able to develop a product candidate that targets cellular metabolism in preclinical studies, we may not succeed in demonstrating safety and efficacy of the product candidate in human clinical trials. Our focus on using our proprietary technology to screen for and identify product candidates targeting cellular metabolism may not result in the discovery and development of commercially viable medicines to treat cancer or RGDs.

We may not be successful in our efforts to identify or discover potential product candidates.

A key element of our strategy is to identify and test compounds that target cellular metabolism in a variety of different types of cancer and RGDs, as well as in immune cells for the treatment of cancer. A significant portion of the research that we are conducting involves new compounds and drug discovery methods, including our proprietary technology. The drug discovery that we are conducting using our proprietary technology may not be successful in identifying compounds that are useful in treating cancer or RGDs. In addition, our efforts in the emerging field of metabolic immuno-oncology may not be as successful as our efforts to date in cancer metabolism and RGDs. Furthermore, our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- · the research methodology used may not be successful in identifying appropriate biomarkers or potential product candidates; or
- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be medicines that will receive marketing approval and achieve market acceptance.

Research programs to identify new product candidates require substantial technical, financial and human resources. We may choose to focus our efforts and resources on a potential product candidate that ultimately proves to be unsuccessful.

If we are unable to identify suitable compounds for preclinical and clinical development, we will not be able to obtain product revenue in future periods, which likely would result in significant harm to our financial position and adversely impact our stock price.

We depend heavily on the success of our most advanced product candidates, all of which are still in clinical development. Clinical trials of our product candidates may not be successful. If we are unable to commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.

We have invested a significant portion of our efforts and financial resources in the identification of our most advanced product candidates, AG-221, AG-120 and AG-881 for the treatment of hematological and solid tumors and AG-348 and AG-519 for the treatment of PK deficiency. We or our collaborator have initiated clinical trials for these product candidates. We have not commenced clinical trials for any of our other product candidates. Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of these product candidates by our collaborators and us. The success of our product candidates will depend on many factors, including the following:

- successful enrollment in, and completion of, clinical trials;
- · safety, tolerability and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority for marketing approval
- timely receipt of marketing approvals from applicable regulatory authorities;
- establishing both clinical and commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- the performance of our collaborators;
- obtaining and maintaining patent and trade secret protection and non-patent exclusivity for our medicines;
- · launching commercial sales of the medicines, if and when approved, whether alone or in collaboration with others;
- · acceptance of the medicines, if and when approved, by patients, the medical community and third-party payors;
- · effectively competing with other therapies;
- continuing acceptable safety profile for the medicines following approval;
- enforcing and defending intellectual property rights and claims; and
- achieving desirable medicinal properties for the intended indications.

Many of these factors are beyond our control, including clinical development, the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing and sales efforts of any collaborator. If we or our collaborators do not achieve one or more of these factors in a timely manner or at all, we or our collaborators could experience significant delays or an inability to successfully commercialize our most advanced product candidates, which would materially harm our business.

If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

We, and any collaborators, are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining marketing approval from the FDA. Foreign regulatory authorities, such as the European Medicines Agency, or the EMA, impose similar requirements. We have not previously submitted a new drug application, or NDA, to the FDA or similar drug approval filings to comparable foreign regulatory authorities for any of our product candidates. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. The clinical development of our product candidates is susceptible to the risk of failure inherent at any stage of product development, including failure to demonstrate efficacy in a clinical trial or across a broad population of patients, the occurrence of adverse events that are severe or medically or commercially unacceptable, failure to comply with protocols or applicable regulatory requirements and determination by the FDA or any comparable foreign regulatory authority that a product candidate may not continue development or is not approvable. It is possible that even if one or more of our product candidates has a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any. Similarly, in our clinical trials we may fail to detect toxicity of or intolerability caused by our product candidates, or mistakenly believe that our product candidates are toxic or not well tolerated when that is not in fact the case.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us, or any future collaborators, and impair our ability to generate revenue from product sales, regulatory and commercialization milestones and royalties. Moreover, if we or our collaborators are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we or our collaborators are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we or our collaborators may:

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

Our failure to successfully complete clinical trials of our product candidates and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market any of our product candidates would significantly harm our business.

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

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

- regulators or institutional review boards may not authorize us, our collaborators or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we or our collaborators may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;

- clinical trials of our product candidates may produce negative or inconclusive results, and we or our collaborators may decide, or regulators may require us, to conduct additional clinical trials, including testing in more subjects, or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate; enrollment in these clinical trials, which may be particularly challenging for some of the orphan diseases we target in our RGD programs, may be slower than we anticipate; or participants may drop out of these clinical trials at a higher rate than we anticipate;
- third-party contractors used by us or our collaborators may fail to comply with regulatory requirements or meet their contractual obligations in a
 timely manner, or at all;
- we or our collaborators might have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- regulators, institutional review boards, or the data safety monitoring board for such trials may require that we, our collaborators or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than anticipated;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; and
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us, our collaborators or our investigators, regulators or institutional review boards to suspend or terminate the trials.

Product development costs for us, or any collaborators, will increase if we, or they, experience delays in testing or pursuing marketing approvals and we, or they, may be required to obtain additional funds to complete clinical trials and prepare for possible commercialization of our product candidates. We do not know whether any preclinical tests or clinical trials will begin as planned, will need to be restructured, or will be completed on schedule or at all. Significant preclinical study or clinical trial delays also could shorten any periods during which we, or any future collaborators, may have the exclusive right to commercialize our product candidates or allow our competitors, or the competitors of any collaborators, to bring products to market before we, or any collaborators, do and impair our ability, or the ability of any collaborators, to successfully commercialize our product candidates and may harm our business and results of operations. In addition, many of the factors that lead to clinical trial delays may ultimately lead to the denial of marketing approval of any of our product candidates.

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

We or our collaborators may not be able to initiate or continue clinical trials for our product candidates if we or they are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or analogous regulatory authorities outside the United States. Enrollment may be particularly challenging for some of the orphan diseases we target in our RGD programs. In addition, some of our competitors may have ongoing clinical trials for product candidates that would treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

Patient enrollment is also affected by other factors including:

- · severity of the disease under investigation;
- · availability and efficacy of approved medications for the disease under investigation;
- · eligibility criteria for the study in question;
- perceived risks and benefits of the product candidate under study;
- · efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- · proximity and availability of clinical trial sites for prospective patients.

Utilizing our precision medicine approach, we focus our development activities on genetically or biomarker defined patients most likely to respond to our therapies. As a result, the potential patient populations for our clinical trials are narrowed, and we may

experience difficulties in identifying and enrolling a sufficient number of patients in our clinical trials. In particular, the successful completion of our clinical development programs for AG-348 and AG-519 for the treatment of PK deficiency is dependent upon our ability to enroll a sufficient number of patients with PK deficiency. PK deficiency is a rare disease with a small patient population. Further, there are only a limited number of specialist physicians that regularly treat patients with PK deficiency and major clinical centers that support PK deficiency are concentrated in a few geographic regions. The small population of patients, the nature of the disease and limited trial sites may make it difficult for us to enroll enough patients to complete our clinical trials for AG-348 and AG-519 for PK deficiency in a timely and cost-effective manner.

In addition, other companies are conducting clinical trials, or may in the future conduct clinical trials, which may have similar eligibility criteria as our current or future clinical trials. For example, Novartis International AG, or Novartis, is currently conducting a phase 1 clinical trial of its IDH1 mutant inhibitor, IDH305, in patients with advanced malignancies, and this trial and other trials may compete with our clinical trials of AG-120 and/or AG-881 for eligible patients with hematological and/or other malignancies harboring an IDH1 mutation. Competition for these patients may make it particularly difficult for us to enroll enough patients to complete our clinical trials for AG-120 or AG-881 in a timely and cost-effective manner.

Furthermore, we rely on contract research organizations, or CROs, and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance. Our or our collaborators' inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

If serious adverse side effects or unexpected characteristics are identified during the development of our product candidates, we may need to abandon or limit our development of some of our product candidates.

All of our lead product candidates are still in clinical stage development and their risk of failure is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive marketing approval. Adverse events or undesirable side effects caused by, or other unexpected properties of, our product candidates could cause us, any future collaborators, an institutional review board or regulatory authorities to interrupt, delay or halt clinical trials of one or more of our product candidates and could result in a more restrictive label, or the delay or denial of marketing approval by the FDA or comparable foreign regulatory authorities. If adverse effects were to arise in patients being treated with any of our product candidates, it could require us to halt, delay or interrupt clinical trials of such product candidate or adversely affect our ability to obtain requisite approvals to advance the development and commercialization of such product candidate. If any of our product candidates is associated with adverse events or undesirable side effects or has properties that are unexpected, we, or any future collaborators, may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in earlier stage testing for treating cancer, RGDs or other diseases have later been found to cause side effects that prevented further development of the compound.

Results of preclinical studies and early clinical trials may not be predictive of results of future clinical trials.

The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of clinical trials do not necessarily predict success in future clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and we could face similar setbacks. The design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for the product candidates. Even if we, or future collaborators, believe that the results of clinical trials for our product candidates warrant marketing approval, the FDA or comparable foreign regulatory authorities may disagree and may not grant marketing approval of our product candidates.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. If we fail to receive positive results in clinical trials of our product candidates, the development timeline and regulatory approval and commercialization prospects for our most advanced product candidates, and, correspondingly, our business and financial prospects would be negatively impacted.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial medicines or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable medicines. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

If we are unable to successfully develop companion diagnostics for our therapeutic product candidates, or experience significant delays in doing so, we may not realize the full commercial potential of our therapeutics.

Because we are focused on precision medicine, in which predictive biomarkers will be used to identify the right patients for our drug candidates, we believe that our success may depend, in part, on our ability to develop companion diagnostics, which are assays or tests to identify an appropriate patient population for these drug candidates. There has been limited success to date industry-wide in developing these types of companion diagnostics. To be successful, we need to address a number of scientific, technical and logistical challenges. We have little experience in the development of diagnostics and may not be successful in developing appropriate diagnostics to pair with any of our therapeutic product candidates that receive marketing approval. Companion diagnostics are subject to regulation by the FDA and similar regulatory authorities outside the United States as medical devices and require separate regulatory approval prior to commercialization. Given our limited experience in developing diagnostics, we rely and expect to continue to rely in part or in whole on third parties for their design and manufacture. We also depend on Celgene for the development of diagnostics for some of our cancer therapeutic product candidates. If any parties, including without limitation Celgene or us, or any third parties engaged by Celgene or us are unable to successfully develop companion diagnostics for our therapeutic product candidates, or experience delays in doing so:

- the development of our therapeutic product candidates may be adversely affected if we are unable to appropriately select patients for enrollment in our clinical trials;
- our therapeutic product candidates may not receive marketing approval if safe and effective use of a therapeutic product candidate depends on an in vitro diagnostic; and
- we may not realize the full commercial potential of any therapeutics that receive marketing approval if, among other reasons, we are unable to appropriately select patients who are likely to benefit from therapy with our medicines.

As a result, our business would be harmed, possibly materially.

We have never obtained marketing approval for a product candidate and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any of our product candidates.

We have never obtained marketing approval for a product candidate. It is possible that the FDA may refuse to accept for substantive review any NDAs that we submit for our product candidates or may conclude after review of our data that our application is insufficient to obtain marketing approval of our product candidates. If the FDA does not accept or approve our NDAs for any of our product candidates, it may require that we conduct additional clinical trials, preclinical studies or manufacturing validation studies and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA-required trials or studies, approval of any NDA or application that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional trials or studies, if performed and completed, may not be considered sufficient by the FDA to approve our NDAs. Any delay in obtaining, or an inability to obtain, marketing approvals would prevent us from commercializing our product candidates, generating revenue and achieving and sustaining profitability. If any of these outcomes occur, we may be forced to abandon our development efforts for our product candidates, which could significantly harm our business.

Even if any of our product candidates receives marketing approval, we or others may later discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, which could compromise our ability, or that of any future collaborators, to market the product.

Clinical trials of our product candidates are conducted in carefully defined sets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials, or those of any future collaborator, may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If, following approval of a product candidate, we, or others, discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, any of the following adverse events could occur:

- regulatory authorities may withdraw their approval of the product or seize the product;
- we, or any future collaborators, may be required to recall the product, change the way the product is administered or conduct additional clinical trials;
- · additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular product;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a "black box" warning or a contraindication;
- we, or any future collaborators, may be required to create a Medication Guide outlining the risks of the previously unidentified side effects for distribution to patients;
- we, or any future collaborators, could be sued and held liable for harm caused to patients;
- · the product may become less competitive; and
- our reputation may suffer.

Even if any of our product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

If any of our product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. For example, current cancer treatments like chemotherapy and radiation therapy are well established in the medical community, and doctors may continue to rely on these treatments. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenue and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments;
- the approval, availability, market acceptance and reimbursement for the companion diagnostic;
- the ability to offer our medicines for sale at competitive prices;
- · convenience and ease of administration compared to alternative treatments;
- · the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- ensuring uninterrupted product supply;
- the strength of marketing and distribution support;
- · sufficient third-party coverage or reimbursement; and
- the prevalence and severity of any side effects.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates, we may not be successful in commercializing our product candidates if and when they are approved.

We have little experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any approved medicine for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource these functions to other third parties. We are in the early stages of building a sales and marketing infrastructure to sell, or participate in sales activities with our collaborators for, some of our product candidates if and when they are approved.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

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

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future medicines;
- the lack of complementary medicines to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

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

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

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidates, and we and our collaborators will face competition with respect to any product candidates that we or they may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we are developing our product candidates, such as acute myelogenous leukemia, or AML, and high risk myelodysplasia. For example, Jazz Pharmaceuticals plc, Novartis and Abbvie Inc. (in collaboration with Roche Holdings Inc.) are each developing therapies to treat AML. Some competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches, for example, in the area of RGDs. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

We are developing most of our initial product candidates for the treatment of cancer. There are a variety of available drug therapies marketed for cancer. In many cases, these drugs are administered in combination to enhance efficacy, and cancer drugs are frequently prescribed off-label by healthcare professionals. Some of the currently approved drug therapies are branded and subject to patent protection, and others are available on a generic basis. Many of these approved drugs are well established therapies and are widely accepted by physicians, patients and third-party payors. Insurers and other third-party payors may also encourage the use of generic products. We expect that if our product candidates are approved, they will be priced at a significant premium over competitive generic products. This may make it difficult for us to achieve our business strategy of using our product candidates in combination with existing therapies or replacing existing therapies with our product candidates.

We are also pursuing product candidates to treat patients with RGDs. There are a variety of treatment options available, including a number of marketed enzyme replacement therapies, for treating patients with RGDs. In addition to currently marketed therapies, there are also a number of products that are either enzyme replacement therapies or gene therapies in various stages of clinical development to treat RGDs. These products in development may provide efficacy, safety, convenience and other benefits that are not provided by currently marketed therapies. As a result, they may provide significant competition for any of our product candidates for which we obtain marketing approval.

There are also a number of product candidates in preclinical or clinical development by third parties to treat cancer and RGDs by targeting cellular metabolism. These companies include large pharmaceutical companies, including AstraZeneca plc, Eli Lilly and Company, Roche and its subsidiary Genentech, Inc., GlaxoSmithKline plc, Merck & Co., Novartis with its IDH1 mutant inhibitor IDH305, Pfizer, Inc., and Genzyme, a Sanofi company. There are also biotechnology companies of various sizes that are developing therapies to target cellular metabolism, including Alexion Pharmaceuticals, Inc., BioMarin Pharmaceutical Inc., Calithera Biosciences, Inc., Cornerstone Pharmaceuticals, Inc., Forma Therapeutics Holdings LLC with its IDH1 mutant inhibitor FT-2102, Shire Biochem Inc., Raze Therapeutics, Inc. and Selvita S.A. In addition, there are several companies developing immunotherapies, including metabolic immunotherapies, targeting cancer, including AstraZeneca PLC, Merck, Bristol-Myers Squibb Company, bluebird bio, Inc.,

Juno Therapeutics, Inc., Incyte Corporation, Calithera Biosciences, Inc., Pfizer, Novartis, Kite Pharma, Inc. and Jounce Therapeutics, Inc. Our competitors may develop products that are more effective, safer, more convenient or less costly than any that we are developing or that would render our product candidates obsolete or non-competitive. In addition, our competitors may discover biomarkers that more efficiently measure metabolic pathways than our methods, which may give them a competitive advantage in developing potential products. Our competitors may also obtain marketing approval from the FDA or other regulatory authorities for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other clinical stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

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

The commercial success of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by third-party payors, including government health administration authorities and private health coverage insurers. If coverage and reimbursement is not available, or reimbursement is available only to limited levels, we, or any future collaborators, may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us, or any future collaborators, to establish or maintain pricing sufficient to realize a sufficient return on our or their investments. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved drugs. Marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we, or any future collaborators, might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, which may negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability or the ability of any future collaborators to recoup our or their investment in one or more product candidates, even if our product candidates obtain marketing approval.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Therefore, our ability, and the ability of any future collaborators, to commercialize any of our product candidates will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from third-party payors. Third-party payors decide which medications they will cover and establish reimbursement levels. The healthcare industry is acutely focused on cost containment, both in the United States and elsewhere. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability or that of any future collaborators to sell our product candidates profitably. These payors may not view our products, if any, as cost-effective, and coverage and reimbursement may not be available to our customers, or those of any future collaborators, or may not be sufficient to allow our products, if any, to be marketed on a competitive basis. Cost-control initiatives could cause us, or any future collaborators, to decrease the price we, or they, might establish for products, which could result in lower than anticipated product revenue. If the prices for our products, if any, decrease or if governmental and other third-party payors do not provide coverage or adequate reimbursement, our prospects for revenue and profitability will suffer.

There may also be delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Reimbursement rates may vary, by way of example, according to the use of the product and the clinical setting in which it is used. Reimbursement rates may also be based on reimbursement levels already set for lower cost drugs or may be incorporated into existing payments for other services.

In addition, increasingly, third-party payors are requiring higher levels of evidence of the benefits and clinical outcomes of new technologies and are challenging the prices charged. We cannot be sure that coverage will be available for any product candidate that we, or any future collaborator, commercialize and, if available, that the reimbursement rates will be adequate. Further, the net reimbursement for drug products may be subject to additional reductions if there are changes to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. An inability to promptly obtain coverage and adequate payment rates from both government-funded and private payors for any of our product candidates for which we, or any future collaborator, obtain marketing approval could significantly harm our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Product liability lawsuits against us or our collaborators could cause us or our collaborators to incur substantial liabilities and could limit commercialization of any medicines that we or they may develop.

We and our collaborators face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we or they commercially sell any medicines that we or they may develop. If we or our collaborators cannot successfully defend ourselves or themselves against claims that our product candidates or medicines caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

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

Although we maintain product liability insurance coverage, it may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage when we continue clinical trials and if we successfully commercialize any medicine. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. In addition, if one of our collaboration partners were to become subject to product liability claims or were unable to successfully defend themselves against such claims, any such collaboration partner could be more likely to terminate such relationship with us and therefore substantially limit the commercial potential of our products.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

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

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cyber security incidents, could harm our ability to operate our business effectively.

Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our clinical and commercialization activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our product research, development and commercialization efforts could be delayed.

Risks Related to Our Dependence on Third Parties

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

In April 2010, we entered into the 2010 Agreement and in May 2016, we entered into the 2016 Agreement. These collaborations involve complex allocations of rights, provide for milestone payments to us based on the achievement of specified clinical development, regulatory and commercial milestones, provide us with royalty-based revenue if certain product candidates are successfully commercialized and provide for cost reimbursements of certain development activities. The discovery phase under the 2010 Agreement concluded in April 2016 and we will no longer receive additional payments to extend the term of the discovery phase for that agreement. In April 2015, we entered into the AG-881 Agreements. We cannot predict the success of these collaborations.

We may seek other third-party collaborators for the development and commercialization of our product candidates. Our likely collaborators for any collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. If we enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our product candidates, including our collaborations with Celgene, pose the following risks to us:

- Collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations. For example, under
 the 2010 Agreement, the AG-881 Agreements and programs under a co-development and co-commercialization agreement pursuant to the 2016
 Agreement, development and commercialization plans and strategies for licensed programs, such as AG-221, will be conducted in accordance
 with a plan and budget approved by a joint committee comprised of equal numbers of representatives from each of us and Celgene, as to which
 Celgene may have final decision-making authority.
- Collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development
 or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors
 such as an acquisition that diverts resources or creates competing priorities. For example, under the 2010 Agreement and the 2016 Agreement, it
 is possible for Celgene to elect not to progress into preclinical development a product candidate that we have nominated and the joint research
 committee confirmed, without triggering a termination of the collaboration arrangement.
- Collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product
 candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing, which may result in a
 need for additional capital to pursue further development or commercialization of the applicable product candidate. For example, under the 2010
 Agreement and the 2016 Agreement, it is possible for Celgene to terminate the agreement, upon 90 days prior written notice, with respect to any
 product candidate at any point in the research, development and clinical trial process, without triggering a termination of the remainder of the
 collaboration arrangement.
- Collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our medicines or
 product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized
 under terms that are more economically attractive than ours.

- Collaborators with marketing and distribution rights to one or more medicines may not commit sufficient resources to the marketing and distribution of such medicine or medicines.
- Collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation. For example, under specified circumstances Celgene has the first right to maintain or defend our intellectual property rights with respect to AG-221 under the 2010 Agreement and, although we may have the right to assume the maintenance and defense of our intellectual property rights if Celgene does not, our ability to do so may be compromised by Celgene's actions.
- Disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our medicines or product candidates or that result in costly litigation or arbitration that diverts management attention and resources.
- We may lose certain valuable rights under circumstances identified in our collaborations, including, in the case of our agreements with Celgene, if we undergo a change of control.
- Collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates. For example, Celgene can terminate its agreements with us, in their entirety or with respect to AG-221 or any program under the 2016 Agreement, upon 90 days' notice and can terminate each entire agreement with us in connection with a material breach of the agreement by us that remains uncured for a period ranging from 60 to 90 days.
- · Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all.
- If a present or future collaborators of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated.

We may seek to establish additional collaborations, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to collaborate with additional pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our product candidate.

We may also be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. For example, during the discovery phase of the 2016 Agreement, we may not directly or indirectly develop, manufacture or commercialize, except pursuant to the agreement, any medicine or product candidate with specified activity against certain metabolic targets except in connection with certain third-party collaborations or with respect to certain targets the rights to which have reverted back to us pursuant to the terms of the 2016 Agreement. Following the discovery phase until termination or expiration of the 2010 Agreement, either in its entirety or with respect to the relevant program, we may not directly or indirectly develop, manufacture or commercialize, outside of the collaboration, any medicine or product candidate with specified activity against any collaboration target that is within a licensed program or against any former collaboration target against which Celgene is conducting an independent program under the agreement. Following the discovery phase of the 2016 Agreement until termination or expiration of the applicable co-development and co-commercialization agreement or license agreement under the 2016 Agreement, we may not directly or indirectly develop, manufacture or commercialize, outside of the collaboration, any medicine or product candidate with specified activity against the collaboration target that is the subject of such co-development and co-commercialization agreement or license agreement, except in connection with certain third-party collaborations or with respect to certain targets the rights to which have reverted back to us pursuant to the terms of the 2016 Agreement.

Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

We rely and expect to continue to rely on third parties to conduct our clinical trials and some aspects of our research and preclinical testing, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or testing.

We do not independently conduct clinical trials of any of our product candidates. We rely and expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials. In addition we currently rely and expect to continue to rely on third parties to conduct some aspects of our research and preclinical testing. Any of these third parties may terminate their engagements with us, some in the event of an uncured material breach and some at any time. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third-parties or to do so on commercially reasonable terms. Switching or adding additional third parties involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays may occur in our product development activities. Although we seek to carefully manage our relationships with our CROs, we could encounter similar challenges or delays in the future and these challenges or delays could have a material adverse impact on our business, financial condition and prospects.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with current good clinical practices, or cGCP, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the European Medicines Agency, or EMA, or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with cGCP regulations. In addition, our clinical trials must be conducted with product produced under current good manufacturing practices, or cGMP, regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, clinicaltrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. In addition, these third parties are not our employees, and except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our on-going clinical, nonclinical and preclinical programs. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our medicines. As a result, our results of operations and the commercial prospects for our medicines would be harmed, our costs could increase and our ability to generate revenue could be delayed.

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

We contract with third parties for the manufacture of our product candidates for preclinical and clinical testing and expect to continue to do so for late-stage clinical trials and for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or medicines or that such supply will not be available to us at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not have any manufacturing facilities. We currently rely, and expect to continue to rely, on third-party manufacturers for the manufacture of our product candidates for preclinical and clinical testing and for commercial supply of any of these product candidates for which we or our collaborators obtain marketing approval. To date, we have obtained materials for AG-221, AG-120, AG-881, AG-348 and AG-519 for our ongoing preclinical and clinical testing from third-party manufacturers. We do not have any long-term supply agreements with the third-party manufacturers, and we purchase our required drug supply on a purchase order basis.

We may be unable to establish any long-term supply agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- · the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us; and
- · reliance on the third party for regulatory compliance, quality assurance, environmental and safety and pharmacovigilance reporting.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements on a global basis. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or medicines, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our medicines and harm our business and results of operations.

Any medicines that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply for bulk drug substances. If any one of our current contract manufacturers cannot perform as agreed, we may be required to replace that manufacturer. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or medicines may adversely affect our future profit margins and our ability to commercialize any medicines that receive marketing approval on a timely and competitive basis.

Risks Related to Our Intellectual Property

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

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary medicines and technology. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and medicines that are important to our business. We do not yet have issued patents for all our lead product candidates in all markets we intend to commercialize.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

We may in the future license patent rights that are valuable to our business from third parties, in which event we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology or medicines underlying such licenses. We cannot be certain that these patents and applications will be prosecuted and enforced in a manner consistent with the best interests of our business. If any such licensors fail to maintain such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated and our right to develop and commercialize any of our products that are the subject of such licensed rights could be adversely affected. In addition to the foregoing, the risks associated with patent rights that we license from third parties also apply to patent rights we own.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our technology or medicines or that effectively prevent others from commercializing competitive technologies and medicines. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore we cannot be certain that we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

Assuming the other requirements for patentability are met, prior to March 2013, in the United States, the first to make the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. Beginning in March 2013, the United States transitioned to a first inventor to file system in which, assuming the other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent. We may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office, or become involved in opposition, derivation, revocation, reexamination, post-grant and inter partes review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize medicines without infringing third-party patent rights.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and medicines. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

Competitors may infringe our patents and other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

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

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infininging the proprietary rights and intellectual property of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. We have in the past and may in the future become party to, or threatened with, adversarial proceedings or

litigation regarding intellectual property rights with respect to our medicines and technology, including interference proceedings before the U.S. Patent and Trademark Office. For example, in 2011, The Leonard and Madlyn Abramson Family Cancer Research Institute at the Abramson Cancer Center of the University of Pennsylvania initiated a lawsuit against us, one of our founders, Craig B. Thompson, M.D., and Celgene, alleging misappropriation of intellectual property and, in 2012, the Trustees of the University of Pennsylvania initiated a similar lawsuit against us and Dr. Thompson. Each of these lawsuits was settled in 2012. No other legal proceedings have been filed against us to date. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we or one of our collaborators are found to infringe a third party's intellectual property rights, we or they could be required to obtain a license from such third party to continue developing and marketing our medicines and technology. However, we or our collaborators may not be able to obtain any required license on commercially reasonable terms or at all. Even if we or our collaborators were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us. We or our collaborators could be forced, including by court order, to cease developing and commercializing the infringing technology or medicine. In addition, we or our collaborators could be found liable for monetary damages. A finding of infringement could prevent us or our collaborators from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we or our collaborators have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of our employees, consultants or advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. Other than the litigation initiated by the Leonard and Madlyn Abramson Family Cancer Research Institute at the Abramson Cancer Center of the University of Pennsylvania and by the Trustees of the University of Pennsylvania described above, no such claims have been filed against us to date.

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

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

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

In addition to seeking patents for some of our technology and medicines, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. With respect to our proprietary cellular metabolism technology platform, we consider trade secrets and know-how to be our primary intellectual property. Trade secrets and know-how can be difficult to protect. In particular, we anticipate that with respect to this technology platform, these trade secrets and know-how will over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology, and the movement of personnel skilled in the art from academic to industry scientific positions.

We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or

unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be harmed.

Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters

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

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, export and import, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the EMA and comparable regulatory authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We and our collaborators have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party contract research organizations to assist us in this process.

Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we or our collaborators ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved medicine not commercially viable.

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

A fast track designation by the FDA may not actually lead to a faster development or regulatory review or approval process.

In the United States, AG-221 and AG-120 received fast track designation for treatment of patients with acute myelogenous leukemia, or AML, that harbor an IDH2 and IDH1 mutation, respectively. If a drug is intended for the treatment of a serious or life-threatening disease or condition and the drug demonstrates the potential to address unmet medical needs for this disease or condition, the drug sponsor may apply for FDA fast track designation. The FDA has broad discretion whether or not to grant fast track designation, so even if we believe a particular product candidate is eligible for such designation, the FDA may decide not to grant it. Even though AG-221 and AG-120 have received fast track designation for treatment of patients with AML that harbor an IDH2 and IDH1 mutation, respectively, we may not experience a faster development process, review or approval, if at all, compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

Failure to obtain marketing approval in foreign jurisdictions would prevent our medicines from being marketed in such jurisdictions.

In order to market and sell our medicines in the European Union and many other jurisdictions, we or our collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain

FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, a product be approved for reimbursement before the product can be approved for sale in that country. We or our collaborators may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our medicines in any market.

Any product candidate for which we or our collaborators obtain marketing approval could be subject to restrictions or withdrawal from the market and we may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our medicines, when and if any of them are approved.

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

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

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

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

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

Our relationships with healthcare providers, physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which, in the event of a violation, could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

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

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation or arranging of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals
 or entities for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal
 healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation
 to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties,
 currently set at \$5,500 to \$11,000 per false claim;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes
 obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually
 identifiable health information:
- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs to report payments and other transfers of value to physicians and teaching hospitals, with data collection beginning in August 2013; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws and transparency statutes, may apply to sales
 or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including
 private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

Current and future legislation may increase the difficulty and cost for us and any future collaborators to obtain marketing approval of our other product candidates and affect the prices we, or they, may obtain.

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

For example, in March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the PPACA. Among the provisions of the PPACA of potential importance to our business and our product candidates are the following:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- expansion of healthcare fraud and abuse laws, including the civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs;
- · expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- · new requirements to report certain financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- a new Independent Payment Advisory Board, or IPAB, which has authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription drugs; and
- a Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models.

Other legislative changes have been proposed and adopted since the PPACA was enacted. These changes include the Budget Control Act of 2011, which, among other things, led to aggregate reductions to Medicare payments to providers of up to 2% per fiscal year that started in 2013 and, due to subsequent legislation, will continue until 2025. In addition, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding and may otherwise affect the prices we may obtain for any of our product candidates for which regulatory approval is obtained.

We expect that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our medicines. Moreover, legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us and any future collaborators to more stringent product labeling and post-marketing testing and other requirements.

Risks Related to Employee Matters and Managing Growth

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

We are highly dependent on the principal members of our management and scientific teams, each of whom is employed "at will," meaning we or they may terminate the employment relationship at any time. We do not maintain "key person" insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors, including our scientific co-founders, may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately, disclose unauthorized activities to us, or comply with securities laws. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, including for illegal insider trading activities, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

We expect to expand our development, regulatory and future sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expected expansion of our operations or recruit and train additional qualified personnel. Moreover, the expected physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We may engage in acquisitions that could disrupt our business, cause dilution to our stockholders or reduce our financial resources.

In the future, we may enter into transactions to acquire other businesses, products or technologies. Because we have not made any acquisitions to date, our ability to do so successfully is unproven. If we do identify suitable candidates, we may not be able to make such acquisitions on favorable terms, or at all. Any acquisitions we make may not strengthen our competitive position, and these transactions may be viewed negatively by customers or investors. We may decide to incur debt in connection with an acquisition or issue our common stock or other equity securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities of the acquired business that are not covered by the indemnification we may obtain from the seller. In addition, we may not be able to successfully integrate the acquired personnel, technologies and operations into our existing business in an effective, timely and non-disruptive manner. Acquisitions may also divert management attention from day-to-day responsibilities, increase our expenses and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or the effect that any such transactions might have on our operating results.

Risks Related to Our Common Stock

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

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

- establish a classified board of directors such that not all members of the board are elected at one time;
- · allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors:
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written
 consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a shareholder rights plan, or so-called "poison pill," that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

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

If securities analysts do not publish research or reports about our business or if they publish negative, or inaccurate, evaluations of our stock, the price of our stock and trading volume could decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price and trading volume to decline.

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

Although our common stock is listed on the NASDAQ Global Select Market, an active trading market for our shares may not be sustained. If an active market for our common stock does not continue, it may be difficult for our stockholders to sell their shares without depressing the market price for the shares or sell their shares at all. An inactive trading market for our common stock may also impair our ability to raise capital to continue to fund our operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

The price of our common stock is likely to be volatile, which could result in substantial losses for purchasers of our common stock.

The trading price of our common stock has been, and may continue to be, volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. For example, since January 1, 2014 the price of our common stock on the NASDAQ Global Select Market has ranged from \$21.70 per share to \$138.85 per share. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including:

· regulatory actions with respect to our product candidates or our competitors' products and product candidates;

- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- the timing and results of clinical trials of product candidates;
- · commencement or termination of collaborations for our development programs;
- failure or discontinuation of any of our development programs;
- results of clinical trials of product candidates of our competitors;
- · regulatory or legal developments in the United States and other countries;
- · developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to develop additional product candidates or products;
- actual or anticipated changes in estimates as to financial results or development timelines;
- · announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or other stockholders;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- · changes in the structure of healthcare payment systems;
- · market conditions in the pharmaceutical and biotechnology sectors;
- · general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Certain stockholders hold a substantial number of shares of our common stock. If such stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline.

In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our stock incentive plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act of 1933, as amended, or the Securities Act, and, in any event, we have filed a registration statement permitting shares of common stock issued on exercise of options to be freely sold in the public market. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Certain holders of our common stock are entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates. Any sales of securities by these stockholders who have exercised registration rights could have a material adverse effect on the trading price of our common stock.

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

As of June 30, 2016, our executive officers, directors and a small group of stockholders, in the aggregate, beneficially owned shares representing a significant percentage of our capital stock. As a result, if these stockholders were to choose to act together, they would be able to significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, could significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

Future sales and issuances of our common stock or rights to purchase common stock could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to those of holders of our common stock.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a company undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carry forwards and other pre-change tax attributes (such as research tax credits) to offset its post-change taxable income or taxes may be limited. Our prior equity offerings and other changes in our stock ownership, some of which are outside of our control, may have resulted or could in the future result in an ownership change. For example, in 2012, we completed a review of our changes in ownership through December 31, 2011, and determined that we had two qualified ownership changes since inception. The changes of ownership will result in net operating loss and research and development credit carry forwards that we expect to expire unutilized. If additional limitations were to apply, utilization of a portion of our net operating loss and tax credit carry forwards could be further limited in future periods and a portion of the carry forwards could expire before being available to reduce future income tax liabilities.

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

As a public company, and particularly since January 1, 2015 when we ceased to be an "emerging growth company," we have incurred and will continue to incur significant legal, accounting and other expenses. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The NASDAQ Global Select Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and will make some activities more time-consuming and costly. In addition, stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish with our periodic Exchange Act reports a report by our management on our internal control over financial reporting and are required to include with our annual report an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404, we have engaged in a process to document and evaluate our internal control over financial reporting, which has been, and will continue to be, both costly and challenging. In this regard, we will need to continue to dedicate internal resources, engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, from time to time, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements

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

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

Item 6. Exhibits.

The exhibits listed in the Exhibit Index to this Quarterly Report on Form 10-Q are incorporated herein by reference.

SIGNATURES

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

	AGIOS PHARMACEUTICALS, INC.		
Date: August 8, 2016	Ву:	/s/ David P. Schenkein David P. Schenkein President and Chief Executive Officer	
Date: August 8, 2016	By:	(principal executive officer) /s/ Glenn Goddard	
	<i></i>	Glenn Goddard Senior Vice President, Finance (principal financial and accounting officer)	

EXHIBIT INDEX

		Incorporated by Reference				
Exhibit Number	Description of Exhibit	Form	File Number	Date of Filing	Exhibit Number	Filed Herewith
3.1	Restated Certificate of Incorporation	8-K	001-36014	July 29, 2013	3.1	
3.2	Amended and Restated By-Laws	8-K	001-36014	July 29, 2013	3.2	
10.1†	Master Research and Collaboration Agreement, dated May 17, 2016, by and among the Registrant, Celgene Corporation and Celgene RIVOT Ltd.					X
10.2	Severance Benefits Plan	8-K	001-36014	April 22, 2016	10.1	
31.1	Certification of principal executive officer pursuant to Rule 13a 14(a)/15d 14(a) of the Securities Exchange Act of 1934, as amended					X
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.					X
32.1	Certification of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
32.2	Certification of principal financial officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
101.INS	XBRL Instance Document					X
101.SCH	XBRL Taxonomy Extension Schema Document					X
101.CAL	XBRL Taxonomy Calculation Linkbase Document					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	XBRL Taxonomy Label Linkbase Document					X
101.PRE	XBRL Taxonomy Presentation Linkbase Document					X

[†] Confidential treatment requested as to portions of the exhibit. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

EXECUTION VERSION

Exhibit 10.1

MASTER RESEARCH AND COLLABORATION AGREEMENT

by and among

AGIOS PHARMACEUTICALS, INC.

and

CELGENE CORPORATION

and

CELGENE RIVOT LTD.

Dated as of May 17, 2016

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Schedule 9.2.9 Agios Patents

MASTER RESEARCH AND COLLABORATION AGREEMENT

This Master Research and Collaboration Agreement (this "<u>Agreement</u>") is entered into as of May 17, 2016 (the "<u>Effective Date</u>") by and among Agios Pharmaceuticals, Inc., a Delaware corporation ("<u>Agios</u>"), on the one hand, and Celgene Corporation, a Delaware corporation ("<u>Celgene Corp.</u>"), with respect to all rights and obligations under this Agreement in the United States, and Celgene RIVOT Ltd., a Bermuda entity ("<u>Celgene RIVOT</u>"), with respect to all rights and obligations under this Agreement outside of the United States (Celgene RIVOT and Celgene Corp. together, "<u>Celgene</u>"), on the other hand. Celgene and Agios are each referred to herein by name or as a "<u>Party</u>", or, collectively, as the "<u>Parties</u>."

RECITALS

- WHEREAS, Agios is a clinical-stage company engaged in the research and development of novel therapies relating to cellular metabolism, including for the treatment of cancer through targeting cancer metabolism or the immune system;
- **WHEREAS**, Celgene is engaged in the research, development and commercialization of therapeutic products to treat various diseases and conditions, including for the treatment of cancer and diseases and conditions of the immune system;
- **WHEREAS**, the Parties intend to collaborate on the research and development of immunotherapies against certain metabolic targets that exert their antitumor efficacy primarily via the immune system;
- **WHEREAS**, Agios may conduct certain research and development activities to identify therapeutics directed to certain metabolic targets, and Celgene will obtain exclusive options to enter into a co-development and co-commercialization agreement or a license agreement with Agios with respect to such therapeutics, as further described herein;
- WHEREAS, upon each exercise of each such option, the Parties shall enter into a separate co-development and co-commercialization agreement or license agreement, on the terms and subject to the conditions set forth herein;
- **NOW, THEREFORE**, in consideration of the foregoing and the mutual agreements set forth below, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE I DEFINITIONS

1.1 Terms.

1.1.1 "2010 Agreement" means the Discovery and Development Collaboration and License Agreement between Agios and Celgene dated April 14, 2010, as amended.

- 1.1.2 "Active" or "Activity" means, with respect to a given chemical entity in relation to a given Program Target, that such chemical entity has a level of potency against the applicable Program Target, in the same direction of modulation, expressed as [**], as applicable, for a Development Candidate for such Program, as measured in a cellular, or, if not available, biochemical, assay for such Program Target, as designated by the JRC. The JRC may establish more specific baseline criteria for activity in modulating a particular Program Target based on the foregoing criteria. *For example, if the [**]*.
- 1.1.3 "Affiliate" means, as to any Person, any other Person that, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such Person, as the case may be, for so long as such control exists. As used in this Section 1.1.3, "control" means: (a) to possess, directly or indirectly, the power to direct the management and policies of a Person, whether through ownership of voting securities or by contract relating to voting rights or corporate governance; or (b) direct or indirect beneficial ownership of at least fifty percent (50%) (or such lesser percentage that is the maximum allowed to be owned by a foreign Person in a particular jurisdiction) of the voting share capital in a Person. For purposes of this Agreement and any Development & Commercialization Agreement, neither Celgene nor Agios shall be deemed an Affiliate of the other Party.
 - 1.1.4 "Agios Intellectual Property" means Agios Know-How and Agios Patents, collectively.
- 1.1.5 "Agios Know-How" means any Know-How that is (a) Controlled by Agios as of the Effective Date or during the Term, and (b) necessary or useful for the Development, Manufacture and/or Commercialization of any Program Compound(s) or Program Product(s).
- 1.1.6 "<u>Agios Lead Shared Program</u>" means a Shared 50/50 Program, other than a Celgene Lead Shared Program, for which Agios will be the "Lead U.S. Party" (as defined in <u>Appendix A</u>), subject to the terms and conditions of the applicable Co-Development and Co-Commercialization Agreement.
- 1.1.7 "Agios Patents" means any and all Patents that (a) are Controlled by Agios as of the Effective Date or during the Term, and (b) Cover the Development, Manufacture and/or Commercialization of any Program Compound(s) or Program Product(s) (including the composition of matter, manufacture or any use thereof).
- 1.1.8 "Antitrust Law" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976 and the rules and regulations promulgated thereunder (the "HSR Act"), the Sherman Act, as amended, the Clayton Act, as amended, the Federal Trade Commission Act, as amended, and any other Laws related to merger control or designed to prohibit, restrict or regulate actions having the purpose or effect of monopolization or restraint of trade, in the following jurisdictions: the United States, all states and territories thereof, Australia, Brazil, Canada, the countries that are officially recognized as member states of the European Union from time to time (the "EU"), Republic of Korea, Japan, Mexico, Taiwan, and any other jurisdiction that Celgene, in its good faith judgment, determines requires a pre-merger notification filing prior to consummation of the transactions contemplated by the Development & Commercialization Agreements in accordance with Section 3.2 of this Agreement.

- 1.1.9 "beneficial owner," "beneficially owns," "beneficial ownership" and terms of similar import used in this Agreement shall, with respect to a Person, have the meaning set forth in Rule 13d-3 under the Securities Exchange Act of 1934, as amended (i) assuming the full conversion into, and exercise and exchange for, shares of common stock, other voting stock or any securities exercisable for common stock or other voting stock beneficially owned by such Person and (ii) determined without regard for the number of days in which such Person has the right to acquire such beneficial ownership.
- 1.1.10 "<u>Business Day</u>" means a day other than a Saturday or Sunday or federal holiday in Cambridge, Massachusetts or Summit, New Jersey.
- 1.1.11 "<u>Calendar Quarter</u>" means a calendar quarter ending on the last day of March, June, September or December; <u>provided</u>, <u>however</u>, <u>that</u> (a) the first Calendar Quarter shall begin on the Effective Date and end on the last day of June, 2016, and (b) the final Calendar Quarter shall end on the last day of the Term.
- 1.1.12 "<u>Calendar Year</u>" means a period of time commencing on January 1 and ending on the following December 31; <u>provided</u>, <u>however</u>, <u>that</u> (a) the first Calendar Year shall begin on the Effective Date and end on December 31, 2016, and (b) the final Calendar Year shall end on the last day of the Term.
- 1.1.13 "Celgene Collaboration Intellectual Property" means any Patents or Know-How, or Celgene's and/or its Affiliates' interest therein, that is developed or generated by or on behalf of Celgene and/or its Affiliate(s) through the use of Agios Know-How, Joint Collaboration Know-How or materials disclosed or transferred by Agios to Celgene in the conduct of the Collaboration during the Option Term and is necessary or useful for the Development, Manufacture and/or Commercialization of any Program Compound(s) or Program Product(s).
 - 1.1.14 "Celgene Intellectual Property" means Celgene Know-How and Celgene Patents, collectively.
- 1.1.15 "Celgene Know-How" means any Know-How that is (a) Controlled by Celgene as of the Effective Date or during the Term; (b) necessary or useful for the Development, Manufacture and/or Commercialization of any Program Compound(s) or Program Product(s); and (c) contributed by Celgene, in Celgene's sole discretion, to the Collaboration, as evidenced by written notice from Celgene to Agios; <u>but excluding</u> Celgene Collaboration Intellectual Property.
- 1.1.16 "Celgene Lead Shared Program" means the Shared 65/35 Program or any Shared 50/50 Program for which Celgene will be the "Lead U.S. Party" (as defined in <u>Appendix A</u>), subject to the terms and conditions of the applicable Co-Development and Co-Commercialization Agreement.
- 1.1.17 "Celgene Patents" means any Patents that (a) are Controlled by Celgene as of the Effective Date or during the Term; (b) Cover the Development, Manufacture and/or Commercialization of any Program Compound(s) or Program Product(s) (including the

composition of matter, manufacture or any use thereof); and (c) are contributed by Celgene, in Celgene's sole discretion, to the Collaboration, as evidenced by written notice from Celgene to Agios; but excluding Celgene Collaboration Intellectual Property.

- 1.1.18 "Change of Control" of a Party means any of the following, in a single transaction or a series of related transactions: (a) the sale or disposition of all or substantially all of the assets of such Party to a Third Party, (b) the direct or indirect acquisition by a Third Party (other than an employee benefit plan (or related trust) sponsored or maintained by such Party or any of its Affiliates) of beneficial ownership of more than [**] percent ([**]%) of the then-outstanding common shares or voting power of such Party or any direct or indirect entity which holds, directly or indirectly, beneficial ownership of more than [**] percent ([**]%) of the then-outstanding common shares or voting power of such Party (a "Parent Entity"), or (c) the merger or consolidation of such Party or any Parent Entity with or into a Third Party, unless, following such merger or consolidation, the stockholders of such Party or Parent Entity immediately prior to such merger or consolidation beneficially own directly or indirectly more than [**] percent ([**]%) of the then-outstanding common shares or voting power of the entity resulting from such merger or consolidation.
- 1.1.19 "<u>Chemistry, Manufacturing and Controls</u>" or "<u>CMC</u>" means the part of pharmaceutical development that is directed to the Development and Manufacture of products, the specifications therefor, and other parameters which indicate that the finished drug or biologic product and the manufacturing process are consistent and controlled, in each case, as specified by the FDA or other applicable Regulatory Authorities in the chemistry, manufacturing and controls section of an IND or other regulatory filing in the United States, or the equivalent section of regulatory filings made outside of the United States.
 - 1.1.20 "Claims" means any and all suits, claims, actions, proceedings or demands brought by a Third Party.
- 1.1.21 "<u>Commercialization</u>" or "<u>Commercialize</u>" means any activities directed to using, marketing, promoting, distributing, importing, offering to sell and/or selling a product, after or in expectation of receipt of Regulatory Approval for such product (but excluding Development).
- 1.1.22 "<u>Commercially Reasonable Efforts</u>" means, with respect to the performing Party under this Agreement or any Development & Commercialization Agreement, [**].
- 1.1.23 "Companion Diagnostic" means a biomarker or diagnostic test that is developed by a Party or jointly by the Parties in the course of the Collaboration as a companion diagnostic for use with a Program Compound or Program Product in accordance with the Regulatory Approval(s) therefor to generate a result for the purposes of diagnosing a disease or condition, or to facilitate the application of the Program Compound or Program Product in the cure, mitigation, treatment, or prevention of disease, including a biomarker or diagnostic test used to diagnose the likelihood that a specific patient will contract a disease or condition or to predict which patients are suitable candidates for a specific form of therapy using the Program Compound or Program Product.

- 1.1.24 "Confidential Information" means (a) all confidential or proprietary information relating to any Program Target(s), Program Compound(s) or Program Product(s), including information in the Data Packages, and (b) all other confidential or proprietary documents, technology, Know-How or other information (whether or not patentable) actually disclosed by one Party to the other pursuant to this Agreement, the 2010 Agreement (solely with respect to information relating to the [**]) or the Prior Confidentiality Agreement, including information regarding a Party's technology, products, business information or objectives and reports under Section 2.7, and all proprietary biological materials of a Party.
- 1.1.25 "<u>Continuation Program</u>" means a Research Program under which Agios may continue to carry out Development activities directed to the identification and nomination of a Development Candidate as of the end of the Research Term and that Celgene designates as a Continuation Program in accordance with Section 2.4.2.
- 1.1.26 "Control" or "Controlled" means, with respect to any (a) Know-How or other information or materials, (b) any compounds, or (c) intellectual property right, the possession (whether by license (other than a license granted under this Agreement) or ownership) by a Party of the ability to grant to the other Party access and/or a license, as provided herein, without violating the terms of any agreement with any Third Party existing as of the Effective Date or thereafter during the Term. Notwithstanding the foregoing, for the purpose of defining whether intellectual property, Patents, Know-How or Confidential Information is Controlled by a Party, if such intellectual property, Patents, Know-How or Confidential Information is first acquired, licensed or otherwise made available to such Party after the Effective Date, or the effective date of the applicable Development & Commercialization Agreement, as applicable, and if the use, practice or exploitation thereof by or on behalf of the other Party, its Affiliates or sublicensees would require the first Party to pay any amounts to the Third Party from which the first Party acquired, licensed or otherwise obtained such intellectual property, Patents, Know-How or Confidential Information ("Additional Amounts"), such intellectual property, Patents, Know-How or Confidential Information to the extent specified in this Agreement or the applicable Development & Commercialization Agreement.
- 1.1.27 "Cover," "Covering" or "Covered" means that, with respect to a product or technology, but for a license granted to a Person under the Patents under which such license is granted, the Development, Manufacture, Commercialization or other use of such product or practice of such technology by such Person would infringe a claim of any such Patents or, with respect to a claim included in any patent application, would infringe such claim if such patent application were to issue as a patent.
- 1.1.28 "Damages" means all claims, threatened claims, damages, losses, suits, proceedings, liabilities, costs (including reasonable legal expenses, costs of litigation and reasonable attorney's fees), or judgments, whether for money or equitable relief, of any kind and is not limited to matters asserted by Third Parties against a Party, but includes claims, threatened claims, damages, losses, suits, proceedings, liabilities, costs (including reasonable legal expenses, costs of litigation and reasonable attorney's fees) or judgments incurred or sustained

by a Party in the absence of Third Party claims; <u>provided that</u> no Party shall be liable to hold harmless or indemnify the Agios Indemnified Parties or Celgene Indemnified Parties, as applicable, for any claims, threatened claims, damages, losses, suits, proceedings, liabilities, costs or judgments for punitive or exemplary damages, except to the extent the Party seeking indemnification is actually liable to a Third Party for such punitive or exemplary damages in connection with a claim by such Third Party.

1.1.29 "<u>Data Package</u>" means, on a Program-by-Program basis, a data package prepared in accordance with the terms and conditions of this Agreement (including Section 1.1.62) by Agios with respect to Development activities conducted under a Program and provided by Agios to Celgene upon the occurrence of the following events:

[**]

The foregoing Data Packages shall contain the applicable information outlined in Schedule 1.1.29 for such Data Package, in a form reasonable under the circumstances.

- 1.1.30 "<u>Defense</u>" means any actions brought to defend a Patent against a challenge to such Patent, including without limitation interferences, oppositions, reexaminations, *inter partes* reviews or post-grant reviews, excluding any actions included within Prosecution. "<u>Defend</u>" will have the correlative meaning.
- 1.1.31 "<u>Designated Development Program</u>" means a Research Program that has been designated by Celgene as a Designated Development Program in accordance with Section 2.3.2(b).
- 1.1.32 "<u>Develop</u>" or "<u>Development</u>" means discovery, research, preclinical, non-clinical and clinical development activities, including activities relating to screening, assays, test method development and stability testing, toxicology, pharmacology, formulation, quality assurance/quality control development, clinical trials (including Phase IV clinical trials), technology transfer, statistical analysis, process development and scale-up, pharmacokinetic studies, data collection and management, report writing and other pre-Regulatory Approval activities.
- 1.1.33 "<u>Development & Commercialization Agreement</u>" means an agreement in the form attached hereto as <u>Appendix A</u> ("<u>Co-Development and Co-Commercialization Agreement</u>") or in the form attached hereto as <u>Appendix B</u> ("<u>License Agreement</u>"), as applicable.
- 1.1.34 "<u>Development Candidate</u>" means, on a Program-by-Program basis, a Program Compound in such Program that is (a) Developed by or on behalf of Agios or any of its Affiliates prior to or after the Effective Date until expiration of the Option Term and (b) nominated by either Agios or Celgene in accordance with Section 2.3.1 and has been determined or deemed, as applicable, to meet the Development Candidate Criteria pursuant to Section 2.3.2(a).
 - 1.1.35 "Development Candidate Criteria" means the criteria set forth in Schedule 1.1.35.

- 1.1.36 "Dollars" or "\$" means the legal tender of the United States.
- 1.1.37 "Executive Officers" means Celgene's Chief Executive Officer (or the officer or employee of Celgene then serving in a substantially equivalent capacity) or his designee and Agios' Chief Executive Officer (or the officer or employee of Agios then serving in a substantially equivalent capacity) or his designee; <u>provided that</u> any such designee must have decision-making authority on behalf of the applicable Party.
 - 1.1.38 "FDA" means the United States Food and Drug Administration, or any successor agency thereof.
- 1.1.39 "FDCA" means the United States Federal Food, Drug, and Cosmetic Act, and the regulations promulgated thereunder, each as amended from time to time.
- 1.1.40 "FTE" means the equivalent of the work of one (1) full-time employee of a Party or its Affiliates for one (1) year (consisting of [**] hours per year) in directly conducting Development, Manufacturing and/or Commercialization activities hereunder. Any Party's employee who devotes fewer than [**] hours per year on the applicable activities shall be treated as an FTE on a pro-rata basis, calculated by dividing the actual number of hours worked by such employee on such activities by [**]. Any employee who devotes more than [**] hours per year on the applicable activities shall be treated as one (1) FTE. For the avoidance of doubt, FTE shall not include the work of general corporate or administrative personnel, except for the portion of such personnel's work time actually spent on conducting scientific, technical or commercial activities directly related to the Development, Manufacture or Commercialization of Program Products.
- 1.1.41 "<u>FTE Rate</u>" means, during the Term: (a) with respect to Development activities, \$[**] per FTE and (b) with respect to Commercialization activities, \$[**] per FTE. On January 1, 2017 and on January 1st of each subsequent Calendar Year, the foregoing rate shall be increased for the Calendar Year then commencing by the percentage increase, if any, in the Consumer Price Index ("<u>CPI</u>") as of December 31 of the then most recently completed Calendar Year with respect to the level of the CPI on December 31, 2015. As used in this definition, Consumer Price Index or CPI means the Consumer Price Index Urban Wage Earners and Clerical Workers, US City Average, All Items, 1982-84 = 100, published by the United States Department of Labor, Bureau of Labor Statistics (or its successor equivalent index).
- 1.1.42 "Good Clinical Practices" or "GCP" means the ethical and scientific quality standards for designing, conducting, recording, and reporting trials that involve the participation of human subjects as are required by applicable Regulatory Authorities or Law in the relevant jurisdiction. In the United States, GCP shall be based on Good Clinical Practices established through FDA guidances (including Guideline for Good Clinical Practice ICH Harmonized Tripartite Guideline (ICH E6)), and, outside the United States, GCP shall be based on Guideline for Good Clinical Practice ICH Harmonized Tripartite Guideline (ICH E6).

- 1.1.43 "<u>Good Laboratory Practices</u>" or "<u>GLP</u>" means the then-current good laboratory practice standards promulgated or endorsed by the FDA, as defined in U.S. 21 C.F.R. Part 58 (or such other comparable regulatory standards in jurisdictions outside the United States, as they may be updated from time to time).
- 1.1.44 "Good Manufacturing Practices" or "GMP" means all applicable standards relating to manufacturing practices for fine chemicals, intermediates, bulk products and/or finished pharmaceutical products, including (a) all applicable requirements detailed in the FDA's current Good Manufacturing Practices regulations, U.S. 21 C.F.R. Parts 210 and 211 and "The Rules Governing Medicinal Products in the European Community, Volume IV, Good Manufacturing Practice for Medicinal Products", as each may be amended from time to time, and (b) all applicable Laws promulgated by any Governmental Authority having jurisdiction over the Manufacture of any Post-Exercise Product.
- 1.1.45 "Governmental Authority" means any: (a) nation, principality, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, officer, official, representative, organization, unit, body or entity and any court or other tribunal); (d) multinational organization or body; or (e) individual, entity or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority or power of any nature.
- 1.1.46 "<u>I&I Field</u>" means the treatment, prevention or palliation of Indications in which there is an immune system dysregulation, including, without limitation, an inappropriate or excessive immune response against normal tissue present in the body such that the immune system recognizes such normal tissue cells as non-self.
- 1.1.47 "<u>I&I Program</u>" means any Post-Exercise Program (assuming exercise of an Option) that would not be an IO Program.
- 1.1.48 "IND" means any Investigational New Drug application, filed with the FDA pursuant to Part 312 of Title 21 of the U.S. Code of Federal Regulations, including any supplements or amendments thereto. References herein to IND shall include, to the extent applicable, any comparable filing(s) outside the United States (such as a Clinical Trial Application ("CTA") in the countries that are officially recognized as member states of the EU).
- 1.1.49 "Indication" means any human disease, condition or syndrome, or sign or symptom of, or associated with, a human disease, condition or syndrome.
- 1.1.50 "<u>Inventions</u>" means all inventions, whether or not patentable, that are designed, discovered, generated, invented or conceived by or on behalf of either Party or its respective Affiliates or both Parties or their respective Affiliates, whether solely or jointly with any Third Party, in the course of activities performed under this Agreement or any Development & Commercialization Agreement, as applicable.

- 1.1.51 "<u>IO Field</u>" means the treatment, prevention or palliation of oncology and/or hematologic malignancy Indications through the use of immunotherapies, the efficacy of which is demonstrated to be mediated primarily through the immune system.
- 1.1.52 "<u>IO Program</u>" means any Post-Exercise Program (assuming exercise of an Option) for which, based upon then-current good scientific practice and understanding (taking into account published studies and industry-generated, Agios-generated or Celgene-generated data), at the time of exercise of such Option, the initial contemplated Indication would be in the IO Field.

1.1.53 "Joint Collaboration IP" means, collectively:

- (a) "Joint Collaboration Know-How," which means all Know-How, including physical embodiments of Program Compound(s), Program Product(s) and Companion Diagnostics, that is discovered, generated or invented by or on behalf of both Parties or their respective Affiliates, whether solely or jointly with any Third Party, pursuant to the conduct of activities under the Collaboration at any time during the Term; and
 - (b) "Joint Collaboration Patents," which means Patents that Cover any Joint Collaboration Know-How.
- 1.1.54 "Know-How" means any tangible or intangible trade secrets, know-how, expertise, discoveries, inventions, information, data or materials, including ideas, concepts, formulas, methods, procedures, designs, technologies, compositions, plans, applications, technical data, assays, manufacturing information or data, samples, chemical and biological materials and all derivatives, modifications and improvements thereof.
- 1.1.55 "Law" means any law, statute, rule, regulation, ordinance or other pronouncement having the effect of law, of any federal, national, multinational, state, provincial, county, city or other political subdivision, as from time to time enacted, repealed or amended, including Good Clinical Practices and adverse event reporting requirements, guidance from the International Conference on Harmonization or other generally accepted conventions, the FDCA and similar laws and regulations in countries outside the United States, and all other rules, regulations and requirements of the FDA and other applicable Regulatory Authorities.
 - 1.1.56 "Licensed Product" means a Program Product that is the subject of a Licensed Program.
- 1.1.57 "<u>Licensed Program</u>" means a Post-Exercise Program as to which the Parties have entered into a License Agreement.
- 1.1.58 "Manufacture" or "Manufacturing" means, as applicable, all activities associated with the production, manufacture, processing, filling, packaging, labeling, shipping and storage of a drug substance or drug product, and/or any components thereof, including process and formulation development, process validation, stability testing, manufacturing scale-up, preclinical, clinical and commercial manufacture and analytical methods development and validation, product characterization, quality assurance and quality control development, testing and release.

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1.1.59 "[**]" means [**].
1.1.60 "[**]" means [**].
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- 1.1.61 "Metabolic Target" means any one or more isoforms or mutated forms of a metabolic enzyme (or any combination thereof) that interconverts specific metabolites, or a transporter (including isoforms or mutated forms) that transports specific metabolites into or out of a cell or a subcellular compartment. For the avoidance of doubt, Metabolic Target will exclude, for example, [**]. The Parties understand and agree that, subject to the terms and conditions of Section 2.1.1(d), any one or more isoforms or mutated forms of a metabolic enzyme (or any combination thereof) that interconverts specific metabolites, or a transporter (including isoforms or mutated forms) that transports specific metabolites into or out of a cell or a subcellular compartment shall be deemed to be one "Metabolic Target" under this Agreement. Subject to the terms and conditions of Section 2.1.1(d), isoforms may be considered by the JSC to be separated into distinct Metabolic Targets if (a) [**] and (b) [**].
- 1.1.62 "Option Data Package Verification Date" means, with respect to an Option Data Package, the date that is [**] days after the date of receipt by Celgene of such Option Data Package; provided that, if Celgene requests additional reasonable information and clarifications during such [**] day period, then such [**] day period will be automatically extended (as necessary) until the later of (a) [**] days following receipt by Celgene (or any designee) of such additional reasonable information and clarifications are supplied by Agios and (b) the original [**] day period.
- 1.1.63 "Option Exercise Notice" means, on a Program-by-Program basis, the written notice provided to Agios by Celgene pursuant to Section 3.1.2(a), such notice constituting Celgene's exercise of its Option with respect to a Qualified Early Exercise I&I Program, Designated Development Program or a Continuation Program to convert it into a Post-Exercise Program.
- 1.1.64 "Option Term" means the period commencing on the Effective Date and ending on the later of (a) the expiration of the Research Term or (b) the expiration of the last-to-expire Option Exercise Window for any Continuation Program or any Designated Development Program; provided, however, that the Option Term shall not extend after January 1, 2030.
- 1.1.65 "Patent" means (a) patents and patent applications anywhere in the world, (b) all divisionals, continuations, continuations in-part thereof or any other patent application claiming priority, or entitled to claim priority, directly or indirectly to (i) any such patents or patent applications or (ii) any patent or patent application from which such patents or patent applications claim, or is entitled to claim, direct or indirect priority, and (c) all patents issuing on any of the foregoing anywhere in the world, together with all registrations, reissues, re-examinations, patents of addition, renewals, patent term extensions, supplemental protection certificates, or extensions of any of the foregoing anywhere in the world.
- 1.1.66 "Person" means any corporation, limited or general partnership, limited liability company, joint venture, trust, unincorporated association, governmental body, authority, bureau or agency, any other entity or body, or an individual.

- 1.1.67 "Phase I Study" means a human clinical trial of a product, the principal purpose of which is a preliminary determination of safety, tolerability and pharmacokinetics in study subjects where potential pharmacological activity may be determined or similar clinical study prescribed by the Regulatory Authorities, from time to time, pursuant to applicable Law or otherwise, including for example the trials referred to in 21 C.F.R. §312.21(a), as amended (or the non-United States equivalent thereof).
- 1.1.68 "Phase II Study" means a human clinical trial intended to explore a variety of doses, dose response, and duration of effect, and to generate evidence of clinical safety and effectiveness for a particular Indication or Indications in a target patient population, or a similar clinical study prescribed by the relevant Regulatory Authorities, from time to time, pursuant to applicable Law or otherwise, including for example the trials referred to in 21 C.F.R. §312.21(b), as amended (or the non-United States equivalent thereof).
- 1.1.69 "Phase III Study" means a human clinical trial of a product in any country that would satisfy the requirements of 21 C.F.R. §312.21(c), as amended (or the non-United States equivalent thereof) and is intended to (a) establish that the product is safe and efficacious for its intended use, (b) define contraindications, warnings, precautions and adverse reactions that are associated with the product in the dosage range to be prescribed, and (c) support Regulatory Approval for such product.
- 1.1.70 "<u>Pivotal Clinical Trial</u>" means a human clinical trial of a product on a sufficient number of subjects that, prior to commencement of the trial, satisfies both of the following ((a) and (b)):
 - (a) such trial is designed to establish that such product has an acceptable safety and efficacy profile for its intended use, and to determine warnings, precautions, and adverse reactions that are associated with such product in the dosage range to be prescribed, which trial is intended to support Regulatory Approval of such product, or a similar clinical study prescribed by the U.S. or EMA; and
 - (b) such trial is a registration trial designed to be sufficient to support the filing of an application for a Regulatory Approval for such product in the U.S. or another country or some or all of an extranational territory, as evidenced by (i) an agreement with or statement from the FDA or the EMA on a Special Protocol Assessment or equivalent, or (ii) other guidance or minutes issued by the FDA or EMA, for such registration trial.
 - 1.1.71 "Post-Exercise Product" means a Shared Product or a Licensed Product, as applicable.
- 1.1.72 "<u>Post-Exercise Program</u>" means a Qualified Early Exercise I&I Program, Designated Development Program or Continuation Program, in each case as to which Celgene has exercised its Option.

1.1.73 "Pre-Exercise Phase I Development" means:

- (a) for any Indication in the IO Field, the conduct of a first Phase I Study of a first Development Candidate of a Designated Development Program or a Continuation Program through a single-agent, dose-escalation Phase I Study, [**] data to warrant advancing the Program Compound, if appropriate, to combination and/or Phase II Studies [**] and preclinical Development necessary to enable the conduct of such Phase I Study; and
- (b) for any Indication in the I&I Field, "Pre-Exercise Phase I Development" means the conduct of (I) first single ascending dose and multiple ascending dose Phase I Studies of a first Development Candidate of a Designated Development Program or a Continuation Program in [**] data to warrant advancing the Program Compound, if appropriate, to combination and/or further Phase II Studies. Notwithstanding the foregoing or anything to the contrary herein or in any applicable License Agreement, as to any Qualified Early Exercise I&I Program as to which Celgene exercises its Option as set forth in Section 3.1.1(b), Pre-Exercise Phase I Development shall be deemed to have been completed, and Agios shall have no responsibility therefor (including for any applicable Ongoing Clinical Trial (as defined in Appendix B) hereunder or under the applicable License Agreement following such early Option exercise by Celgene.
- 1.1.74 "<u>Pre-Exercise Program</u>" means a Research Program, Designated Development Program, or Continuation Program.
- 1.1.75 "<u>Prior Confidentiality Agreement</u>" means the Mutual Confidentiality Agreement between Agios and Celgene, dated as of December 16, 2015.
 - 1.1.76 "Program" means a Pre-Exercise Program or a Post-Exercise Program.
- 1.1.77 "Program Compound" means a chemical entity (including any salt, fluorinated derivative, free acid, free base, clathrate, solvate, hydrate, hemihydrates, anhydride, ester, chelate, conformer, congener, crystal form, crystal habit, polymorph, amorphous solid, isomer, stereoisomer, enantiomer, racemate, prodrug, isotopic or radiolabeled equivalent, metabolite, conjugate, complex or mixture of such chemical entity, each a "Related Compound") Developed or Controlled by Agios or any Affiliates identified as [**], as of the date of its inclusion in a Program or thereafter found to have such activity (whether or not during the Research Term or, in the case of any Related Compound, during or after the Research Term) against a Program Target, in the applicable direction of modulation, in the course of conducting a Program. For the avoidance of doubt, Compounds (as defined in Appendix A or Appendix B) shall be limited to (a) the Program Compounds that the Parties reasonably agree at the time of Option exercise are Active against the applicable Program Target and are listed on Exhibit A to the applicable Development & Commercialization Agreement, which, for the avoidance of doubt, shall include the applicable Development Candidate and (b) such other Compounds (as defined in Appendix A or Appendix B) that are Active against the applicable Program Target.

- 1.1.78 "Program Product" means a product that contains as an active ingredient a Program Compound.
- 1.1.79 "<u>Program Target</u>" means a Metabolic Target that, together with Program Compounds that are either activators or inhibitors of such Metabolic Target, is the focus of a Program. For clarity, each Program will only include activators or inhibitors, but not both, of a Metabolic Target, but if a Metabolic Target is the focus of both an activator Program and an inhibitor Program, such Metabolic Target shall be deemed a Program Target of each such Program.
- 1.1.80 "Prosecution" or "Prosecute" means the filing, preparation, prosecution and maintenance of Patents, including any and all pre-grant proceedings before any patent authority, such as interferences.
- 1.1.81 "Publication" means any publication in a scientific journal, any scientific abstract to be presented to any audience, any presentation at any scientific conference, including slides and texts of oral or other public presentations, any other scientific presentation and any other oral, written or electronic scientific disclosure directed to any audience that pertains to any Program Target(s), Program Compound(s) or Program Product(s), or the use of any of the foregoing, or the data or result from any work under any Program.
 - 1.1.82 "Publication Guidelines" means the criteria for Publication set forth on Schedule 1.1.82.
- 1.1.83 "Qualified Early Exercise I&I Program" means a Research Program that, at the time of Celgene's exercise of its Option therefor pursuant to Section 3.1.1(b), (a) has achieved the criteria set forth in Schedule 1.1.83, (b) does not include any Program Compounds that have been nominated or designated as Development Candidates in accordance with Section 2.3.1 or 2.3.2, (c) includes Program Compounds that have been identified as having potential application in the I&I Field and (d) does not include Program Compounds that are being Developed in the conduct of the Collaboration for potential application in the IO Field. Notwithstanding the foregoing, once Celgene has exercised its Option as to [**] Qualified Early Exercise I&I Programs in accordance with Section 3.1.1(b), no other Research Programs shall be Qualified Early Exercise I&I Programs, and Celgene shall have no further right to exercise Options therefor under Section 3.1.1(b).
- 1.1.84 "<u>Regulatory Approval</u>" means all approvals of the applicable Regulatory Authority necessary for the commercial marketing and sale of a product for a particular indication in a country (including separate Regulatory Authority pricing or reimbursement approvals whether or not legally required in order to sell the product in such country, it being understood that, as of the Effective Date, no such Regulatory Authority pricing or reimbursement approval requirement is applicable in the United States).

- 1.1.85 "Regulatory Authority" means a federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity with authority over the testing, manufacture, use, storage, import, promotion, marketing or sale (including pricing and reimbursement approval) of a product in a country or territory.
- 1.1.86 "Research Program" means a program comprising Development activities by and on behalf of Agios and its Affiliates directed to a Program Target and Program Compounds that are either activators of the Program Target or inhibitors of the Program Target (*i.e.*, if both activators and inhibitors of a Program Target will be pursued, each will be deemed as a separate Research Program) in the IO Field or I&I Field; it being understood and agreed that (a) the JRC shall, from time to time, designate each such program as a Research Program in accordance with Section 2.2.1 (but any failure of the JRC to so designate shall not affect in any way the designation of any such program as a "Research Program" or prevent Celgene from exercising an Option under this Agreement); (b) each Research Program may be conducted pursuant to a research plan (which Agios may prepare and may be amended from time to time by the JRC pursuant to ARTICLE IV) governing the activities of the Collaboration to be conducted by Agios and its Affiliates (and, with Celgene's prior written consent, Celgene and its Affiliates) during the Option Term (each such research plan, the "Research Plan"), and (c) any failure to include any Development activities directed to a Program Target and Program Compounds in a Research Plan shall not, in any way, exclude such activities from constituting a Research Program or prevent Celgene from exercising an Option under this Agreement. The [**]Program and the [**] Program shall be deemed to be Research Programs as of the Effective Date.
- 1.1.87 "Research Term" means the period commencing on the Effective Date and, unless earlier terminated in accordance with this Agreement, if Celgene does not exercise its option to extend the Research Term pursuant to Section 2.1.2, ending on the fourth (4th) anniversary of the Effective Date, or, if Celgene exercise its option(s) to extend the Research Term pursuant to Section 2.1.2, ending on the fifth (5th), sixth (6th), seventh (7th) or eighth (8th) anniversary of the Effective Date, as applicable.
- 1.1.88 "<u>Shared 50/50 Program</u>" means a Post-Exercise Program as to which the Parties are required hereunder, or have, entered into a Co-Development and Co-Commercialization Agreement pursuant to which Profit or Loss (as defined in <u>Appendix A</u>) is allocated fifty percent (50%) to Celgene and fifty percent (50%) to Agios.
- 1.1.89 "Shared 65/35 Program" means the Post-Exercise Program as to which the Parties are required hereunder, or have, entered into a Co-Development and Co-Commercialization Agreement pursuant to which Profit or Loss (as defined in <u>Appendix A</u>) is allocated sixty-five percent (65%) to Celgene and thirty-five percent (35%) to Agios.
- 1.1.90 "Shared Product" means a Program Product that is the subject of a Shared Program (including any such Program Product after an Agios Opt-Out Date (as defined in <u>Appendix A</u>) with respect to such Program Product pursuant to a Co-Development and Co-Commercialization Agreement).
 - 1.1.91 "Shared Program" means the Shared 65/35 Program or a Shared 50/50 Program.

- 1.1.92 "[**]" means [**].
- 1.1.93 "[**] <u>Program</u>" means the Agios program conducted before the Effective Date and during the Term and comprising Development activities directed to inhibition of the Program Target [**].
 - 1.1.94 "Third Party" means any Person other than Agios or Celgene or each Party's respective Affiliates.
- 1.1.95 "<u>United States</u>" or "<u>U.S.</u>" means the United States of America and all of its territories and possessions, including Puerto Rico.
- 1.2 <u>Additional Definitions</u>. Each of the following terms has the meaning described in the corresponding section of this Agreement indicated below:

DEFINITION:	SECTION:
[**]	5.2.3(c)
Accounting Standards	Appendix C
Acquirer Program	5.2.3(e)(iv)
Additional Amounts	1.1.26
Agios	Preamble
Agios Indemnified Parties	10.1.1
Agios Program Assets	9.3.2
Agreement	Preamble
Alliance Manager	4.7
Alternating Mechanism	3.1.2(c)
Antitrust Clearance Date	3.2.2
Bankruptcy Code	5.1.7
Celgene	Preamble
Celgene Corp.	Preamble
Celgene Indemnified Parties	10.2.1
Celgene RIVOT	Preamble
Closed Target	2.1.1(f)
Closed Target Notice	2.1.1(f)
Co-Co Agreement	9.3.1(e)(ii)
Co-Development and Co-Commercialization Agreement	1.1.33
Collaboration	2.1
Committee	4.1.1
Competitive Program	5.2.3(d)
Competitive Program Party	5.2.3(d)
Control	1.1.3
Cooperating Party	8.3.2(c)
CPI	1.1.41
CTA	1.1.48
Cure Period	11.3.1

DEFINITION: SECTION: Deemed DC Program 2.4.3 Defend 1.1.30 Designation Fee 6.2 Development Candidate Nomination Data Package 1.1.29(a) **Development Costs** Appendix C **Disclosing Party** 8.1 Dispute 12.1 DOJ 3.2.2 Early Option Exercise Window 3.1.1(b) Effective Date Preamble Electronic Delivery 12.14 End-of-Research Term Program Data Package 1.1.29(b) 1.1.8 EU force majeure event 12.5 FTC 3.2.2 [**] 5.2.3(e)(ii) HSR Act 1.1.8 HSR/Antitrust Filing 3.2.2 Implementation Date 3.2.2 [**] 6.6.1 JCC 4.1.1 JDC 4.1.1 JPC 4.1.1 **JRC** 4.1.1 JSC 4.1.1 License Agreement 1.1.33 Limited Information 2.1.1(f) Manufacturing Costs Appendix C Material Breach 11.3.1 Material Receiving Party 2.11.1 Materials 2.11.1 Option 3.1.1(a) Option Data Package 1.1.29(c) Option Exercise Window 3.1.1(a) Out-of-Pocket Costs Appendix C Parent Entity 1.1.18 Party or Parties Preamble Payee Party 6.6.1 Paying Party 6.6.1 Productivity Requirement 2.1.2(b) 2.1.1(c) **Proposed Targets**

DEFRUEION	CECTION
<u>DEFINITION:</u>	<u>SECTION:</u>
Purpose	2.11.1
Qualified Scientist	2.1.1(d)
Receiving Party	8.1
Redacted Version	8.3.2(a)
Regulatory Expenses	Appendix C
Related Compound	1.1.77
Requesting Party	8.3.2(c)
Research Plan	1.1.86(b)
ROW Co-Co Agreement	9.3.1(e)(i)
Research Term Extension Fee	6.3
Scientific Panel	2.1.1(d)
SEC	8.3.2(a)
Subcommittee	4.1.2
Term	11.1
Third Party License	7.5.2
Third Party Program	2.2.2
Transferring Party	2.11.1
U.S. Co-Co Agreement	9.3.1(e)(i)

ARTICLE II COLLABORATION; PRE-OPTION EXERCISE DEVELOPMENT

2.1 <u>Scope and Collaboration Overview.</u> Pursuant to this Agreement and as further provided in this ARTICLE II, during the Research Term, Agios: (a) may conduct discovery activities to identify programs for designation as Research Programs and shall provide regular updates to Celgene at JRC meetings in accordance with ARTICLE IV with respect to its activities pursuant to each Research Program, together with all material data and information in Agios' possession relating to Program Targets, (b) shall be responsible for the research strategy and the conduct of activities under each Research Program, (c) may nominate Program Compounds from Research Programs as Development Candidates pursuant to the terms and conditions of this Agreement, and (d) as to Development Candidates in Designated Development Programs and Continuation Programs, may conduct Pre-Exercise Phase I Development. The activities conducted pursuant to this ARTICLE II, the activities performed by a Party or the Parties relating to the [**] Program and the [**] Program under the 2010 Agreement before the Effective Date, as well as activities conducted pursuant to Development & Commercialization Agreements following Celgene's exercise of its Option rights, together, shall be the "Collaboration".

2.1.1 Agios Responsibility for Research and Pre-Option Exercise Development.

- (a) Commencing on the Effective Date, during the Research Term prior to the exercise by Celgene of an Option on a Program-by-Program basis, Agios may, in its discretion, conduct Development activities with respect to each Program with the goal of identifying Development Candidates and Developing and progressing such Development Candidates in Designated Development Programs and Continuation Programs through Pre-Exercise Phase I Development. During the Research Term, Agios shall have sole discretion regarding which Programs it selects to progress, and the Development activities performed thereunder, and following Celgene's designation of a Designated Development Program pursuant to Section 2.3.2(b), Agios (x) may conduct Pre-Exercise Phase I Development and (y) shall offer Celgene the opportunity to obtain rights to the applicable Designated Development Program through the exercise of Celgene's Option in accordance with ARTICLE III. Following Celgene's designation of a Continuation Program in accordance with Section 2.4.2, Agios (i) may conduct Development activities with the goal of identifying and nominating a Program Compound from such Continuation Program as a Development Candidate and, pursuant to Section 2.4.3, conduct Pre-Exercise Phase I Development, and (ii) shall offer Celgene the opportunity to obtain the rights to the applicable Continuation Program through the exercise of Celgene's Option in accordance with ARTICLE III. Agios may decide to cease activities under any Program it conducts prior to the exercise of the Option by Celgene at any time (and, for clarity, no such cessation of activity shall in any way affect Celgene's rights to exercise such Option under this Agreement).
- (b) During the Research Term, Agios shall discuss with Celgene, on a regular basis at JRC meetings, Metabolic Targets as potential Program Targets identified by Agios in the course of its ongoing research activities in the IO Field and I&I Field as well as discuss with Celgene material developments in or new data or information in Agios' possession and Control relating to previously identified Metabolic Targets; provided that Agios shall not have any obligation to discuss with Celgene any developments, data or information relating to Programs that have reverted to Agios pursuant to Section 2.12.
- (c) Beginning with the first meeting of the JRC and at every other JRC meeting thereafter during the Research Term (meaning [**]): (i) Agios shall prepare and the Parties shall review a list of any Metabolic Targets for which activities would be the subject of a Research Program in the next [**], including any Metabolic Target suggested by Celgene which Agios may consider in its sole discretion (collectively, the "Proposed Targets") and any available reports, data and other information related thereto; and (ii) for each Proposed Target, the Parties shall discuss whether to include such Proposed Target in a Research Plan as a Program Target.
- (d) If during the Research Term either (but not both) of the Parties believes that [**], then the Parties agree to submit such matter to a panel of three Qualified Scientists (each and every such panel of three Qualified Scientists, a "Scientific Panel") appointed as provided in this Section 2.1.1(d) to determine whether or not [**], all in accordance with the procedures as provided in this Section 2.1.1(d); it being understood and agreed that, in connection with any review and determination by the Scientific Panel, the Scientific Panel will render a decision that is consistent with the definition of Metabolic Target as to whether or not any [**] under this Agreement. Within [**] following any such request for a Scientific Panel,

each of Agios and Celgene shall nominate a Qualified Scientist to participate on the applicable Scientific Panel and, if the Parties are unable to agree upon a third Qualified Scientist for such Scientific Panel within [**] following any such request for a Scientific Panel, then the initial two Qualified Scientists shall select such third Qualified Scientist. Each Scientific Panel shall act as follows: (i) each Qualified Scientist (and the Scientific Panel as a whole) shall act as an expert and not as an arbitrator; (ii) each decision of the Scientific Panel shall be by majority vote of the three Qualified Scientists; and (iii) the decision of the Scientific Panel is, in the absence of fraud or manifest error, final and binding on the Parties. The costs of the Scientific Panel shall be shared equally by Agios and Celgene. For purposes of this Agreement, a "Qualified Scientist" shall mean any scientist (A) with at least ten (10) years of applicable pharmaceutical industry experience in the IO Field or I&I Field, (B) who has not worked for or been engaged by either Party in the three (3) year period immediately prior to the formation of the applicable Scientific Panel, and (C) who does not own equity in either Party. If such Scientific Panel determines that any [**] (based upon the terms and conditions of this Agreement and then-current good scientific practice and understanding, data generated, and the proposed discovery and development research Programs. Conversely, if such Scientific Panel determines that [**] (based upon the terms and conditions of this Agreement and then-current good scientific practice and understanding, data generated, and the proposed discovery and development research plan with respect to such Program), then only one Metabolic Target shall be deemed to exist as part of one Research Program.

(e) The Parties understand and agree that in no event shall a Party be entitled to request that a Scientific Panel review any matter for which a Scientific Panel has previously rendered a decision in accordance with Section 2.1.1(d).

(f) Notwithstanding anything to the contrary contained herein, Celgene shall be entitled to designate, in a written notice ("Closed Target Notice") to Agios, any Metabolic Target or Proposed Target, or Program Target as a Metabolic Target for which Celgene wishes to receive specified or no additional information and/or to have a Third Party designee receive and review such information (any such designated Target, a "Closed Target"); it being understood and agreed that Celgene shall be entitled to modify (i) the designation of any Closed Target such that the corresponding Metabolic Target is no longer a Closed Target, and (ii) the information restrictions and recipients then-imposed with respect to such Closed Target. In each initial Closed Target Notice and in any subsequent modifications to such Closed Target Notice, Celgene shall include (x) the identity of the corresponding Closed Target, (y) a detailed written description of the limited information, if any, that Celgene wishes to receive for such Closed Target (such limited information the "Limited Information"), and (z) the identity and address of Celgene's designee (if any) that Celgene wishes to receive the Limited Information.

2.1.2 Extension of Research Term.

(a) <u>Initial Extension Right</u>. Celgene may, at its election, extend the Research Term for up to two (2) one (1) year extension periods (each to run consecutively after the end of the then-current Research Term) by giving notice to Agios of each such election at least [**] prior to the expiration of the then-current Research Term and paying the Research Term Extension Fee as set forth in Section 6.3.

(b) Productivity Extension Right. If (i) Celgene has elected to extend the Research Term for both of the foregoing one (1) year extension periods as provided in Section 2.1.2(a), and (ii) [**] prior to the sixth (6th) anniversary of the Effective Date, Celgene has not designated at least [**] Program Compounds for [**] different Research Programs (other than Program Compounds that are inhibitors of [**] or [**]) as Development Candidates pursuant to Section 2.3.2(b), which have been (in the case of each such [**] Program Compounds) dosed in a patient as part of a Phase I Study (the "Productivity Requirement"), then Celgene may, at its election, extend the Research Term for an additional one (1) year period (to run after the end of the then-current Research Term) by providing notice to Agios of such election at least [**] prior to the sixth (6th) anniversary of the Effective Date and paying the Research Term Extension Fee as set forth in Section 6.3. If, prior to the seventh (7th) anniversary of the Effective Date, the Productivity Requirement has still not been satisfied, then Celgene may, at its election, extend the Research Term for one (1) additional year, by providing notice to Agios of such election at least [**] prior to the seventh (7th) anniversary of the Effective Date and paying the Research Term Extension Fee as set forth in Section 6.3.

2.2 <u>Designation of Research Programs</u>.

- 2.2.1 <u>Designation of Research Programs</u>. From time to time during the Research Term, each Party may identify potential Research Programs and recommend them to the JRC for designation as Research Programs. The JRC shall review such recommendations and determine whether or not to designate each proposed Research Program in accordance with Section 4.3.2(a). If Celgene's JRC representatives oppose the designation of a Research Program, but such designation occurs in accordance with the escalation and final decision-making provisions of ARTICLE IV, then Celgene may, by giving notice of such election to Agios within [**] after the designation of such Research Program, elect to drop such Research Program from the Collaboration, in which case all rights thereto shall revert to Agios in accordance with Section 2.12 and such Research Program shall otherwise be treated as never having been included in the Collaboration. Except as provided in the immediately preceding sentence, no failure by Agios to identify or the JRC to approve any Development activities by and on behalf of Agios and its Affiliates directed to a Program Target and Program Compounds that are either activators or inhibitors of such Program Target in the IO Field or I&I Field as contemplated by this Section 2.2.1 shall prevent such Development activities from being deemed a "Research Program" (and, accordingly, Celgene shall have an Option for any such Research Program under this Agreement).
- 2.2.2 Third Party Programs. During the Research Term, if Agios identifies a Third Party research and development program, or Third Party intellectual property assets that could be used as the basis for a research and development program, in each case in the IO Field or in the I&I Field (each such program or assets, a "Third Party Program"), which Third Party Program Agios desires to license or acquire for designation as a Program hereunder, Agios may license or acquire such Third Party Program, in which case such Third Party Program shall be designated as a Program hereunder and, except as specifically set forth in any Development & Commercialization Agreement, all licensing costs and expenses relating to such Third Party Program shall be paid for by Agios.

2.3 Nomination of Development Candidates; Designation of Designated Development Programs.

Package. Based upon the Development Candidate Criteria and the results of Development activities with respect to a Research Program, Agios may nominate a Program Compound directed to the Program Target that is the subject of such Research Program as a Development Candidate, by providing written notification thereof to Celgene and the JRC. In addition, following [**], Celgene may propose to nominate a Program Compound directed to any Program Target as a Development Candidate, by providing written notification thereof to Agios and the JRC. Within [**] following any such proposed nomination, Agios shall use its reasonable efforts (without any requirement to perform any additional pre-clinical testing activity but solely based upon work then completed to date) to deliver to Celgene a Development Candidate Nomination Data Package; provided that, for any Program nominated by Celgene, Agios shall include only as much data or information as is available at the time of Celgene's request for such Development Candidate Nomination Data Package.

2.3.2 <u>Designation of Designated Development Programs; Payment of Designation Fee.</u>

Following nomination of a Program Compound as a Development Candidate and delivery of a (a) Development Candidate Nomination Data Package by Agios pursuant to Section 2.3.1, the JRC shall determine, in accordance with Section 4.3.2(c), whether such Program Compound meets the Development Candidate Criteria as follows: (i) any such determination by the JRC must be unanimous; or (ii) in the event that the JRC does not unanimously agree that such Program Compound meets the Development Candidate Criteria, then (A) the Parties shall refer such dispute to a Scientific Panel appointed as provided in this Section 2.3.2(a) for determination of whether or not such Program Compound meets the Development Candidate Criteria; it being understood and agreed that, in connection with any review and determination by the Scientific Panel, the Scientific Panel will render a decision that is consistent with the Development Candidate Criteria; (B) within [**] following any such request for a Scientific Panel, each of Agios and Celgene shall nominate a Qualified Scientist to participate on the applicable Scientific Panel and, if the Parties are unable to agree upon a third Qualified Scientist for such Scientific Panel within [**] following any such request for a Scientific Panel, then the initial two Qualified Scientists shall select such third Qualified Scientist. Each Scientific Panel shall act as follows: (I) each Qualified Scientist (and the Scientific Panel as a whole) shall act as an expert and not as an arbitrator; (II) each decision of the Scientific Panel shall be by majority vote of the three Qualified Scientists; (III) the decision of the Scientific Panel is, in the absence of fraud or manifest error, final and binding on the Parties; (IV) the costs of the Scientific Panel shall be shared equally by Agios and Celgene; and (V) the Parties agree that only if such Scientific Panel determines that the Program Compound meets the Development Candidate Criteria, will such Program Compound shall be deemed a Development Candidate. Conversely, if such Scientific Panel determines that any such Program Compound does not meet the Development Candidate Criteria, then such Program Compound shall remain eligible for nomination as a Development Candidate during the Research Term. Following the proposed nomination of a Program Compound as a Development Candidate by

Celgene pursuant to Section 2.3.1 and subject to Celgene's written confirmation to Agios within [**] following receipt of the Development Candidate Nomination Data Package pursuant to Section 2.3.1 (or a Scientific Panel's determination) that such Program Compound is a Development Candidate, such Program Compound shall be deemed to satisfy the Development Candidate Criteria (whether or not the Development Candidate Criteria have actually been satisfied). Agios shall use reasonable efforts to respond to requests from the JRC and Celgene for additional reasonable information and clarifications regarding content of the Development Candidate Nomination Data Package.

- (b) Celgene shall be entitled, in its sole discretion, to designate any applicable Research Program as a Designated Development Program either: (i) in the case of a Program Compound nominated by Agios as a Development Candidate pursuant to Section 2.3.1, within [**] following delivery by Agios of a Development Candidate Nomination Data Package and determination by the JRC that the applicable Program Compound meets the Development Candidate Criteria, or (ii) in the case of a Program Compound nominated by Celgene as a Development Candidate pursuant to Section 2.3.1 following [**], at any time following such [**] until [**] following the receipt by Celgene of the applicable Development Candidate Nomination Data Package, either of which designations Celgene shall make by giving notice thereof to Agios prior to the end of the applicable [**] period and paying the Designation Fee as set forth in Section 6.2. During such [**] period, Agios shall use reasonable efforts to respond to requests from Celgene for additional reasonable information and clarifications regarding content of the Development Candidate Nomination Data Package. If Celgene makes such designation, Agios may thereafter conduct Pre-Exercise Phase I Development as to such Designated Development Program.
- 2.3.3 <u>Disposition of Programs Not Designated as Designated Development Programs</u>. If a Program Compound has been determined or deemed, as applicable, to meet the Development Candidate Criteria pursuant to Section 2.3.2(a), and Celgene does not designate the applicable Research Program as a Designated Development Program in accordance with Section 2.3.2(b) and therefore does not pay the Designation Fee, then such Research Program shall be dropped from the Collaboration and all rights thereto shall revert to Agios in accordance with Section 2.12.
 - 2.4 Disposition of Programs After the End of the Research Term.
- 2.4.1 <u>Designated Development Programs After the End of the Research Term.</u> Agios' conduct of Pre-Exercise Phase I Development as to Designated Development Programs that were designated prior to the end of the Research Term may continue following the expiration of the Research Term, and the Parties' respective rights and obligations as to such Designated Development Programs shall continue in accordance with this Agreement following such Research Term expiration without any change on account of such expiration.
- 2.4.2 <u>Programs that are Not Designated Development Programs as of the End of the Research Term.</u> Upon expiration of the Research Term, Agios shall provide Celgene with an End-of-Research Term Program Data Package as to each Research Program (including, if applicable, the [**] Program or the [**] Program), excluding any Qualified Early Exercise I&I Program as to which the Parties have entered into a License Agreement, from which no

Development Candidate has been nominated and designated. Celgene shall have a period of [**] following Celgene's receipt of each End-of-Research Term Program Data Package from Agios pursuant to this Section 2.4.2 to elect, in its sole discretion, to designate up to three (3) such ongoing Research Programs as a Continuation Program (including, for the avoidance of doubt, the Deemed DC Program), which elections Celgene shall make by giving notice thereof to Agios prior to the end of such [**] period and paying the Designation Fees for each such Continuation Program as set forth in Section 6.2. During such [**] period, Agios shall use reasonable efforts to respond to requests from Celgene for additional reasonable information and clarifications regarding content in any End-of-Research Term Program Data Package, provided that, unless otherwise agreed by Agios, such [**] period shall not be extended to facilitate such responses. If Celgene makes any such election, Agios may elect in its sole discretion to conduct Development activities with the goal of identifying and nominating a Program Compound in such Continuation Program as a Development Candidate and thereafter may conduct Pre-Exercise Phase I Development as to such Continuation Program. The Parties' respective rights and obligations as to such Continuation Programs shall otherwise be the same as for Designated Development Programs (that were designated as Designated Development Programs prior to the end of the Research Term) and shall continue in accordance with this Agreement following the Research Term expiration.

- 2.4.3 <u>Treatment of Continuation Programs</u>. If Celgene designates one or more Continuation Programs (including, if applicable, the [**] Program or the [**] Program) in accordance with Section 2.4.2, the Continuation Program that, in Celgene's reasonable determination, has progressed the furthest shall constitute the "<u>Deemed DC Program</u>." Each Continuation Program (including the Deemed DC Program) shall be conducted without adjustment to the terms contemplated by Section 2.4.2 (*i.e.*, any Pre-Exercise Phase I Development activities for such Continuation Program that may be conducted by Agios shall be at Agios' sole discretion and expense).
- 2.4.4 <u>Disposition of Programs Not Designated as Continuation Programs</u>. Any Research Program that Celgene does not designate as a Continuation Program in accordance with Section 2.4.2 shall be dropped from the Collaboration and all rights thereto shall revert to Agios in accordance with Section 2.12.
- 2.5 <u>Completion of Pre-Exercise Phase I Development</u>. Upon Agios' completion of Pre-Exercise Phase I Development as to any Designated Development Program or Continuation Program, or earlier upon Celgene's written request, Agios shall provide Celgene with an Option Data Package for such Program (in any case within [**] following such completion of Pre-Exercise Phase I Development as to any Designated Development Program or Continuation Program or Celgene's request, as applicable). During the period between Celgene's receipt of such Option Data Package and the applicable Option Data Package Verification Date, Agios shall use reasonable efforts to respond to requests from Celgene for additional reasonable information and clarifications regarding content of the Option Data Package.
- 2.6 <u>Regulatory Affairs</u>. Agios shall be responsible for and shall control all regulatory matters relating to each Pre-Exercise Program. For all regulatory matters concerning any Pre-Exercise Program, until such time that Celgene either exercises its Option and enters into a Development & Commercialization Agreement or such Pre-Exercise Program reverts to Agios in accordance with Section 2.12, Agios shall consult with Celgene with respect to filing strategy and document preparation, and shall reasonably consider all timely comments made by Celgene with respect thereto.

- 2 . 7 Reports; Results; Testing by the Parties. Each Party shall maintain complete, current and accurate records of all Development activities conducted by it under the Collaboration, and all data and other information resulting from such activities. Such records shall fully and properly reflect all work done and results achieved in the performance of the Development activities in good scientific manner appropriate for regulatory and patent purposes. Each Party shall document all non-clinical studies and clinical trials for Programs in formal written study records according to applicable Laws, including national and international guidelines such as ICH, GCP, GLP and GMP. Each Party shall have the right to review and copy such records maintained by the other Party at reasonable times, as reasonably requested by a Party. At each meeting of the JRC or the JDC held pursuant to Section 4.8.2, each Party shall provide the other Party a written progress report summary (which may consist solely of slides) on the status of its activities under each Program during the Research Term, including summaries of data associated with such Party's activities, it being understood that Celgene may reasonably request additional information regarding any such written progress report summary.
- 2 . 8 <u>No Representation.</u> Neither Party makes any representation, warranty or guarantee that the Collaboration will be successful, or that any other particular results will be achieved with respect to the Collaboration, any Program, any Program Target, any Program Compound, any Development Candidate or any Program Product hereunder.
- 2 . 9 <u>Subcontracting</u>. Subject to the terms of this Agreement or any Development & Commercialization Agreement, as applicable, each Party shall have the right to engage Affiliates or Third Party subcontractors to perform certain of its obligations under this Agreement or any Development & Commercialization Agreement, as applicable. Any such Affiliate or subcontractor shall meet the qualifications typically required by such Party for the performance of work similar in scope and complexity to the subcontracted activity and perform such work consistent with the terms of this Agreement or any Development & Commercialization Agreement, as applicable; provided, however, that any Party engaging an Affiliate or subcontractor hereunder shall remain fully responsible and obligated for such activities. Unless otherwise agreed by the Parties, each Party will obligate each Third Party subcontractor to agree in writing to assign to such Party ownership of, or grant to such Party an exclusive, royalty-free, worldwide, perpetual and irrevocable license (with the right to grant sublicenses) to, any inventions arising under its agreement with such Third Party to the extent related to Development, Manufacture or Commercialization with respect to Program Compounds, as applicable; and such Party shall structure such assignment or exclusive license so as to enable such Party to sublicense such Third Party inventions to the other Party pursuant to the applicable provisions of this Agreement and of any applicable Development & Commercialization Agreement (including permitting such other Party to grant further sublicenses).
- 2.10 <u>Academic Collaborators</u>. If either Party collaborates with an academic institution and/or one or more individuals at an academic institution to perform research on Program Targets or Program Compounds, such Party shall be required to obligate such academic collaborator to agree in writing to grant the same rights specified in Section 2.9 with respect to

ownership or licenses to inventions; it being understood and agreed that, [**], which sublicensing rights must permit sublicensing to the other Party pursuant to the applicable provisions of this Agreement and of any applicable Development & Commercialization Agreement (including permitting such other Party to grant further sublicenses).

2.11 Material Transfer.

- 2.11.1 <u>Transfer.</u> On a Program-by-Program basis, during the Option Term, either Party (the "<u>Transferring Party</u>") shall transfer, if such Party agrees in writing to make such transfer (such agreement not to be unreasonably withheld) upon reasonable request by the other Party (the "<u>Material Receiving Party</u>"), certain tangible materials (the "<u>Materials</u>") for use by the Material Receiving Party in furtherance of its rights and the conduct of its obligations under this Agreement, as mutually agreed by the Parties and set forth in an appropriate material transfer agreement (the "<u>Purpose</u>"). The Parties agree that the exchanged Materials shall be used in compliance with applicable Law and the terms and conditions of this Agreement, and shall not be reverse engineered or chemically analyzed, except as required for verification purposes (if needed).
- 2.11.2 <u>License; Ownership.</u> At the time the Transferring Party provides Materials to the Material Receiving Party as provided herein and to the extent not separately licensed under this Agreement, the Transferring Party hereby grants to the Material Receiving Party a non-exclusive license under the Patents and Know-How Controlled by the Transferring Party to use such Materials solely for the Purpose, and such license, upon termination of this Agreement (subject to ARTICLE XI), completion of the Purpose, or discontinuation of the use of such Materials (whichever occurs first), shall automatically terminate. Except as otherwise provided under this Agreement, all such Materials delivered by the Transferring Party to the Material Receiving Party shall remain the sole property of the Transferring Party, shall only be used by the Material Receiving Party in furtherance of the Purpose, and shall be returned to the Transferring Party or destroyed, in the Transferring Party's sole discretion, upon the termination of this Agreement (subject to ARTICLE XI), the expiration of the Option Exercise Window with respect to any Program to which such Materials solely relate (unless the Option is exercised for the Program for which such transfer occurred), or upon the discontinuation of the use of such Materials (whichever occurs first). The Material Receiving Party shall not permit the Materials to be used by or delivered to or for the benefit of any Third Party without the prior written consent of the Transferring Party unless such Third Party is a Third Party subcontractor as set forth in Section 2.9.
- 2.11.3 No Warranties; Liability. THE MATERIALS SUPPLIED BY THE TRANSFERRING PARTY UNDER THIS SECTION 2.11 ARE SUPPLIED "AS IS" AND, EXCEPT AS OTHERWISE SET FORTH IN THIS AGREEMENT, THE TRANSFERRING PARTY MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE MATERIALS OR USE THEREOF DO NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS OF A THIRD PARTY. The Material Receiving Party assumes all liability for Damages that may arise from its use, storage or disposal of the Materials. Except as otherwise set forth in this Agreement, the Transferring Party shall

not be liable to the Material Receiving Party for any loss, claim or demand made by the Material Receiving Party, or made against the Material Receiving Party by any Third Party, due to or arising from the use of the Materials, except to the extent such loss, claim or demand is caused by the gross negligence or willful misconduct of the Transferring Party.

2.12 Reversion of Rights.

- 2.12.1 <u>Programs</u>. If Section 2.2.1, Section 2.3.3, Section 2.4.4, Section 3.1.3 or Section 11.5.1(a) specifies that rights to a Program are to be dropped from the Collaboration or if Celgene does not exercise its Option with respect to any Programs within the applicable Option Exercise Window for such Program, then (a) all rights granted by Agios to Celgene with respect to such Program, if any, shall revert to Agios, and (b) subject to ARTICLE VIII, Celgene shall return to Agios, or destroy, at Agios' option, all Confidential Information and/or Materials provided by Agios to Celgene in relation to such Program; <u>provided</u>, <u>however</u>, <u>that</u> any Confidential Information and/or Materials that also relate to a non-terminated Program may be retained by Celgene.
- 2.12.2 Reversion License. Effective upon any of the events set forth in Section 2.12.1 with respect to a Program, Celgene hereby grants to Agios [**] with the right to grant sublicenses as set forth in Section 5.1.4, under Celgene's rights in Celgene Collaboration Intellectual Property and Joint Collaboration IP, to Develop, Manufacture and/or Commercialize Program Compounds or Program Products under such Program; provided that, for this purpose, "Celgene Collaboration Intellectual Property" means Celgene Collaboration Intellectual Property only to the extent that it is actually used in such Program prior to the applicable reversion set forth in this Section 2.12; provided further that the foregoing license under this Section 2.12.2 shall be [**] with respect to the applicable Program to the extent of claims within the Patents included in the Celgene Collaboration Intellectual Property and Joint Collaboration IP that Cover a composition of matter of any such Program Compound or Program Product. Agios shall not owe royalties or milestones with respect to any license in this Section 2.12.2, but Agios shall be solely responsible for any payments owed by Celgene to any Third Party licensors of Celgene Collaboration Intellectual Property or Joint Collaboration IP, and shall be responsible for complying with the terms of any license agreements with such third Party licensors, in either case, directly related to Agios' exercise of such licenses
- 2.12.3 Optioned Programs. For the avoidance of doubt, none of the reversion events described in this Section 2.12 shall affect Celgene's rights with respect to any other Program for which Celgene retains Option rights or has delivered an Option Exercise Notice pursuant to Section 3.1.2(a).

ARTICLE III OPTION EXERCISE; DEVELOPMENT & COMMERCIALIZATION AGREEMENTS

- 3.1 Option Grant and Exercise.
 - 3.1.1 Option Grant by Agios.

- (a) Subject to the terms and conditions of this Agreement on a Designated Development Program-by-Designated Development Program and Continuation Program-by-Continuation Program basis, Agios hereby grants to Celgene, with respect to each Designated Development Program and Continuation Program, an exclusive option (each, an "Option"), exercisable at any time during the period commencing on the date that a Development Candidate for such Designated Development Program is designated pursuant to the terms and conditions of this Agreement or the date on which a Continuation Program is designated pursuant to the terms and conditions of this Agreement, as applicable, and ending [**] following the applicable Option Data Package Verification Date (each such period for each Designated Development Program and Continuation Program, as applicable, the "Option Exercise Window") to enter into a Development & Commercialization Agreement with respect to such Designated Development Program or Continuation Program, pursuant to this Section 3.1.
- (b) In addition, subject to the terms and conditions of this Agreement on an Qualified Early Exercise I&I Program-by-Qualified Early Exercise I&I Program basis, Celgene may exercise an Option with respect to up to [**] Qualified Early Exercise I&I Programs at any time during the Research Term that such Qualified Early Exercise I&I Program remains a Qualified Early Exercise I&I Program (the "Early Option Exercise Window"), to enter into a License Agreement with respect to such Qualified Early Exercise I&I Program.

3.1.2 Option Exercise.

- (a) Celgene shall have the right, but not the obligation, to exercise the Option for a given Designated Development Program or Continuation Program by delivering an Option Exercise Notice to Agios within the applicable Option Exercise Window. Celgene shall have the right, but not the obligation, to exercise the Option for a given Qualified Early Exercise I&I Program by delivering an Option Exercise Notice to Agios within the Early Option Exercise Window. Upon such exercise, the applicable Qualified Early Exercise I&I Program, Designated Development Program or Continuation Program shall become a "Post-Exercise Program". Within [**] following each Option Exercise Notice delivery, Celgene (or an Affiliate designated by Celgene) and Agios and each Affiliate of Agios that holds Agios Intellectual Property relating to the applicable Qualified Early Exercise I&I Program, Designated Development Program or Continuation Program will enter into (i) a Co-Development and Co-Commercialization Agreement with respect to any such Post-Exercise Program that is an I&I Program, [**] Program or [**] Program, or (ii) a License Agreement with respect to any such Post-Exercise Program that is an I&I Program; and in either case will update the exhibits and schedules thereto, as applicable, including to identify the Program Compound(s) and Program Target that are the subject of such Development & Commercialization Agreement. Following the applicable Implementation Date for Development in accordance therewith.
- (b) At any time during the Option Exercise Window, with respect to any Designated Development Program or Continuation Program that is an IO Program, other than the [**] Program and/or [**] Program, Celgene shall have the right to designate one of such IO Programs as the Shared 65/35 Program. Celgene shall indicate in the applicable Option

Exercise Notice whether it is designating any such IO Program as the Shared 65/35 Program. For clarity: (i) if Celgene exercises its Option with respect to the [**] Program or the [**] Program, such Program shall be a Shared 50/50 Program subject to the provisions set forth in Section 3.1.2(c) below, and (ii) for so long as Celgene has not previously designated an IO Program (other than the [**] Program and/or [**] Program) as the Shared 65/35 Program, it shall always be entitled to designate an IO Program as the Shared 65/35 Program at the time of the exercise of the Option for such IO Program (and such designated Shared 65/35 Program shall not be considered as a "Shared 50/50 Program" for any purpose under Section 3.1.2(c) below, including with regard to the Alternating Mechanism).

- (c) Subject to Celgene's right to select the Shared 65/35 Program pursuant to Section 3.1.2(b), at any time during the Option Exercise Window, with respect to any Designated Development Program or Continuation Program that is an IO Program (including for purposes of this Section 3.1.2(c) the [**] Program and [**] Program), Agios shall have the option of designating the first Shared 50/50 Program as an Agios Lead Shared Program on or prior to the execution of the applicable Co-Commercialization and Co-Development Agreement. If Agios does not elect to designate the first Shared 50/50 Program as an Agios Lead Shared Program, then such Shared 50/50 Program shall be a Celgene Lead Shared Program and the second Shared 50/50 Program shall be an Agios Lead Shared Program. Thereafter, the designation of any further Shared 50/50 Programs shall alternate between the Parties, *i.e.*, if the prior designated Shared 50/50 Program was an Agios Lead Shared Program, the next designated Shared 50/50 Program would be a Celgene Lead Shared Program, and vice versa, with respect to each subsequently designated Shared 50/50 Program (the "Alternating Mechanism"). By way of example, if the first Shared 50/50 Program is designated an Agios Lead Shared Program, and the second IO Program for which Celgene exercises its Option is designated the Shared 65/35 Program pursuant to Section 3.1.2(b), then the third IO Program for which Celgene exercises an Option as a Shared 50/50 Program shall be automatically designated a Celgene Lead Shared Program.
- 3.1.3 <u>Expiration of Option Exercise Windows.</u> If Celgene does not exercise an Option during the applicable Option Exercise Window, then the corresponding Designated Development Program or Continuation Program shall be dropped from the Collaboration in accordance with Section 2.12 and shall no longer be subject to Celgene's rights under this Agreement, including ARTICLE V and all rights thereto shall revert to Agios in accordance with Section 2.12.

3.2 Government Approvals.

3.2.1 Efforts. Each of Agios and Celgene will use its commercially reasonable good faith efforts to eliminate any concern on the part of any Governmental Authority regarding the legality of any proposed Development & Commercialization Agreement including, if required by Governmental Authorities, promptly taking all steps to remove any and all impediments to consummation of the transactions contemplated by the Development & Commercialization Agreements, including obtaining government antitrust clearance, cooperating in good faith with any Governmental Authority investigation, promptly producing any documents and information and providing witness testimony if requested by a Governmental Authority. Notwithstanding anything to the contrary in this Agreement and the Development & Commercialization Agreements, this Section 3.2 and the term "commercially reasonable good faith efforts" do not require that either Party (a) [**], (b) [**], or (c) [**].

3.2.2 HSR/Antitrust Filings. Each of Agios and Celgene will, within [**] after the execution of the relevant Development & Commercialization Agreement (or such later time as may be agreed to in writing by the Parties) file with the U.S. Federal Trade Commission ("FTC") and the Antitrust Division of the U.S. Department of Justice ("DOJ") any HSR/Antitrust Filing required of it under the HSR Act and, as soon as practicable, file with the appropriate Governmental Authority any other HSR/Antitrust Filing required of it under any other Antitrust Law as determined in the reasonable opinion of either Party with respect to the transactions contemplated by the relevant Development & Commercialization Agreement. The Parties shall cooperate with one another to the extent necessary in the preparation of any such HSR/Antitrust Filing. Each Party shall be responsible for its own costs, expenses and filing fees associated with any HSR/Antitrust Filing; provided, however, that the Parties shall [**]. In the event that the Parties make an HSR/Antitrust Filing under this Section 3.2, the relevant Development & Commercialization Agreement shall terminate (a) at the election of either Party, immediately upon notice to the other Party, in the event that the FTC, DOJ or other Governmental Authority obtains a preliminary injunction or final order under Antitrust Law enjoining the transactions contemplated by such Development & Commercialization Agreement, or (b) at the election of either Party, immediately upon notice to the other Party, in the event that the Antitrust Clearance Date shall not have occurred on or prior to [**] after the effective date of the last HSR/Antitrust Filing submitted to a Governmental Authority in relation to the relevant Development & Commercialization Agreement. Notwithstanding anything to the contrary contained herein, except for the terms and conditions of this Section 3.2, none of the terms and conditions contained in the relevant Development & Commercialization Agreement shall be effective until the "Implementation Date," which is agreed and understood to mean the later of (i) the execution date of the relevant Development & Commercialization Agreement, (ii) if a determination is made pursuant to this Section 3.2 that an HSR/Antitrust Filing is not required to be made under any Antitrust Law for the relevant Development & Commercialization Agreement, the date of such determination, or (iii) if a determination is made pursuant to this Section 3.2 that an HSR/Antitrust Filing is required to be made under any Antitrust Law for the relevant Development & Commercialization Agreement, the Antitrust Clearance Date. As used herein: (x) "Antitrust Clearance Date" means the earliest date on which the Parties have actual knowledge that all applicable waiting periods under the HSR Act and any comparable waiting periods as required under any other Antitrust Law, in each case with respect to the transactions contemplated by the relevant Development & Commercialization Agreement have expired or have been terminated; and (y) "HSR/Antitrust Filing" means (i) a filing by Agios and Celgene with the FTC and the DOJ of a Notification and Report Form for Certain Mergers and Acquisitions (as that term is defined in the HSR Act), together with all required documentary attachments thereto or (ii) any comparable filing by Agios or Celgene required under any other Antitrust Law, in each case ((i) and (ii)) with respect to the transactions contemplated by the Development & Commercialization Agreements.

3.2.3 <u>Information Exchange</u>. Each of Agios and Celgene will, in connection with any HSR/Antitrust Filing, (a) reasonably cooperate with each other in connection with any communication, filing or submission and in connection with any investigation or other inquiry,

including any proceeding initiated by a private party; (b) keep the other Party and/or its counsel informed of any communication received by such Party from, or given by such Party to, the FTC, the DOJ or any other U.S. or other Governmental Authority and of any communication received or given in connection with any proceeding by a private party, in each case regarding the transactions contemplated by any Development & Commercialization Agreement; (c) consult with each other in advance of any meeting or conference with the FTC, the DOJ or any other Governmental Authority or, in connection with any proceeding by a private party, with any other Person, and to the extent permitted by the FTC, the DOJ or such other Governmental Authority or other Person, give the Parties and/or their counsel the opportunity to attend and participate in such meetings and conferences; and (d) to the extent practicable, permit the other Party and/or its counsel to review in advance any submission, filing or communication (and documents submitted therewith) intended to be given by it to the FTC, the DOJ or any other Governmental Authority; provided that materials may be redacted to remove references concerning the [**]. Agios and Celgene, as each deems advisable and necessary, may reasonably designate any competitively sensitive material to be provided to the other under this Section 3.2.3 as "Antitrust Counsel Only Material." Such materials and the information contained therein shall be given only to the outside antitrust counsel of the recipient and will not be disclosed by such outside counsel to employees, officers or directors of the recipient unless express permission is obtained in advance from the source of the materials (Agios or Celgene, as the case may be) or its legal counsel.

- 3.2.4 <u>Assistance Unrelated to Antitrust Law</u>. Subject to this Section 3.2, Agios and Celgene shall cooperate and use respectively all reasonable efforts to make all other registrations, filings and applications, to give all notices and to obtain as soon as practicable all governmental or other consents, transfers, approvals, orders, qualifications, authorizations, permits and waivers, if any, and to do all other thing necessary or desirable for the consummation of the transactions as contemplated hereby.
- 3.2.5 No Further Obligations. If any Development & Commercialization Agreement is terminated pursuant to this Section 3.2, then, notwithstanding any provision in this Agreement to the contrary, neither Party shall have any further obligation to the other Party with respect to the subject matter of the relevant Development & Commercialization Agreement; provided that, prior to termination of a Development & Commercialization Agreement pursuant to this Section 3.2, Celgene shall instead be permitted to [**], if required to comply with any Antitrust Law; provided further that, the right to [**] set forth in the prior proviso shall not apply if a breach by Celgene of its obligations under Section 5.2 is a material cause of the failure to obtain clearance under Antitrust Laws and, in such event, rights to such Program shall revert to Agios in accordance with the terms of the applicable Development & Commercialization Agreement.

ARTICLE IV GOVERNANCE

4.1 General.

- 4.1.1 Governance Committees. The Parties shall establish (a) a Joint Steering Committee ("JSC") to oversee and coordinate the overall conduct of all Programs hereunder; (b) a Joint Research Committee ("JRC") to oversee and coordinate discovery, research and pre-clinical Development activities with respect to each Research Program until nomination of a Development Candidate for such Research Program; (c) a Joint Development Committee ("JDC") for each Program as to which a Development Candidate has been nominated and designated and for which Celgene retains an Option; (d) a Joint Commercialization Committee ("JCC") to oversee Commercialization activities under a Development & Commercialization Agreement; and (e) a Joint Patent Committee ("JPC") to oversee Patent Prosecution and enforcement (the JSC, the JRC, the JDC, the JCC and the JPC shall each be referred to as a "Committee"). Each Committee shall have decision-making authority with respect to the matters within its purview to the extent expressly and as more specifically provided herein; it being understood and agreed that with respect to any Program that is subject to an executed License Agreement, no Committee shall have any review or decision-making authority. For the avoidance of doubt, from and after the Effective Date, no "Committee" or other working group established under the 2010 Agreement shall have the authority to address any matters involving this Collaboration.
- 4.1.2 From time to time, each Committee may establish subcommittees to oversee particular projects or activities, as it deems necessary or advisable (each, a "<u>Subcommittee</u>"). Each Subcommittee shall consist of such number of members as the applicable Committee determines is appropriate from time to time. Such members shall be individuals with expertise and responsibilities in the relevant areas such as [**], as applicable to the stage of the project or activity. Such Subcommittees shall operate under the same principles as are set forth in this ARTICLE IV for the Committee forming such Subcommittee.
- 4.1.3 Execution of Co-Development and Co-Commercialization Agreement. On a Program-by-Program basis, upon execution of the applicable Co-Development and Co-Commercialization Agreement for such Program, such Program and matters related thereto shall continue to be within the purview of the applicable Committee, in accordance with and pursuant to the terms of the applicable Co-Development and Co-Commercialization Agreement.
- 4.1.4 <u>Certain Interactions with and Effects on the 2010 Agreement</u>. Upon and after the Effective Date, notwithstanding anything to the contrary in the 2010 Agreement (with each quoted term below having the meaning given in the 2010 Agreement):
- (a) All activities regarding Development, Manufacturing and Commercialization of Program Compounds and Program Products for the [**] Program or the [**] Program under the 2010 Agreement and all future such activities shall be conducted solely under this Agreement.
- (b) None of the Parties' activities performed in accordance with this Agreement (including those activities specifically permitted upon and after termination) shall be deemed a violation of, nor shall they be subject to, the 2010 Agreement.
- (c) No Program Compound or Program Product for the [**] Program or the [**] Program is or can be (i) included as an "Agreement Compound" or in any of the classes of compounds comprising "Agreement Compounds", (ii) part of the "Compound List," (iii) included in any of the "Picks", or (iv) part of an "Agios Reverted Program," or "Celgene Reverted Program", each of (i) (iv) under the 2010 Agreement.

- (d) No payments, including any "IND Amount" or "Phase I Amount", any milestones or any royalties, will be due under the 2010 Agreement with respect to any Program Compounds and Program Products under this Agreement (including the [**] Program or the [**] Program).
- (e) No decision of any "Committee" or working group under the 2010 Agreement shall have any binding effect on any Committee or working group under this Agreement, and no decision of any Committee or working group under this Agreement shall have any binding effect on any "Committee" or working group under the 2010 Agreement notwithstanding that the members of any such committees may contain some or all of the same individual representatives for each Party.
- (f) All "Confidential Information" disclosed under the 2010 Agreement that solely relates to the [**] Program or the [**] Program shall be deemed to be Confidential Information disclosed under this Agreement and not the 2010 Agreement. All "Confidential Information" disclosed under the 2010 Agreement that relates to, but does not solely relate to, the [**] Program or the [**] Program shall be deemed "Confidential Information" disclosed under the 2010 Agreement and also Confidential Information disclosed under this Agreement; provided, however, that any disclosure of such information that is permitted under this Agreement shall not be deemed a breach of this Agreement and any disclosure of such information that is permitted under this Agreement shall not be deemed a breach of the 2010 Agreement.

4.2 <u>Joint Steering Committee</u>.

4.2.1 <u>Establishment</u>. Within [**] following the Effective Date, Agios and Celgene shall establish the JSC. The JSC shall have oversight over each Program, subject to Sections 4.10 and 4.11.

4.2.2 <u>Duties</u>. The JSC shall:

- (a) manage the strategic direction of the Collaboration;
- (b) oversee implementation of the Collaboration in accordance with this Agreement;
- (c) review and monitor progress of the Collaboration and serve as a forum for exchanging information and facilitating discussions regarding the conduct of the Collaboration;
- (d) oversee and coordinate the conduct of all Programs and related matters within the responsibilities of the Committees hereunder;
 - (e) discuss and determine appropriate measures to take in view of Third Party rights;

- (f) provide strategic guidance, and coordinate efforts between the Parties, with respect to any Publications and, by mutual agreement, approve requests for Publication, from either Party, according to the Publication Guidelines and Section 8.4 hereof;
- (g) serve as a forum for dispute resolution in accordance with Section 4.10 with respect to matters that are not resolved at the JRC, JDC, JCC or JPC; and
- (h) perform such other duties as are specifically assigned to the JSC under this Agreement or any Development & Commercialization Agreement.

4.3 Joint Research Committee.

4.3.1 <u>Establishment</u>. Within [**] following the Effective Date, Agios and Celgene shall establish the JRC. The JRC shall have oversight over each Research Program until a Development Candidate has been nominated and designated for such Program, subject to Sections 4.10 and 4.11.

4.3.2 <u>Duties</u>. The JRC shall:

- (a) approve the designation of Research Programs in accordance with Section 2.2.1;
- (b) oversee, review and provide strategic guidance to the Parties with respect to the conduct of each Research Program, including the prioritization of Research Programs;
- (c) review the basis [**] that a Program Compound has met the criteria for a Development Candidate and determine whether such Program Compound has met such criteria;
 - (d) [**];
- (e) in conjunction with the JDC, discuss additional Indications for Development of Program Compounds or Development Candidates of Designated Development Programs or Continuation Programs;
 - (f) oversee the initial development of any biomarkers;
- (g) oversee and coordinate the Parties' activities with respect to the IND-enabling activities and Manufacture of pre-clinical and clinical supply of Program Compounds and Program Products (to the extent the JDC has not yet been formed);
- (h) provide a forum for the Parties (i) to discuss the objectives of each Research Program; and (ii) to exchange and review scientific information and data relating to the activities being conducted under each Research Program;

- (i) provide a forum for the Parties to identify and discuss which Research Programs satisfy the criteria for Qualified Early Exercise I&I Programs and are eligible for early Option exercise by Celgene pursuant to Section 3.1.1(b);
 - (j) discuss and attempt to resolve any disputes in the JRC; and
 - (k) perform such other duties as are specifically assigned to the JRC under this Agreement.
- 4.3.3 <u>Dissolution</u>. The JRC shall be dissolved and its activities and authority terminated upon the end of the Option Term.

4.4 <u>Joint Development Committee</u>.

4.4.1 <u>Establishment</u>. Within [**] following Celgene's first designation of a Designated Development Program pursuant to Section 2.3.2(b) or of a Continuation Program pursuant to Section 2.4.2, Agios and Celgene shall establish the JDC. The JDC shall have oversight over Development activities with respect to each Designated Development Program or Continuation Program and as to which Celgene retains an Option hereunder or that has become a Shared Program.

4.4.2 <u>Duties Prior to Option Exercise by Celgene</u>. The JDC shall:

- (a) Review and approve the applicable Development plans for each Designated Development Program and Continuation Program and any proposed updates or amendments to such Development plans, and propose revisions to each of such Development plans as needed;
- (b) review and approve the content of any IND for a Program Product and oversee, review and coordinate the studies required for the preparation of the CMC section of an IND for filing with Regulatory Authorities for the Program Products, including studies relating to analytical methods and purity analysis;
- (c) provide a forum for the Parties to share information with respect to the Development of Program Compounds and Program Products, including reviewing and commenting on updates on such Development;
- (d) provide a forum for the Parties to discuss whether to conduct additional Development activities for a Related Compound (other than the designated Development Candidate for a Designated Development Program or a Program Compound for a Continuation Program) for a Designated Development Program or Continuation Program;
 - (e) [**];
 - (f) [**];
- $(g) \quad \text{oversee, review and coordinate process research and development activities (including Manufacturing and formulation development activities);}$

- (h) oversee and coordinate the Parties' activities with respect to the Manufacture of pre-clinical and clinical supply of Program Compounds and Program Products, including discussion, review and implementation of any Supply Plan(s) (as defined in Exhibit A);
 - (i) discuss and attempt to resolve any disputes in the JDC; and
- (j) perform such other duties as are specifically assigned to the JDC under this Agreement or a Development & Commercialization Agreement.
 - 4.4.3 <u>Duties Post Option Exercise by Celgene</u>. The JDC shall, solely with respect to any Shared Program under an executed Co-Development and Co-Commercialization Agreement:
- (a) review and recommend to the JSC approval of the initial Development Plan (as provided in the Co-Development and Co-Commercialization Agreement) and any proposed updates or amendments to the Development Plan (and applicable Development Budget) (each as defined in <u>Appendix A</u>) as needed;
- (b) oversee, review, coordinate and provide strategic guidance to the Parties on the Development of the Compounds and Licensed Products (each as defined in <u>Appendix A</u>), including assigning activities to be performed by each Party, subject to the provisions of the Co-Development and Co-Commercialization Agreement;
- (c) review and coordinate such committees' activities with respect to the Development of the Compounds and Licensed Products with the Parties activities under the Co-Development and Co-Commercialization Agreement;
- (d) subject to and within the parameters of each Development Plan (i) oversee the implementation of the Development Plan (including evaluation of clinical trial protocols and review of the conduct of clinical trials conducted pursuant to the Development Plan); and (ii) oversee and approve the overall strategy and positioning of all material submissions and filings with the applicable Regulatory Authorities;
- (e) oversee the Development of any Companion Diagnostics, including the Development of any biomarkers;
- (f) oversee, review and coordinate (in conjunction with the JCC) formulation and Manufacturing development studies, together with associated regulatory activities;
- (g) oversee, review and coordinate the Parties' activities with respect to Manufacturing of Compounds and Licensed Product for Development purposes, including, in conjunction with the JCC, pre-clinical and clinical supply;
- (h) develop and approve a publication plan for any Publications made prior to the First Commercial Sale (as defined in the Co-Development and Co-Commercialization Agreement) of a Shared Product;

- (i) discuss and attempt to resolve any disputes in the JDC; and
- (j) perform such other duties as are specifically assigned to the JDC under the Co-Development & Co-Commercialization Agreement.

4.5 Joint Commercialization Committee.

No later than the earlier of (a) the date upon which the Parties commence the first Phase III Study, or (b) the date upon which the Parties commence the first Pivotal Clinical Trial, or within [**] after request by either Party if requested by either Party earlier, the Parties shall establish the JCC. The Parties intend that the JCC shall have the responsibility for overseeing the Commercialization of Shared Products under the Collaboration pursuant to the terms of each Co-Development and Co-Commercialization Agreement.

4.5.1 Meetings. The first scheduled meeting of the JCC shall be held no later than [**] after establishment of the JCC unless otherwise agreed by the Parties. After the first scheduled meeting of the JCC until the JCC is disbanded, the JCC shall meet in person or telephonically at least [**], as further provided in Section 4.8. The JCC shall disband upon the expiration or termination of all Co-Development and Co-Commercialization Agreements. Each Party will bear all expenses it incurs in regard to participating in all meetings of the JCC, including all travel and living expenses.

4.5.2 Duties. The JCC shall:

- (a) approve the initial Commercialization Plan (as defined in <u>Appendix A</u>) for each Shared Product and, each year thereafter, shall review and approve the Commercialization Plan for the then-current Calendar Year and the next succeeding Calendar Year:
 - (b) oversee implementation of the Commercialization Plan;
- (c) review and coordinate the Commercialization activities of Celgene and Agios with respect to Shared Products, including pre-launch and post-launch activities in the United States;
- (d) review and comment on approaches and plans proposed by the applicable Lead Party in the relevant portion of the Territory (each as defined in <u>Appendix A</u>) [**];
 - (e) discuss any branding and/or co-branding matters;
 - (f) establish target numbers regarding reach and frequency of sales performance;
 - (g) discuss, review and implement any Supply Plan(s) (as defined in Appendix A);
 - (h) discuss and attempt to resolve any disputes in the JCC; and
- (i) such other responsibilities as may be set forth in a Co-Development and Co-Commercialization Agreement or mutually agreed by the Parties from time to time. For

purposes of clarity, the JCC shall not have any authority beyond the specific matters set forth in this Section 4.5. In any case where a matter within the JCC's authority arises, the JCC shall convene a meeting and consider such matter as soon as reasonably practicable, but in no event later than [**] after the matter is first brought to the JCC's attention (or, if earlier, at the next regularly scheduled JCC meeting).

4.6 Joint Patent Committee.

4.6.1 <u>Establishment</u>. The initial members of the JPC for each Party will be determined by each Party, respectively, within [**] after the Effective Date. The Parties intend that the JPC shall have the responsibility for sharing information and coordinating Patent Prosecution matters involving Agios Patents, Celgene Patents, Patents included in the Celgene Collaboration Intellectual Property and Joint Collaboration Patents.

4.6.2 <u>Duties</u>. The JPC shall:

- (a) discuss the current status of all Agios Patents, Celgene Patents, Patents included in the Celgene Collaboration Intellectual Property and Joint Collaboration Patents;
- (b) discuss filing and claiming strategies involving Agios Patents, Celgene Patents, Patents included in the Celgene Collaboration Intellectual Property and Joint Collaboration Patents both existing as of the Effective Date as well as any new applications filed after the Effective Date;
- (c) coordinate the timing and conduct of transfer of the Parties' responsibilities under a Co-Development and Co-Commercialization Agreement with respect to Prosecution;
- (d) coordinate the Parties' respective activities in preparation for potential litigation involving the assertion of the Agios Patents, Celgene Patents, Patents included in the Celgene Collaboration Intellectual Property and Joint Collaboration Patents;
 - (e) discuss and attempt to resolve any disputes in the JPC; and
- (f) perform such other duties as are specifically assigned to the JPC under this Agreement or any Co-Development and Co-Commercialization Agreement.
- 4.7 <u>Alliance Managers</u>. Each Party shall appoint one designated representative to serve as an alliance manager ("<u>Alliance Manager</u>") with responsibility for being the primary point of contact between the Parties with respect to the Collaboration. The Alliance Managers shall attend JSC, JRC, JDC, JCC and JPC meetings, as necessary, as non-voting observers. Nothing herein shall prohibit a Party from appointing its Alliance Manager as a member of one or more Committees.
 - 4.8 General Committee Membership and Procedures.

4.8.1 Committee Membership. Each Committee shall each be composed of three (3) representatives from each of Celgene and Agios (provided that the JPC shall be composed of two (2) representatives from each of Celgene and Agios), each of which representatives shall be of the seniority and experience appropriate for service on the applicable Committee in light of the functions, responsibilities and authority of such Committee and the status of Development of the Program Products being pursued hereunder from time to time. Each Party may replace any of its representatives on any Committee at any time with prior written notice to the other Party; provided that such replacement meets this standard. Each Committee shall appoint a chairperson from among its members, with the chairperson for the JRC and JDC being a representative from [**], and the chairperson for the JSC being a representative from [**]. The JSC shall appoint the chairpersons for the JCC and the JPC. Within [**] following each Committee meeting, the chairperson of each Committee shall circulate to all Committee members a draft of the minutes of such meeting. The Committee shall then approve, by mutual agreement, such minutes within [**] following circulation.

4.8.2 Committee Meetings.

- (a) The JSC and JRC shall hold an initial joint meeting within [**] after the Effective Date or as otherwise agreed by the Parties. The JDC shall meet at the time the JDC is formed in accordance with Section 4.4.1. Thereafter, each Committee shall meet at least [**], unless the respective Committee members otherwise agree. All Committee meetings shall be conducted in person or, for [**] of such meetings each year, by teleconference, unless otherwise determined by the applicable Committee.
- (b) Unless otherwise agreed by the Parties, all in-person meetings for each Committee shall be held on an alternating basis between Agios' facilities in Cambridge, Massachusetts (or such future location as Agios' facilities may move to) and Celgene's facilities in Summit, New Jersey, Seattle, Washington, San Francisco, California or San Diego, California, as determined by Celgene (or such future location as Celgene's facilities may move to). A reasonable number of other representatives of a Party may attend any Committee meeting as non-voting observers; provided that such additional representatives are under obligations of confidentiality and non-use applicable to the Confidential Information of the other Party that are at least as stringent as those set forth in ARTICLE VIII; and provided further that the Parties, reasonably in advance of the applicable Committee meeting, approve the list of non-voting observers to attend such meeting. Each Party shall be responsible for all of its own personnel and travel costs and expenses relating to participation in Committee meetings.
- 4 . 9 <u>Responsibilities under Specific Agreements</u>. Following the execution of a Development & Commercialization Agreement for a given Program:
- 4.9.1 <u>License Agreement.</u> After the Parties have entered into a License Agreement to govern the further Development and Commercialization of Licensed Product under a specified Program, no Committee shall have any review or decision-making authority.
- 4 . 9 . 2 <u>Co-Development and Co-Commercialization Agreement</u>. After the Parties have entered into a Co-Development and Co-Commercialization Agreement to govern the further Development and Commercialization of Shared Products for a specified Program, the

Committees other than the JRC shall continue to have review and oversight of the Development, Manufacture and Commercialization of Shared Products as set forth in this Agreement and the applicable Co-Development and Co-Commercialization Agreement.

4.10 <u>Decision-Making</u>.

- 4.10.1 Committee; Referral to JSC and to Executive Officers. All decisions of a Committee shall be made by unanimous vote, with each Party's Representatives collectively having one (1) vote, and shall be set forth in minutes approved by both Parties. Upon [**] prior written notice, either Party may convene a special meeting of a Committee for the purpose of resolving any failure to reach agreement on a matter within the scope of the authority and responsibility of such Committee. No Committee shall have the authority to resolve any dispute involving the breach or alleged breach of this Agreement and shall not have any power to amend, modify or waive the terms of this Agreement (including any amendment of the Development Candidate Criteria), any Development & Commercialization Agreement or any Supply Agreement (or any other agreement between the Parties), or to alter, increase, expand or waive compliance by a Party with a Party's obligations under this Agreement or any Development & Commercialization Agreement. If the JRC, JDC, JCC or JPC is unable to reach agreement on any matter so referred to it for resolution by one or both Parties within [**] after the matter is referred to it or first considered by it, such matter shall be referred to the Executive Officers for resolution.
- 4.10.2 <u>Decision-Making Authority</u>. If the matter is not resolved by the Executive Officers after discussions between such Executive Officers within [**] after referral to the Executive Officers, then, on a Program-by-Program basis, subject to Section 4.11 and except as otherwise provided herein (a) [**] Executive Officer shall have the right to decide the unresolved matter as to [**] and (b) the right to decide the unresolved matter as to [**].
- 4.10.3 Notwithstanding the foregoing, neither Party shall have the right to finally resolve a dispute pursuant to Section 4.10.2:
 - (i) in a manner that excuses such Party from any of its obligations specifically enumerated

under this Agreement;

other Party under this Agreement;

- (ii) in a manner that negates any consent rights or other rights specifically allocated to the
 - (iii) to resolve any dispute involving the breach or alleged breach of this Agreement;
- (iv) to resolve a matter if the provisions of this Agreement specify that unanimous or mutual agreement of the Parties or a Committee, or consent of the other Party, is required for such matter;
 - (v) in a manner that would require the other Party to perform any act that is inconsistent

with any Law;

(vi) to determine whether or not a milestone event has been achieved under a Development & Commercialization Agreement or whether or not a Qualified Early Exercise I&I Program has satisfied the criteria set forth on Schedule 1.1.83; or

(vii) otherwise expand a Party's rights or reduce a Party's obligations under this Agreement or any Development & Commercialization Agreement.

- 4.11 <u>Scope of Governance</u>. Notwithstanding the creation of each of the Committees, each Party shall retain the rights, powers and discretion granted to it under this Agreement (including, in the case of Celgene, Celgene's rights to designate Designated Development Programs pursuant to Section 2.3.2(b), to designate Continuation Programs pursuant to Section 2.4.2, and to elect whether to exercise Options pursuant to Section 3.1), and no Committee shall be delegated or vested with rights, powers or discretion unless such delegation or vesting is expressly provided herein, or the Parties expressly so agree in writing. It is understood and agreed that issues to be formally decided by a particular Committee are only those specific issues that are expressly provided in this Agreement to be decided by such Committee, as applicable.
- 4.12 Agios Right to Discontinue Participation. Notwithstanding anything in this ARTICLE IV to the contrary, Agios shall have the right to discontinue its participation in, and to not appoint members to, any Committee or any subcommittee or project team upon [**] prior written notice to Celgene; provided that, within such [**] period, Agios shall have [**] in place of its representative [**], subject to Celgene's prior written consent, such consent not to be unreasonably withheld, and [**]. If, at any time, following issuance of such a notice, Agios wishes to resume participation in any committee or Subcommittee, Agios shall notify Celgene in writing and, thereafter, Agios' representatives to such committee or Subcommittee shall be entitled to attend any subsequent meeting of such committee or Subcommittee and to participate in the activities of, and decision-making by, such committee or Subcommittee as provided in this ARTICLE IV as if such notice had not been issued by Agios pursuant to this Section 4.12. If Agios discontinues participation in, or does not appoint members [**] to, any Committee or any subcommittee or project team, (a) it shall not be a breach of this Agreement; (b) no consideration shall be required to be returned; (c) unless and until such members are appointed, Celgene may unilaterally discharge the roles of such Committee, subcommittee or project team, as applicable, for which members were not appointed, including making in Celgene's sole discretion all decisions of such Committee, subcommittee, or project team, including decisions requiring mutual agreement; provided that Celgene shall not unilaterally discharge the roles of such Committee, subcommittee or project team, as applicable, as permitted under this ARTICLE IV unless Agios has not appointed any members within [**] after Celgene has completed its appointment of its members; and (d) Agios shall abide by all decisions made by Celgene on behalf of the applicable Committee, subcommittee, or project team and shall continue to perform its obligations hereunder. If Agios thereafter appoints members to a Committee, subcommittee or project team, Celgene shall no longer have the unilateral right to discharge the role of such Committee, subcommittee or project team, as applicable and the applicable Committee shall be re-formed.

ARTICLE V LICENSES; EXCLUSIVITY

5.1 Licenses.

- 5.1.1 <u>License to Agios</u>. On a Program-by-Program basis, commencing on the Effective Date and extending until expiration of the applicable Option Exercise Window, subject to the terms and on the conditions set forth in this Agreement, Celgene hereby grants and shall cause (within [**] after the Effective Date) its Affiliates to grant to Agios a non-exclusive, worldwide, royalty-free right and license, with the right to grant sublicenses (subject to Section 5.1.4), under the Celgene Intellectual Property and Celgene Collaboration Intellectual Property, solely to permit Agios to perform its obligations under the Research Plan for each Program that is subject to an Option exercisable by Celgene under Section 3.1 to Develop and/or Manufacture, for purposes of such Program, Program Compounds and/or Program Products during the Option Term.
- 5.1.2 <u>License to Celgene.</u> On a Program-by-Program basis, commencing on the Effective Date until the expiration of the applicable Option Exercise Window, subject to the terms and on the conditions set forth in this Agreement, Agios hereby grants to Celgene a non-exclusive, worldwide, royalty-free right and license, with the right to grant sublicenses (subject to Section 5.1.4), under the Agios Intellectual Property, solely to permit Celgene to perform its obligations under the Research Plan for each Program that is subject to an Option exercisable by Celgene under Section 3.1 to Develop and/or Manufacture, for purposes of such Program, Program Compounds and/or Program Products during the Option Term.
- 5.1.3 <u>Additional Licenses</u>. Each Development & Commercialization Agreement will specify additional licenses for the Development, Manufacture and/or Commercialization of Compounds (as defined in <u>Appendix A</u> or <u>Appendix B</u>) and Post-Exercise Products for the Post-Exercise Programs that are subject to such agreement.
- 5.1.4 <u>Sublicenses</u>. Agios shall have the right to grant sublicenses under the rights granted to it under Section 5.1.1 to its Affiliates and Third Party contractors, and Celgene shall have the right to grant sublicenses under the rights granted to it under Section 5.1.2 to its Affiliates and Third Party contractors. Each such sublicense granted by either Party shall be subject to and consistent with the terms and conditions of this Agreement, and each Party shall provide the other Party with an unredacted copy of such sublicense.
- 5.1.5 <u>Rights Retained by the Parties</u>. For purposes of clarity, each Party retains all rights under Know-How and Patents Controlled by such Party not expressly granted to the other Party pursuant to this Agreement.
- 5.1.6 <u>No Implied Licenses</u>. Except as explicitly set forth in this Agreement, neither Party shall be deemed by estoppel, implication or otherwise to have granted the other Party any license or other right to any intellectual property of such Party.
- 5.1.7 <u>Section 365(n) of the Bankruptcy Code</u>. All licenses granted under this Agreement are deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses of

rights to "intellectual property" as defined in Section 101 of such Code. Each Party, as licensee, may fully exercise all of its rights and elections under the Bankruptcy Code. The Parties further agree that, if a Party elects to retain its rights as a licensee under any Bankruptcy Code, such Party shall be entitled to complete access to any technology licensed to it hereunder and all embodiments of such technology. Such embodiments of the technology shall be delivered to the licensee Party not later than: (a) the commencement of bankruptcy proceedings against the licensor, upon written request, unless the licensor elects to perform its obligations under the Agreement, or (b) if not delivered under clause (a), upon the rejection of this Agreement by or on behalf of the licensor, upon written request. Any agreements supplemental hereto will be deemed to be "agreements supplementary to" this Agreement for purposes of Section 365(n) of the Bankruptcy Code. As used herein, "Bankruptcy Code" means the U.S. Bankruptcy Code and any foreign equivalent thereto in any country having jurisdiction over a Party or its assets.

5.2 Exclusivity.

- 5.2.1 Agios. During the Option Term, except as expressly permitted in this Agreement or any Development & Commercialization Agreement, or mutually agreed in writing by the Parties, neither Agios nor its Affiliates shall, directly or indirectly, Develop, Manufacture or Commercialize any [**] (a) in the IO Field that [**], (b) in the I&I Field that [**], (c) that exerts its efficacy primarily through [**] of the Program Target [**] or (d) that exerts its efficacy primarily through [**] of the Program Target [**], in each case ((a), (b), (c) and (d)) [**], except for the following:
- (a) [**] Developed, Manufactured or Commercialized under Programs in accordance with this Agreement or any Development & Commercialization Agreement; and
- (b) [**] that exert their efficacy primarily through the [**] of Program Targets that are the subject of Programs the rights to which have reverted to Agios in accordance with Section 2.12 or 11.5.1(a).
- 5.2.2 <u>Celgene</u>. During the period commencing on the date that Celgene [**] with respect to a [**] and continuing until [**], except as expressly permitted in this Agreement, or mutually agreed in writing by the Parties, neither Celgene nor its Affiliates shall, directly or indirectly, Develop, Manufacture or Commercialize [**] that (a) if such Program is anticipated to be in the IO Field [**], (b) if such Program is anticipated to be in the I&I Field [**], (c) if such Program is the [**] Program, exerts its efficacy primarily through [**] of the Program Target [**] or (d) if such Program is the [**] Program, exerts its efficacy primarily through [**] of the Program Target [**], in each case ((a), (b), (c) and (d)) [**], except for [**] Developed, Manufactured or Commercialized under Programs in accordance with this Agreement or any Development & Commercialization Agreement.

5.2.3 <u>Certain Exceptions to Exclusivity.</u>

(a) <u>Incidental Discoveries</u>. A Party shall be deemed not to be, directly or indirectly (whether such activities are conducted internally or with or through a Third Party), Developing, Manufacturing or Commercializing in violation of the provisions of this Section 5.2 as a result of conducting a research program or discovery effort (or Developing, Manufacturing

or Commercializing a therapeutic modality resulting from such research program or discovery effort) that has as its specified and primary goal, as evidenced by laboratory notebooks or other relevant documents contemporaneously kept, taken as a whole, to discover or Develop compounds that are not within the prohibitions set forth in this Section 5.2.

- (b) <u>Celgene Exception</u>. It is agreed and understood by the Parties that any Celgene research, discovery and commercialization activities [**], whether such activities are undertaken by Celgene alone or in conjunction with one or more partners, licensors, licensees, and/or collaborators, are expressly excluded from the provisions of this Section 5.2. In particular and without limitation, Celgene research, discovery, and commercialization activities related to (i) [**]; (ii) [**]; (iii) [**]; (iv) [**]; or (vi) [**], are expressly excluded from the provisions of this Section 5.2.
- (c) <u>Academic Collaborations</u>. Notwithstanding the provisions of Section 5.2.1 or 5.2.2, as applicable, each Party shall be permitted to perform any of the activities that would otherwise be prohibited under Section 5.2.1 or 5.2.2, as applicable, and in relation to the applicable Program Target, if such activities are (i) the subject of an existing agreement between such Party and an academic institution or academic collaborator entered into prior to the Effective Date, provided that such Party shall not be permitted to amend any such agreement unless such amendment contains provisions consistent with the terms and conditions of such agreement in effect as of the Effective Date with respect to (A) [**], or (ii) the subject of a new agreement entered into between such Party and an academic institution or academic collaborator that contains terms and conditions with respect to the [**] consistent with the terms and conditions of [**]; provided that, if any [**] of an amendment described in (a) or an agreement described in (b) would not be [**] the agreements between such Party and an academic institution or academic collaborator entered into prior to the Effective Date, such Party [**].
- Party or its Affiliates (other than in [**] with respect to such Party) merges or consolidates with, or otherwise acquires, a Third Party that is then engaged in activities that would otherwise constitute a breach of this Section 5.2 by any Party or its Affiliates (a "Competitive Program"); it being understood and agreed that, unless the Parties agree otherwise in writing, such Party that is engaged in a Competitive Program (the "Competitive Program Party") shall, within [**] after the date of such merger, consolidation or acquisition, notify the other Party that it intends to either: (i) terminate, or cause its relevant Affiliate to terminate, the Competitive Program or (ii) divest, or cause its relevant Affiliate to divest, whether by license or otherwise, the Competitive Program. If the Competitive Program Party notifies the other Party within such [**] period that it intends to [**], such Competitive Program, the Competitive Program Party or its relevant Affiliate, shall (i) terminate such Competitive Program as quickly as possible, and in any event within [**] (unless applicable Law requires a longer termination period) after the Competitive Program Party delivers such notice to the other Party; and (ii) confirm to the other Party when such termination has been completed, and the Competitive Program Party's continuation of the Competitive Program Party's exclusivity obligations under Section 5.2.1 or 5.2.2, as applicable. If the Competitive Program Party notifies the other Party within such [**] period that it intends

to divest such Competitive Program, the Competitive Program Party or its relevant Affiliate shall use all reasonable efforts to effect such divestiture as quickly as possible, and in any event within [**] after the Competitive Program Party delivers such notice to the other Party, and shall confirm to the other Party when such divestiture has been completed. If the Competitive Program Party or its relevant Affiliate fails to complete such divestiture within such [**] period, but has used reasonable efforts to effect such divestiture within such [**] period, then, unless otherwise required by applicable Law, such [**] period shall be extended for such additional reasonable period thereafter as is necessary to enable such Competitive Program to be in fact divested, not to exceed an additional [**]; provided that such additional [**] period shall be extended for such period as is necessary to obtain any governmental or regulatory approvals required to complete such divestiture if the Competitive Program Party or its relevant Affiliate is using good faith efforts to obtain such approvals. The Competitive Program Party's continuation of the Competitive Program during such divestiture period shall not constitute a breach of the Competitive Program Party's exclusivity obligations under 5.2.1 or 5.2.2, as applicable.

(e) Certain Permitted Activities.

- (i) The [**] shall not constitute a breach of Section 5.2.1 or 5.2.2, as applicable. Each Party shall report to the JSC on a [**] basis [**] and that would otherwise breach Section 5.2.1 or 5.2.2, as applicable. For clarity, [**] without violation of 5.2.1 or 5.2.2, as applicable, [**] shall not constitute [**] in violation of such Party's exclusivity obligations under this Section 5.2 as long as [**].
- (ii) The [**] shall not constitute a breach of Section 5.2.2; <u>provided that</u> [**] shall be subject to Section 5.2.2 and shall not be permitted under this Section 5.2.3(e)(ii). [**].
- (iii) The restrictions set forth in Section 5.2.1 or 5.2.2, as applicable, shall not be deemed to prevent either Party or its respective Affiliates from (A) fulfilling its obligations under this Agreement, and (B) engaging any subcontractors in accordance with Section 2.9 of this Agreement.
- (iv) If [**] occurs with respect to either Party with a Third Party and the Third Party already is conducting or is planning to conduct activities that would cause a Party or an Affiliate to violate Section 5.2.1 or 5.2.2, as applicable, (an "Acquirer Program"), then such Third Party [**]; provided that (i) [**] in any Acquirer Program, (ii) [**] in any Acquirer Program, (iii) [**] in any such Acquirer Program, and (iv) [**] to such Acquirer Program, including by [**] the activities under this Agreement, and the activities covered under such Acquirer Program (except that this requirement shall not apply to [**] activities under such Acquirer Program).
- (v) <u>Clinical Combinations</u>. Notwithstanding anything to the contrary in this Agreement, for purposes of this Section 5.2, either Party shall, at all times, have the right to conduct clinical Development of Program Products, alone or with Third Parties, in which the [**] for purposes of enabling such Party and such Third Party to include the relevant use of Program Products [**], provided that [**] may grant to any such Third Party the right to sell, offer for sale and otherwise commercially exploit such Program Products.

ARTICLE VI FINANCIAL TERMS

- 6.1 <u>Upfront Payment</u>. In consideration for the rights granted to Celgene under this Agreement, Celgene will make the following one-time, non-refundable, non-creditable upfront payments within [**] after the Effective Date:
 - (a) Celgene Corp. shall pay to Agios [**] U.S. Dollars (\$[**]); and
 - (b) Celgene RIVOT shall pay to Agios [**] U.S. Dollars (\$[**]).
- 6.2 <u>Designation Fees</u>. On a Program-by-Program basis, Celgene will make a non-refundable payment to Agios of Eight Million Dollars (\$8,000,000) (the "<u>Designation Fee</u>") within [**] after Celgene's designation of each such Program for further Development pursuant to Section 2.3.2(b) or 2.4.2, as applicable.
- 6.3 <u>Research Term Extension Fee</u>. Celgene may elect, in its sole discretion, to extend the Research Term pursuant to Section 2.1.2 by making a non-refundable payment to Agios of Forty Million Dollars (\$40,000,000) for each one (1) year extension (the "<u>Research Term Extension Fee</u>") within [**] after receipt of Agios' invoice therefor.
- 6.4 <u>Development Costs and Manufacturing Costs</u>. As between the Parties, except as expressly set forth herein or otherwise agreed by the Parties, Agios shall be solely responsible, on a Program-by-Program basis, for any and all costs and expenses it incurs in connection with the conduct of Development and Manufacturing activities for such Program that occur before Celgene exercises the Option for such Program, after which the costs of further Development, Manufacturing and Commercialization activities, for the applicable Post-Exercise Products shall be borne by the Parties in accordance with the applicable Development & Commercialization Agreement.
- 6.5 <u>Financial Records</u>. Agios shall keep, and shall require its Affiliates to keep, complete and accurate books and records containing all data reasonably required for the calculation and verification of amounts payable by Celgene under this ARTICLE VI in accordance with the applicable Accounting Standards. Agios shall keep, and shall require its Affiliates to keep, such books and records for at least [**] following the end of the Calendar Year to which they pertain. Such books of accounts shall be kept at the principal place of business of the financial personnel with responsibility for preparing and maintaining such records.

6.6 Tax Matters.

6.6.1 Withholding Taxes.

(a) Each Party shall be entitled to deduct and withhold from any amounts payable under this Agreement such taxes as are required to be deducted or withheld therefrom under any provision of applicable Law. The Party that is required to make such withholding (the "Paying Party") will: (i) deduct those taxes from such payment, (ii) timely

remit the taxes to the proper taxing authority, and (iii) send evidence of the obligation together with proof of tax payment to the recipient Party (the "Payee Party") on a timely basis following that tax payment; provided, however, that, before making any such deduction or withholding, the Paying Party shall give the Payee Party notice of the intention to make such deduction or withholding (and such notice, which shall set forth in reasonable detail the authority, basis and method of calculation for the proposed deduction or withholding, shall be given at least a reasonable period of time before such deduction or withholding is required, in order for such Payee Party to obtain reduction of or relief from such deduction or withholding). Each Party agrees to cooperate with the other Parties in claiming refunds or exemptions from such deductions or withholdings under any relevant agreement or treaty or other applicable Law which is in effect to ensure that any amounts required to be withheld pursuant to this 6.6.1(a) are reduced in amount to the fullest extent permitted by applicable Law. In addition, the Parties shall co-operate in accordance with applicable Laws to minimize [**] in connection with this Agreement, as applicable.

- (b) <u>Tax Documentation</u>. Each Party has provided a properly completed and duly executed IRS Form W-9 or applicable Form W-8 to the other Parties. Each Party and any other recipient of payments under this Agreement shall provide to the other Party, at the time or times reasonably requested by such other Parties or as required by applicable Law, such other properly completed and duly executed documentation as will permit payments made under this Agreement to be made without, or at a reduced rate of, withholding for taxes, and the applicable payment shall be made without (or at a reduced rate of) withholding to the extent permitted by such documentation, as reasonably determined by the Paying Party.
- 6.6.2 <u>Tax Cooperation</u>. Upon request, each Party shall use Commercially Reasonable Efforts to cooperate with the other Party to mitigate, reduce or eliminate adverse tax consequences to such other Party from changes in applicable Law, the use of present or future Affiliates of either Party to engage in transactions described in or contemplated by this Agreement, or from other activities or transactions described in or contemplated by this Agreement.
- 6.7 <u>Payments; Currency Exchange</u>. Payments of all amounts payable under this ARTICLE VI shall be made directly by Celgene to the bank account designated in writing by Agios. Unless otherwise expressly stated in this Agreement, all amounts specified in, and all payments made under, this Agreement shall be in United States Dollars. Conversion of sales recorded in local currencies to Dollars shall be performed in a manner consistent with Celgene's normal practices used to prepare its audited financial statements for internal and external reporting purposes. For clarity, Celgene sets currency transaction rates for the month on the last business day of the prior calendar month. Agios has the right to verify that the exchange rates used by Celgene for a given month are within the trading range of the last business day of the prior calendar month.
- 6.8 <u>Late Payments</u>. Celgene shall pay interest to Agios on the aggregate amount of any payments that are not paid on or before the date such payments are due under this Agreement at a rate per annum equal to the lesser of the [**], or the highest rate permitted by applicable Law, calculated on the number of days such payments are paid after the date such payments are due; <u>provided that</u>, with respect to any disputed payments, no interest payment

shall be due until such dispute is resolved and the interest which shall be payable thereon shall be based on the finally-resolved amount of such payment, calculated from the original date on which the disputed payment was due through the date on which payment is actually made.

ARTICLE VII INTELLECTUAL PROPERTY

7.1 Ownership of Inventions. Inventorship of Inventions shall be determined by application of U.S. patent law pertaining to inventorship, and ownership shall follow inventorship.

7.2 Prosecution of Patents.

- 7.2.1 As between the Parties, the Party that [**] a Patent relating to a Program, unless otherwise explicitly provided under a Development & Commercialization Agreement, shall have the sole right (but not the obligation) to Prosecute such Patent, at such Party's expense, and [**], unless otherwise explicitly provided under a Development & Commercialization Agreement, shall have the sole right (but not the obligation) to Prosecute all Joint Collaboration Patents, at [**] sole expense.
- 7.2.2 Until the earlier of (a) Celgene's exercise of its Option and entry into a Development & Commercialization Agreement for a given Designated Development Program or Continuation Program, or (b) the expiration of the Option Exercise Window for such Qualified Early Exercise I&I Program, Designated Development Program or Continuation Program, [**] shall, with respect to any Agios Patent or Joint Collaboration Patent related to such Research Program, Designated Development Program or Continuation Program, (x) keep [**] informed, via the JPC, as to material developments with respect to the Prosecution of such Agios Patent or Joint Collaboration Patent, including by providing copies of all substantive office actions or any other substantive documents in connection with such Agios Patents or Joint Collaboration Patents that [**] receives from any patent office, and (y) provide [**] with a reasonable opportunity to comment substantively on the Prosecution of such Agios Patents or Joint Collaboration Patents, prior to taking material actions (including the filing of initial applications), and will in good faith consider any comments made by and actions recommended by [**], provided, however, that [**] does so promptly and consistently with any applicable filing deadlines.
- 7 . 3 <u>Defense of Claims Brought by Third Parties</u>. If a Party becomes aware of any actual or potential claim that the Development, Manufacture or Commercialization of any Program Compound or Program Product infringes or misappropriates the intellectual property rights of any Third Party, such Party shall [**]. Certain additional rights and obligations of the Parties with respect to any such claim will be set forth in the Development & Commercialization Agreement for such Program (in each case, if applicable).
- 7.4 Enforcement and Defense of Patents. As between the Parties, the Party that [**] a Patent relating to a Program, and [**] with respect to any Joint Collaboration Patents, unless otherwise explicitly provided under a Development & Commercialization Agreement, shall have the sole right, but not the obligation, to institute, prosecute, and control any action or proceeding with respect to any infringement or Defense of such Patent, by counsel of its own choice, in such Party's own name and under such Party's direction, control and expense.

7.5 Third Party Licenses.

- 7.5.1 <u>Notice</u>. On a Program-by-Program basis, if, at any time during the Term, [**] reasonably determines [**] for the Development, Manufacture or Commercialization of any Program Compound or Program Product that is the subject of Development or Manufacturing efforts under this Agreement (and that is the subject of an Option), then [**] will [**].
- 7.5.2 <u>Pre-Option</u>. Prior to the exercise of the Option, on a Program-by-Program basis, [**] shall have the right, but not the obligation, at its sole discretion, to determine whether [**] wishes to obtain one or more licenses, on commercially reasonable terms, from one or more Third Parties for the Development, Manufacture or Commercialization of any Program Compound or Program Product that is the subject of Development or Manufacturing efforts under this Agreement (a "<u>Third Party License</u>") or take other appropriate measures in view of such Third Party rights. In each case, [**] shall have the right [**] with respect to such Third Party rights.
- 7.5.3 <u>Post-Option</u>. On a Program-by-Program basis, following the exercise of the Option for such Program, the rights and obligations of the Parties with respect to obtaining licenses from Third Parties or taking other appropriate measures in view of such Third Party rights shall be as set forth in the Development & Commercialization Agreement for such Post-Exercise Program.
- 7 . 5 . 4 <u>Costs</u>. Subject to Section 2.2.2, unless otherwise allocated in a Development & Commercialization Agreement or agreed by the Parties in writing, the costs associated with negotiating and obtaining rights under any Third Party License obtained under this Section 7.5 shall be borne by [**], and the costs associated with exercising rights under any Third Party License obtained under this Section 7.5 shall be borne by [**].

ARTICLE VIII CONFIDENTIALITY

8.1 <u>Confidential Information</u>. Each Party agrees that a Party (the "<u>Receiving Party</u>") receiving Confidential Information of any other Party (the "<u>Disclosing Party</u>") shall (x) maintain in confidence such Confidential Information using not less than the efforts such Receiving Party uses to maintain in confidence its own proprietary information of similar kind and value, but in no event less than a reasonable degree of effort, (y) not disclose such Confidential Information to any Third Party without the prior written consent of the Disclosing Party, except for disclosures expressly permitted below, and (z) not use such Confidential Information for any purpose except those permitted by this Agreement (it being understood that this clause (z) shall not create or imply any rights or licenses not expressly granted under this Agreement). No Confidential Information of the Disclosing Party shall be used by the Receiving Party except in performing its obligations or exercising rights explicitly granted under this Agreement or a Development & Commercialization Agreement, except to the extent that the Confidential Information:

- (a) was known by the Receiving Party or its Affiliates prior to its date of disclosure to the Receiving Party, as established by written evidence; or
- (b) 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) becomes published or generally known to the public through no fault or omission on the part of the Receiving Party or its Affiliates; or
- (d) is independently developed by or for the Receiving Party or its Affiliates without reference to or reliance upon such Confidential Information, as established by written records.

8.2 Permitted Disclosure. The Receiving Party may provide the Disclosing Party's Confidential Information:

- (a) to the Receiving Party's respective employees, consultants and advisors, and to the employees, consultants and advisors of such Party's Affiliates, who have a need to know such information and materials for performing obligations or exercising rights expressly granted under this Agreement or any Development & Commercialization Agreement and have an obligation to treat such information and materials as confidential;
- (b) to patent offices in order to seek or obtain Patents or to Regulatory Authorities in order to seek or obtain approval to conduct clinical trials or to gain Regulatory Approval with respect to any Program Compound(s) or Program Product(s), as contemplated by this Agreement or any Development & Commercialization Agreement; provided that such disclosure may be made only following reasonable notice to the Disclosing Party and to the extent reasonably necessary to seek or obtain such Patents or approvals; or
- (c) if such disclosure is required by judicial order or applicable Law or to defend or prosecute litigation or arbitration; <u>provided that</u>, prior to such disclosure, to the extent permitted by Law, the Receiving Party promptly notifies the Disclosing Party of such requirement, cooperates with the Disclosing Party to take whatever action it may deem appropriate to protect the confidentiality of the information and furnishes only that portion of the Disclosing Party's Confidential Information that the Receiving Party is legally required to furnish.

8.3 Publicity; Terms of this Agreement; Non-Use of Names.

8.3.1 Except as required by judicial order or applicable Law (in which case, Section 8.3.2 must be complied with) or as explicitly permitted by this ARTICLE VIII, neither Party shall make any public announcement concerning this Agreement without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed. The Party preparing any such public announcement shall provide the other Party with a draft thereof at least [**] prior to the date on which such Party would like to make the public announcement (or, in extraordinary circumstances, such shorter period as required to comply with applicable

Law). Notwithstanding the foregoing, the Parties shall issue a press release, in a form mutually agreed to by the Parties, within [**] after the Effective Date. Neither Party shall use the name, trademark, trade name or logo of the other Party or its employees in any publicity or news release relating to this Agreement or its subject matter, without the prior express written permission of the other Party. For purposes of clarity, either Party may issue a press release or public announcement or make such other disclosure relating to this Agreement if the content of such press release, public announcement or disclosure (a) (i) does not consist of financial information and has previously been made public other than through a breach of this Agreement by the issuing Party or its Affiliates, (ii) is contained in such Party's financial statements prepared in accordance with Accounting Standards, or (iii) is contained in the Redacted Version of this Agreement, and (b) is material to the event or purpose for which the new press release or public announcement is made.

8.3.2 Notwithstanding the terms of this ARTICLE VIII:

- (a) Either Party shall be permitted to disclose the existence and terms of this Agreement to the extent required, in the reasonable opinion of such Party's legal counsel, to comply with applicable Laws, including the rules and regulations promulgated by the Securities and Exchange Commission or any other Governmental Authority. Notwithstanding the foregoing, before disclosing this Agreement or any of the terms hereof pursuant to this Section 8.3.2, the Parties will coordinate in advance with each other in connection with the redaction of certain provisions of this Agreement with respect to any filings with the U.S. Securities and Exchange Commission ("SEC"), London Stock Exchange, the UK Listing Authority, NYSE, the NASDAQ Stock Market or any other stock exchange on which securities issued by a Party or a Party's Affiliate are traded (the "Redacted Version"), and each Party will use commercially reasonable efforts to seek confidential treatment for such terms as may be reasonably requested by the other Party; provided that the Parties will use commercially reasonable efforts to file redacted versions with any governing bodies which are consistent with the Redacted Version.
- (b) Notwithstanding Section 8.1, the Receiving Party may disclose Confidential Information belonging to the Disclosing Party, and Confidential Information deemed to belong to both the Disclosing Party and the Receiving Party, to the extent (and only to the extent) such disclosure is reasonably necessary in the following instances:
- (i) subject to Section 8.3.2(a), complying with applicable Laws (including the rules and regulations of the SEC or any national securities exchange) and with judicial process, if in the reasonable opinion of the Receiving Party's counsel, such disclosure is necessary for such compliance;
- (ii) disclosure, solely on a "need to know basis," to (A) Affiliates, subcontractors, advisors (including attorneys and accountants), (B) subject to Section 8.3.2(b)(iii), investment bankers, and (C) in each case of (A) and (B), their and each of the Parties' respective directors, employees, contractors and agents; provided that, in all cases of (A), (B) and (C), prior to any such disclosure, each disclosee must be bound by written obligations of confidentiality, non-disclosure and non-use no less restrictive than the obligations set forth in this ARTICLE VIII (provided, however, that, in the case of prospective investment

bankers, the term of confidentiality may be [**] from the date of disclosure and in the case of legal advisors, no written agreement shall be required), which for the avoidance of doubt, will not permit use of such Confidential Information for any purpose except those permitted by this Agreement; <u>provided</u>, <u>however</u>, <u>that</u>, in each of the above situations, the Receiving Party shall remain responsible for any failure by any Person who receives Confidential Information pursuant to this Section 8.2.3(b)(ii) to treat such Confidential Information as required under this ARTICLE VIII; and

(iii) in the case of any disclosure of this Agreement, or any executed Development & Commercialization Agreement, to any actual or potential acquirer, assignee, licensee, licensor, investment banker, institutional investor, lender or other financial partners, such disclosure shall solely be [**]; it being understood and agreed that, in connection with a proposed Change of Control with respect to such Party, only [**] this Agreement or such Development & Commercialization Agreement, as applicable, to such Third Party; provided that a Party may also disclose an unredacted version of this Agreement to Third Party attorneys, professional accountants and auditors who are engaged by licensors and lenders and who are under obligations of confidentiality not to disclose the unredacted terms of this Agreement to such licensors or lenders for the purpose of confirming such Party's compliance with the terms of its applicable license and loan agreements with such licensors and lenders.

(c) [**]. Such disclosures may include achievement of milestones, significant events in the development and regulatory process, commercialization activities and the like. In addition to the initial press release described in Section 8.3.1, a Party (the "Requesting Party") may elect to make any such public disclosure of such achievement of milestones, significant events in the Development and regulatory process and Commercialization activities, and in such event it shall first notify the other Party (the "Cooperating Party") of such planned press release or public announcement and provide a draft for review at least [**] in advance of issuing such press release or making such public announcement (or, with respect to press releases and public announcements that are required by applicable Law, or by regulation or rule of any public stock exchange (including NASDAQ), with as much advance notice as possible under the circumstances if it is not possible to provide notice at least [**] in advance); provided, however, that a Party may issue such press release or public announcement without such prior review by the other Party if (i) the contents of such press release or public announcement have previously been made public other than through a breach of this Agreement by the issuing Party and (ii) such press release or public announcement does not materially differ from the previously issued press release or other publicly available information. The Cooperating Party may notify the Requesting Party of any reasonable objections or suggestions that the Cooperating Party may have regarding the proposed press release or public announcement, and the Requesting Party shall reasonably consider any such objections or suggestions that are provided in a timely manner. The principles to be observed in such disclosures shall include accuracy, compliance with applicable Law and regulatory guidance documents, reasonable sensitivity to potential negative reactions of the FDA (and its foreign counterparts) and the need to keep investors informed regarding the Requesting Party's business.

- 8.4 <u>Publications</u>. The Parties agree that decisions regarding the timing and content of Publications shall be subject to the oversight and approval of the JSC and neither Party nor its
- Affiliates shall have the right to make Publications pertaining to any Program Compound(s), Program Product(s) or Program Target(s) except as provided herein. If a Party or its Affiliates desire to make a Publication, such Party must comply with the following procedure:
- 8.4.1 The publishing Party shall provide the JSC and the non-publishing Party with an advance copy of the proposed Publication, and the JSC shall then have [**] prior to submission for any Publication ([**] in the case of an abstract or oral presentation) in which to determine whether the Publication meets the Publication Guidelines and may be published and under what conditions, including (a) delaying sufficiently long to permit the timely preparation and filing of a patent application or (b) specifying changes the JSC reasonably believes are necessary to preserve any Patents or Know-How belonging (whether through ownership or license, including under this Agreement) in whole or in part to the non-publishing Party.
- 8.4.2 In addition, if the non-publishing Party informs the publishing Party that such Publication, in the non-publishing Party's reasonable judgment, discloses any Confidential Information of the non-publishing Party or could be expected to have a material adverse effect on any Know-How which is Confidential Information of the non-publishing Party, such Confidential Information or Know-How shall be deleted from the Publication.
- 8.4.3 Each Party shall have the right to present its Publications approved pursuant to this Section 8.4.3 at scientific conferences, including at any conferences in any country in the world, subject to any conditions imposed by the JSC in its approval.
- 8.4.4 Notwithstanding the foregoing, the Parties acknowledge that, to the extent that any Publication relates to Agios Intellectual Property that Agios has licensed from a Third Party, its licensor(s) may have retained the right to publish certain information, and nothing in this Section 8.4.4 is intended to restrict the exercise of such rights; <u>provided that</u>, to the extent that Agios has the right to review and comment on any such publications, Agios shall, to the extent permissible under its agreements with such Third Parties, exercise such rights after consultation with Celgene.
- 8.4.5 Notwithstanding the foregoing, the Parties acknowledge that, to the extent that any Publication relates to Celgene Intellectual Property that Celgene has licensed from a Third Party, its licensor(s) may have retained the right to publish certain information, and nothing in this Section 8.4.5 is intended to restrict the exercise of such rights; <u>provided that</u>, to the extent that Celgene has the right to review and comment on any such publications, Celgene shall, to the extent permissible under its agreements with such Third Parties, exercise such rights after consultation with Agios.
- 8.4.6 For purposes of convenience, the JSC may delegate its responsibilities under this Section 8.4.6 to one or more representatives of Agios and Celgene.

8.5 <u>Term.</u> All obligations under Sections 8.1, 8.2, 8.3 and 8.6 shall survive termination or expiration of this Agreement and shall expire [**] following termination or expiration of this Agreement.

8.6 Return of Confidential Information.

- 8.6.1 Upon the expiration or termination of this Agreement, the Receiving Party shall return to the Disclosing Party all Confidential Information received by the Receiving Party from the Disclosing Party (and all copies and reproductions thereof). In addition, the Receiving Party shall destroy:
- (a) any notes, reports or other documents prepared by the Receiving Party which contain Confidential Information of the Disclosing Party; and
- (b) any Confidential Information of the Disclosing Party (and all copies and reproductions thereof) which is in electronic form or cannot otherwise be returned to the Disclosing Party.
- 8.6.2 Alternatively, upon written request of the Disclosing Party, the Receiving Party shall destroy all Confidential Information received by the Receiving Party from the Disclosing Party (and all copies and reproductions thereof) and any notes, reports or other documents prepared by the Receiving Party which contain Confidential Information of the Disclosing Party. Any requested destruction of Confidential Information shall be certified in writing to the Disclosing Party by an authorized officer of the Receiving Party supervising such destruction.
- 8.6.3 Nothing in this Section 8.6 shall require the alteration, modification, deletion or destruction of archival tapes or other electronic back-up media made in the ordinary course of business; <u>provided that</u> the Receiving Party shall continue to be bound by its obligations of confidentiality and other obligations under this ARTICLE VIII with respect to any Confidential Information contained in such archival tapes or other electronic back-up media.

8.6.4 Notwithstanding the foregoing,

- (a) the Receiving Party's legal counsel may retain one copy of the Disclosing Party's Confidential Information solely for the purpose of determining the Receiving Party's continuing obligations under this ARTICLE VIII; and
- (b) the Receiving Party may retain the Disclosing Party's Confidential Information and its own notes, reports and other documents;
- (i) to the extent reasonably required (A) to exercise the rights and licenses of the Receiving Party expressly surviving expiration or termination of this Agreement; or (B) to perform the obligations of the Receiving Party expressly surviving expiration or termination of this Agreement; or
 - (ii) to the extent it is impracticable to do so without incurring disproportionate cost.

Notwithstanding the return or destruction of the Disclosing Party's Confidential Information, the Receiving Party shall continue to be bound by its obligations of confidentiality and other obligations under this ARTICLE VIII.

ARTICLE IX REPRESENTATIONS AND WARRANTIES

- 9 . 1 <u>Mutual Representations</u>. Agios and Celgene each represents, warrants and covenants to the other Party, as of the Effective Date, that:
- 9.1.1 <u>Authority</u>. It is duly organized, validly existing and in good standing under the Laws of the jurisdiction of its formation and has full corporate power and authority to enter into this Agreement or any applicable Development & Commercialization Agreement, and to carry out the provisions hereof or thereof, as applicable.
- 9.1.2 <u>Consents</u>. All necessary consents, approvals and authorizations of all government authorities and other Persons required to be obtained by it as of the Effective Date in connection with the execution, delivery and performance of this Agreement or any applicable Development & Commercialization Agreement, and the performance of its obligations hereunder or thereunder, as applicable, have been obtained.
- 9.1.3 No Conflict. Notwithstanding anything to the contrary in this Agreement, the execution and delivery of this Agreement, the performance of such Party's obligations in the conduct of the Collaboration and the licenses and sublicenses to be granted pursuant to this Agreement (a) do not and will not conflict with or violate any requirement of applicable Laws existing as of the Effective Date and (b) do not and will not conflict with, violate, breach or constitute a default under any agreement or any provision thereof, or any contract, oral or written, to which it is a party or by which it or any of its Affiliates is bound, existing as of the Effective Date.
- 9.1.4 <u>Enforceability</u>. This Agreement has been duly executed and delivered on behalf of each Party and is a legal and valid obligation binding upon it and is enforceable in accordance with its terms.
- 9.1.5 <u>Employee Obligations</u>. To its knowledge, none of its or its Affiliates' employees who have been, are or will be involved in the Collaboration are, as a result of the nature of such Collaboration to be conducted by the Parties, in violation of any covenant in any contract with a Third Party relating to non-disclosure of proprietary information, noncompetition or non-solicitation.
- 9.2 <u>Additional Agios Representations</u>. Agios represents, warrants and covenants to Celgene, as of the Effective Date, as follows:

- 9.2.1 Agios possesses sufficient rights, authorizations and consents necessary to grant all rights and licenses it purports to grant to Celgene with respect to the Agios Intellectual Property under this Agreement.
- 9.2.2 Agios has not used, and during the Term will not knowingly use, any Know-How in a Program conducted by Agios that is encumbered by any contractual right of or obligation to a Third Party that conflicts or interferes with any of the rights or licenses granted or to be granted to Celgene hereunder or under any Development & Commercialization Agreement.
- 9.2.3 Agios has not granted, and during the Term Agios will not grant, any right or license, to any Third Party relating to any of the intellectual property rights it Controls, that conflicts with or limits the scope of the rights or licenses granted or to be granted to Celgene hereunder or under any Development & Commercialization Agreement.
- 9.2.4 There are no claims, litigations, suits, actions, disputes, arbitrations, or legal, administrative or other proceedings or governmental investigations pending or, to Agios' knowledge, threatened against Agios, nor is Agios a party to any judgment or settlement, which would be reasonably expected to adversely affect or restrict the ability of Agios to consummate the transactions contemplated under this Agreement and to perform its obligations under this Agreement, or which would affect the Agios Intellectual Property, or Agios' Control thereof, or any Program Target or Program Compound.
- 9.2.5 To Agios' knowledge, the practice of the Agios Intellectual Property as contemplated under this Agreement does not (a) infringe any claims of any Patents of any Third Party or (b) misappropriate any Know-How of any Third Party.
- 9.2.6 None of (a) the Agios Patents owned by Agios or both Controlled by and Prosecuted by Agios and (b) to Agios' knowledge, the Agios Patents Controlled but not Prosecuted by Agios are subject to any pending re-examination, opposition, interference or litigation proceedings.
- 9.2.7 There is no agreement with any Third Party to which Agios or any of its Affiliates is a party pursuant to which Agios Controls any Agios Patent that is necessary or, to Agios' reasonable belief as of the Effective Date, reasonably useful to Develop, Manufacture or Commercialize any Program Compounds.
- 9.2.8 Neither Agios nor any of its Affiliates has granted any liens or security interests on the Agios Intellectual Property and the Agios Intellectual Property is free and clear of any mortgage, pledge, claim, security interest, covenant, easement, encumbrance, lien or charge of any kind, except in each case with respect to licenses, covenants not to sue, immunities from suit, standstills, releases and options which would not, in the aggregate, fundamentally frustrate the purposes of the Collaboration.
- 9.2.9 Schedule 9.2.9 contains a complete and accurate list of all Patents owned by Agios and/or its Affiliates as of the Effective Date that are included in the Patents licensed hereunder, indicating any co-owner(s), if applicable. Except as set forth on Schedule 9.2.9, Agios and its Affiliates do not own any Patent that is necessary or, to Agios' reasonable belief as of the Effective Date, reasonably useful to research, Develop, Manufacture or Commercialize any Program Compounds.

9.2.10 Agios and its Affiliates are not subject to any payment obligations to Third Parties as a result of the execution or performance of this Agreement.

9.3 Covenants.

- 9.3.1 <u>Mutual Covenants</u>. Each Party hereby covenants to the other Party that:
- (a) all employees of such Party or its Affiliates or Third Party subcontractors working under this Agreement, or any Development & Commercialization Agreement, as applicable, will be under appropriate confidentiality provisions at least as protective as those contained in this Agreement, or any Development & Commercialization Agreement, as applicable, and, to the extent permitted under applicable Law, the obligation to assign all right, title and interest in and to their inventions and discoveries, whether or not patentable, to such Party as the sole owner thereof;
- (b) to its knowledge, such Party will not (i) employ or use, nor hire or use any contractor or consultant that employs or uses, any individual or entity, including a clinical investigator, institution or institutional review board, debarred or disqualified by the FDA (or subject to a similar sanction by any Regulatory Authority outside the United States) or (ii) employ any individual who or entity that is the subject of an FDA debarment investigation or proceeding (or similar proceeding by any Regulatory Authority outside the United States), in each of subclauses (i) and (ii) in the conduct of its activities under this Agreement and any Development & Commercialization Agreement, as applicable;
- (c) neither such Party nor any of its Affiliates shall, during the Term, grant any right or license to any Third Party relating to any of the intellectual property rights it owns or Controls which would conflict with any of the rights or licenses granted to the other Party hereunder or under any Development & Commercialization Agreement; and
- (d) such Party and its Affiliates shall perform its activities pursuant to this Agreement and any Development & Commercialization Agreement, as applicable, in compliance (and shall ensure compliance by any of its subcontractors) in all material respects with all applicable Laws, including GCP, GLP and GMP as applicable and with respect to the research, Development, Manufacturing and Commercialization activities hereunder.

(e)

- (i) The Parties shall, within [**] after the Effective Date, [**]; and
- (ii) The Parties agree and acknowledge that (A) <u>Appendices A-1</u> and <u>A-2</u> shall supersede <u>Appendix A</u> for all purposes of this Agreement, and (B) as applicable, references to <u>Appendix A</u> or the "Co-Development and Co-Commercialization Agreement" in the other provisions of this Agreement shall be

deemed replaced with references to the [**] (each, a "<u>Co-Co Agreement</u>") shall be [**]. For the avoidance of doubt, the revision contemplated in this Section 9.3.1(e) shall include any necessary or incidental changes to Exhibits thereof. Neither Party shall take any position or cause their Affiliates to take any position inconsistent with this Section 9.3.1(e) for tax purposes (including with respect to filing U.S. federal income tax returns and in the course of any audit, review or litigation), unless otherwise required by applicable Law.

- (iii) The Parties agree and acknowledge that, notwithstanding any other provision in this Agreement or the Co-Co Agreements, (A) [**], and (B) [**]; and
- (iv) The Parties agree and acknowledge that (A) the terms of this Agreement with respect to the Term and (B) the terms of the form of License Agreement attached hereto as <u>Appendix B</u> [**]. Neither Party shall [**], unless otherwise required by applicable Law.
- 9.3.2 Agios Covenants During Option Term. Except to the extent expressly permitted under ARTICLE V, on a Program-by-Program basis, during the Option Term, neither Agios nor its Affiliates will, other than to an Affiliate of Agios who agrees in writing to be bound by the terms and conditions of this Agreement (a) assign, transfer, convey, encumber (including any liens or charges, but excluding any licenses, which are the subject of subsection (b), below) or dispose of, or enter into any agreement with any Third Party to assign, transfer, convey, encumber (including any liens or charges, but excluding any licenses, which are the subject of subsection (b), below) or dispose of, any assets specifically related to such Program, including with respect to the applicable Program Compound(s), Program Product(s) and then-identified Companion Diagnostic(s), or pre-clinical study or Clinical Trial results or other data specifically related to such Program, or any intellectual property specifically related to any of the foregoing (with respect to each Program, the "Agios Program Assets"), except to the extent such assignment, transfer, conveyance, encumbrance or disposition would not fundamentally frustrate the purpose of this Agreement or any applicable Development & Commercialization Agreement with respect to such Program, (b) license or grant to any Third Party, or agree to license or grant to any Third Party, any rights to any Agios Program Assets if such license or grant would fundamentally frustrate the purpose of this Agreement or any applicable Development & Commercialization Agreement with respect to such Program, or (c) disclose any Confidential Information relating to the Agios Program Assets to any Third Party if such disclosure would fundamentally frustrate the purpose of this Agreement with respect to such Program. Agios and/or its Affiliates shall have the right to assign, transfer, convey or dispose of any assets specifically related to such Program to any Affiliate of Agios, to the extent permitted by Section 12.4.
- 9 . 4 <u>Disclaimer</u>. Except as otherwise expressly set forth in this Agreement or any executed Development & Commercialization Agreement, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY THAT ANY PATENTS ARE VALID OR ENFORCEABLE, AND EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A

PARTICULAR PURPOSE AND NONINFRINGEMENT. Without limiting the generality of the foregoing, each Party disclaims any warranties with regards to: (a) the success of any study or test, including any Program, commenced under this Agreement; (b) the safety or usefulness for any purpose of the technology or materials, including any Program Compound, Program Product or Companion Diagnostic, it provides or discovers under this Agreement; or (c) the validity, enforceability, or non-infringement of any intellectual property rights or technology it provides or licenses to the other Party under this Agreement.

ARTICLE X INDEMNIFICATION; INSURANCE

10.1 By Celgene.

- 10.1.1 Celgene agrees, at Celgene's cost and expense, to defend, indemnify and hold harmless Agios and its Affiliates and their respective directors, officers, employees and agents (the "Agios Indemnified Parties") from and against any Damages arising out of any Claim relating to:
- (a) any breach by Celgene of any of its representations, warranties or obligations pursuant to this Agreement; or
 - (b) the gross negligence or willful misconduct of Celgene.
- 10.1.2 In the event of any such Claim against the Agios Indemnified Parties by any Third Party, Agios shall promptly, and in any event within [**], notify Celgene in writing of the Claim. Celgene shall have the right, exercisable by notice to Agios within [**] after receipt of notice from Agios of the Claim, to assume direction and control of the defense, litigation, settlement, appeal or other disposition of the Claim (provided that such Claim is solely for monetary damages and Celgene agrees to pay all Damages relating to such matter, as evidenced in a written confirmation delivered by Celgene to Agios) with counsel selected by Celgene and reasonably acceptable to Agios; provided that the failure to provide timely notice of a Claim shall not limit an Agios Indemnified Party's right for indemnification hereunder except to the extent such failure results in actual prejudice to Celgene. The Agios Indemnified Parties shall cooperate with Celgene and may, at their option and expense, be separately represented in any such action or proceeding. Celgene shall not be liable for any litigation costs or expenses incurred by the Agios Indemnified Parties without Celgene's prior written authorization. In addition, Celgene shall not be responsible for the indemnification or defense of any Agios Indemnified Party to the extent arising from any negligent or intentional acts by any Agios Indemnified Party or the breach by Agios of any representation, obligation or warranty under this Agreement, or any Claims compromised or settled without its prior written consent. Each Party shall use reasonable efforts to mitigate Damages indemnified under this Section 10.1.

10.2 By Agios.

10.2.1 Agios agrees, at Agios' cost and expense, to defend, indemnify and hold harmless Celgene and its Affiliates and their respective directors, officers, employees and agents (the "Celgene Indemnified Parties") from and against any Damages arising out of any Claim relating to:

- (a) any breach by Agios of any of its representations, warranties or obligations pursuant to this Agreement;
- (b) the gross negligence or willful misconduct of Agios; or
- (c) the Development, Manufacture, Commercialization, use, sale or other disposition by Agios, its Affiliates, licensees (other than Celgene) or sublicensees of any Program Compound(s) or Program Product(s) that have reverted to Agios pursuant to this Agreement.
- 10.2.2 In the event of any such Claim against the Celgene Indemnified Parties by any Third Party, Celgene shall promptly, and in any event within [**], notify Agios in writing of the Claim. Agios shall have the right, exercisable by notice to Celgene within [**] after receipt of notice from Celgene of the Claim, to assume direction and control of the defense, litigation, settlement, appeal or other disposition of the Claim (provided that such Claim is solely for monetary damages and Agios agrees to pay all Damages relating to such matter, as evidenced in a written confirmation delivered by Agios to Celgene) with counsel selected by Agios and reasonably acceptable to Celgene; provided that the failure to provide timely notice of a Claim shall not limit a Celgene Indemnified Party's right for indemnification hereunder except to the extent such failure results in actual prejudice to Agios. The Celgene Indemnified Parties shall cooperate with Agios and may, at their option and expense, be separately represented in any such action or proceeding. Agios shall not be liable for any litigation costs or expenses incurred by the Celgene Indemnified Parties without Agios' prior written authorization. In addition, Agios shall not be responsible for the indemnification or defense of any Celgene Indemnified Party to the extent arising from any negligent or intentional acts by any Celgene Indemnified Party or the breach by Celgene of any representation, obligation or warranty under this Agreement, or any Claims compromised or settled without its prior written consent. Each Party shall use reasonable efforts to mitigate Damages indemnified under this Section 10.2.
- 10.3 <u>Indemnification Following Exercise of an Option</u>. The Development & Commercialization Agreements provide separately for each Party's indemnification obligations with respect to each Program Compound and Program Product that is the subject of such agreement.
- 10.4 <u>Joint Defendants</u>. If any suit is brought against either Party relating in any way to any Program Compound(s) or Program Product(s), 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 10.1 or 10.2 above, then Agios shall be responsible for controlling the defense of such suit in the first instance. During such period that Agios is controlling such defense, with regard to the costs of such defense, including attorneys' fees, Celgene and Agios each shall be responsible for fifty percent (50%) 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 Celgene, 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 10.1 or 10.2, then the indemnification provisions of either Section 10.1 or 10.2, whichever is applicable, shall become applicable and govern further proceedings in the suit, and the Party determined to be responsible shall reimburse the other Party for all prior costs incurred by such other Party for which indemnification should have been obtained in accordance with Section 10.1 or 10.2.

- 10.5 <u>Limitation of Liability</u>. EXCEPT WITH RESPECT TO A BREACH OF ARTICLE V OR ARTICLE VIII, OR A PARTY'S LIABILITY PURSUANT TO ARTICLE III, SECTION 10.1 OR 10.2, NEITHER PARTY NOR ITS RESPECTIVE AFFILIATES SHALL BE LIABLE FOR SPECIAL, INCIDENTAL, CONSEQUENTIAL, EXEMPLARY, PUNITIVE, MULTIPLE OR OTHER INDIRECT OR REMOTE DAMAGES, OR FOR LOSS OF PROFITS, LOSS OF DATA OR LOSS OF USE DAMAGES ARISING IN ANY WAY OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, WHETHER BASED UPON WARRANTY, CONTRACT, TORT, STRICT LIABILITY OR OTHERWISE, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES OR LOSS.
- 10.6 <u>Insurance</u>. Agios, beginning on [**], and Celgene, beginning upon [**], and, both Parties, thereafter during the Term, shall maintain commercial general liability insurance (including product liability insurance) from a recognized, creditworthy insurance company, with coverage limits of at least \$[**] per claim and annual aggregate. Celgene may elect to self-insure all or parts of the limits described above. Within [**] following written request from the other Party, each Party shall furnish to the other Party a certificate of insurance evidencing such coverage. If such coverage is modified or cancelled, the insured Party shall notify the other Party and promptly provide such other Party with a new certificate of insurance evidencing that such insured Party's coverage meets the requirements of this Section 10.6.

ARTICLE XI TERM AND TERMINATION

- 11.1 <u>Term; Expiration</u>. Unless earlier terminated in accordance with this ARTICLE XI, the term of this Agreement (the "<u>Term</u>") shall commence as of the Effective Date and remain in force until the later of (a) the expiration of the last-to-expire of the following (i) all Option Terms, and (ii) the Research Term; and (b) if one or more Options is exercised, the termination or expiration of the last to expire Development & Commercialization Agreement executed with respect to any Program hereunder.
- 11.2 <u>Termination for Convenience</u>. Celgene may terminate this Agreement in its entirety (provided that there are no Programs that are subject to any surviving Development & Commercialization Agreements) or with respect to one or more Programs (provided that such Program(s) are not subject to any surviving Development & Commercialization Agreements) upon [**] prior written notice to Agios hereunder at any time; <u>provided that</u> Celgene shall not have the right to terminate this Agreement until [**] following the Effective Date (it being understood and agreed that Celgene shall be entitled to terminate upon [**] written notice at any time it reasonably determines that such termination is necessary to comply with any Antitrust Law). For the avoidance of doubt, any such termination of any particular Program(s) pursuant to this Section 11.2 shall not terminate any other Program(s).

11.3 Termination for Breach.

11.3.1 Material Breach. Subject to the other terms of this Agreement, this Agreement and the rights granted herein may be terminated by either Party (a) on a Program-by-Program basis prior to Celgene's exercise of its Option for such Program, for the material breach of this Agreement in a manner that fundamentally frustrates the transactions contemplated by this Agreement taken as a whole (each, a "Material Breach") by the other Party of this Agreement with respect to such Program, or (b) on a Program-by-Program basis after Celgene's exercise of its Option for such Program, if a Development & Commercialization Agreement for such Program is terminated for Material Breach by a Party; provided in each of (a) or (b) that the breaching Party has not cured such breach within [**] after the date of written notice to the breaching Party of such breach (or [**] in the case of a breach as a result of nonpayment of any amounts due under this Agreement or a Development & Commercialization Agreement, as applicable) (the "Cure Period"), which notice shall describe such breach in reasonable detail and shall state the non-breaching Party's intention to terminate this Agreement with respect to a given Program, pursuant to this Section 11.3.1 with respect to such Program. For clarity, but subject to Section 11.3.2, the Cure Period for any allegation made in good faith as to a Material Breach under this Agreement with respect to a given Program for events described in subsections (a) or (b) of this Section 11.3.1 will run from the date that written notice was first provided to the breaching Party by the non-breaching Party. Any such termination of this Agreement with respect to a given Program under this Section 11.3.1 shall become effective at the end of the Cure Period, unless the breaching Party has cured any such breach or default prior to the expiration of such Cure Period, or, if such breach is not susceptible to cure within the Cure Period, then, the nonbreaching Party's right of termination shall be suspended only if and for so long as the breaching Party has provided to the nonbreaching Party a written plan that is reasonably calculated to effect a cure and such plan is acceptable to the non-breaching Party, and the breaching Party commits to and carries out such plan as provided to the non-breaching Party within [**] after the date that written notice was first provided to the breaching Party by the non-breaching Party. For the avoidance of doubt, termination of any particular Program(s) pursuant to this Section 11.3.1 shall not terminate (i) this Agreement with respect to any other Program(s) or (ii) any Development & Commercialization Agreement for any other Program. The Parties understand and agree that the totality of this Agreement with respect to a given Program, and the [**].

11.3.2 <u>Disagreement as to Material Breach</u>. If the Parties reasonably and in good faith disagree as to whether there has been a Material Breach pursuant to either subsections (a) or (b) of Section 11.3.1, then subject to Section 12.1: (a) the Party that disputes that there has been a Material Breach may contest the allegation by referring such matter, within [**] for resolution to the Executive Officers, who shall meet promptly to discuss the matter, and determine, within [**] following referral of such matter, whether or not a Material Breach has occurred pursuant to subsections (a) or (b) of Section 11.3.1, as applicable; (b) the relevant Cure Period with respect thereto will be tolled from the date the breaching Party notifies the non-breaching Party of such dispute and through the resolution of such dispute in accordance with the applicable provisions

of this Agreement (provided that if such dispute relates to payment, the Cure Period will only be tolled with respect to payment of disputed amounts, and not with respect to undisputed amounts), (c) it is understood and agreed that during the pendency of such dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder) and (d) if it is finally and conclusively determined that the breaching Party committed such Material Breach, then the breaching Party shall have the right to cure such Material Breach after such determination within the Cure Period.

- 11.3.3 If the Executive Officers are unable to resolve a dispute within such [**] period after it is referred to them, the matter will be resolved as provided in Section 12.1.
- 11.4 <u>Termination for Insolvency</u>. To the extent permitted by Law, this Agreement may be terminated 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; <u>provided</u>, <u>however</u>, <u>that</u>, 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.

11.5 Effects of Termination.

- 11.5.1 <u>Termination by Agios Pursuant to Section 11.3 or 11.4, or by Celgene pursuant to Section 11.2</u>. In the event of termination of this Agreement in part with respect to any one or more Programs, or in its entirety, as applicable, (i) by Agios pursuant to any of Sections 11.3 or 11.4, or (ii) by Celgene pursuant to Section 11.2, notwithstanding anything contained in this Agreement to the contrary, upon the effective date of such termination:
- (a) subject to Sections 11.5.1(c), 11.5.1(d) and 11.6, all rights (including all Options granted to Celgene hereunder) and licenses granted herein to Celgene by Agios with respect to any such terminated Program shall terminate, Celgene shall cease any and all Development, Manufacture and Commercialization activities under this Agreement (if any) with respect to each terminated Program [**], each such terminated Program shall be dropped from the Collaboration, any and all rights in such terminated Program [**] granted by Agios to Celgene shall revert to Agios, and the provisions of Section 2.12 shall apply with respect to such terminated Program;
- (b) Agios shall have no further obligations to Celgene under this Agreement with respect to any terminated Program, subject to Section 11.6;
- (c) all Development & Commercialization Agreements previously entered into by the Parties for Programs for which Celgene exercised its Option that have not been terminated shall continue in full force, in accordance with the terms and conditions of such Development & Commercialization Agreements;
- (d) each Party shall return or destroy all Confidential Information of the other Party with respect to any terminated Programs [**] being Developed, Manufactured or Commercialized under this Agreement, as required by ARTICLE VIII; and

- (e) Section 11.6 shall apply.
- 11.5.2 <u>Termination by Celgene Pursuant to Section 11.3 or 11.4</u>. In the event of termination of this Agreement with respect to any one or more Programs conducted hereunder or in its entirety by Celgene pursuant to Sections 11.3 or 11.4, notwithstanding anything contained in this Agreement to the contrary, upon the effective date of such termination:
- (a) subject to Sections 11.5.2(c), 11.5.2(e) and 11.6, all rights and licenses granted herein to Agios by Celgene with respect to any such terminated Programs [**] shall terminate;
- (b) subject to Section 11.5.2(d) and 11.6, Agios shall have no further obligations to Celgene under this Agreement with respect to any terminated Program;
- (c) all Development & Commercialization Agreements previously entered into by the Parties for Post-Option Programs that have not been terminated shall continue in full force, in accordance with the terms and conditions of such Development & Commercialization Agreements, as applicable;
- (d) with respect to any terminated Program that is a Research Program, Continuation Program or a Designated Development Program and for which Pre-Exercise Phase I Development has not been completed as of the effective date of termination, Agios shall provide Celgene with as complete an Option Data Package for such Program as is reasonable under the circumstances, and Celgene shall have the right to exercise, within [**] after the Option Data Package Verification Date, an Option with respect to such Program to enter into a Development & Commercialization Agreement for such Program (subject to payment by Celgene of the Option exercise fees set forth in the applicable Development & Commercialization Agreement), [**];
- (e) each Party shall return or destroy all Confidential Information of the other Party with respect to any terminated Programs [**] being Developed, Manufactured or Commercialized under this Agreement, as required by ARTICLE VIII; and
 - (f) Section 11.6 shall apply.

11.6 Surviving Provisions.

11.6.1 <u>Accrued Liabilities</u>. Except as otherwise specifically provided herein, termination of this Agreement shall not relieve the Parties of any liability or obligation which accrued hereunder prior to the effective date of such termination, nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement nor prejudice either Party's right to obtain performance of any obligation. In addition, termination of this Agreement shall not terminate provisions which provide by their respective terms for obligations or undertakings following the expiration of the term of this Agreement.

- 11.6.2 <u>Survival</u>. The rights and obligations of the Parties set forth in the following Sections and Articles shall survive the expiration or termination of this Agreement, in addition to those other terms and conditions that are expressly stated to survive termination or expiration of this Agreement (or by their context are intended to survive): Sections 2.12, 3.1.3, 7.1, 8.5, 8.6, 10.1, 10.2, 10.4, 10.5, 11.5, 11.6, 12.2 and 12.3.
- 11.6.3 <u>Equitable Relief</u>. Termination of this Agreement shall be in addition to, and shall not prejudice, the Parties' remedies at law or in equity, including the Parties' ability to receive Damages and/or equitable relief with respect to any breach of this Agreement, regardless of whether or not such breach was the reason for the termination.
- 11.6.4 <u>Relationship to Other Agreements</u>. Termination of this Agreement with respect to a Program shall not affect in any way the terms or provisions of any then-existing executed Development & Commercialization Agreement for any other Program.

ARTICLE XII MISCELLANEOUS

- 12.1 <u>Dispute Resolution</u>. Except for any disagreements that are within the authority of the JSC as provided in ARTICLE IV (which disagreements shall be resolved in accordance with Sections 4.10.1 and 4.10.2), the Parties agree that any disputes arising with respect to the interpretation, enforcement, termination or invalidity of this Agreement (each, a "<u>Dispute</u>") shall first be presented to the Parties' respective Executive Officers for resolution. If the Parties are unable to resolve a given dispute pursuant to this Section 12.1 after discussions between the Executive Officers within [**] after referring such dispute to the Executive Officers, either Party may, at its sole discretion, seek resolution of such matter in accordance with Section 12.2.
- 1 2 . 2 <u>Submission to Court for Resolution</u>. Subject to Section 12.1, the Parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction of the courts located in the Southern District of New York for any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement, and agree not to commence any action, suit or proceeding (other than appeals therefrom) related thereto except in such courts. The Parties further hereby irrevocably and unconditionally waive any objection to the laying of venue of any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement in the courts of New York, and hereby further irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum. Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in Section 12.6 shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any such court.
- 12.3 <u>Governing Law</u>. This Agreement and all questions regarding its validity or interpretation, or the performance or breach of this Agreement, shall be governed by and construed and enforced in accordance with the laws of the State of New York, without reference to conflicts of laws principles.
 - 12.4 Assignment.

- 12.4.1 <u>Generally</u>. This Agreement may not be assigned by any Party, nor may any Party delegate its obligations or otherwise transfer licenses or other rights created by this Agreement, except as expressly permitted hereunder without the prior written consent of the other Party, which consent will not be unreasonably withheld, delayed or conditioned.
- 12.4.2 <u>Celgene</u>. Notwithstanding the limitations in Section 12.4.1, each of Celgene Corp. and Celgene RIVOT may assign all of its rights and obligations under this Agreement to (a) one or more Affiliates solely as provided in this Section 12.4.2 or (b) its successor in interest in connection with the merger, consolidation, or sale of all or substantially all of its assets or that portion of its business pertaining to the subject matter of this Agreement.
- Agios. Notwithstanding the limitations in Section 12.4.1, Agios may assign this Agreement, or all of its rights or obligations hereunder, to (a) one or more Affiliates solely as provided in this Section 12.4.3 or (b) its successor in connection with the merger, consolidation, or sale of all or substantially all of its assets or that portion of its business pertaining to the subject matter of this Agreement; provided, however, that, except in the case where [**], (a) Agios provides Celgene with at least [**] advance written notice of any such assignment(s), (ii) prior to such assignment(s), Agios agrees in a written agreement delivered to Celgene (and upon which Celgene may rely) to remain fully liable for the performance of its obligations under this Agreement by its assignee(s), and (iii) prior to such assignment(s), the assignee(s) agree in a written agreement delivered to Celgene (and upon which Celgene may rely) to assume performance of all such assigned obligations, (iv) in the case of any assignment(s) by Agios, all Agios Intellectual Property and Joint Collaboration IP which Agios Controls, and all Program Assets for each Program will be transferred to such assignee(s) effective as of such assignment(s), and (v) all of the matters referred to in clauses (i), (ii), (iii) and (iv), as applicable, will be set forth in documentation [**] prior to any such assignment(s) ([**]) and in all cases will provide [**]. Subject to the terms of this Section 12.4.3, if Agios wishes to assign any [**], it will be permitted to do so conditioned on [**], pursuant to which such [**].
- 12.4.4 <u>Change of Control</u>. Notwithstanding anything to the contrary in this Agreement, with respect to any intellectual property rights controlled by the acquiring party or its Affiliates (if other than one of the Parties to this Agreement or any Affiliate of a Party immediately before such Change of Control) involved in any Change of Control of either Party, such intellectual property rights [**], or to the extent such technology is developed outside the scope of activities conducted with respect to the Collaboration, any Program, any Program Compounds or Program Products, or any related Companion Diagnostics. The Agios Intellectual Property and the Celgene Intellectual Property shall [**].
- 12.4.5 <u>All Other Assignments Null and Void</u>. The terms of this Agreement will be binding upon and will inure to the benefit of the successors, heirs, administrators and permitted assigns of the Parties. In the event of any assignment by a Party of its rights and obligations under this Agreement, such Party shall remain primarily liable to the other Party for the performance thereof. Any purported assignment in violation of this Section 12.4 will be null and void *ab initio*.

- 12.5 Force Majeure. If the performance of any part of this Agreement by a Party is prevented, restricted, interfered with or delayed by an occurrence beyond the control of such Party (and which did not occur as a result of such Party's financial condition, negligence or fault), including fire, earthquake, flood, embargo, power shortage or failure, acts of war or terrorism, insurrection, riot, lockout or other labor disturbance, governmental acts or orders or restrictions, acts of God (for the purposes of this Agreement, a "force" majeure event"), such Party shall, upon giving written notice to the other Party, be excused from such performance to the extent of such prevention, restriction, interference or delay; provided that the affected Party shall use its Commercially Reasonable Efforts to avoid or remove such causes of non-performance and shall continue performance with the utmost dispatch whenever such causes are removed.
- 12.6 Notices. Unless otherwise agreed by the Parties or specified in this Agreement, all notices required or permitted to be given under this Agreement shall be in writing and shall be sufficient if: (a) personally delivered; (b) sent by registered or certified mail (return receipt requested and postage prepaid); (c) sent by express courier service providing evidence of receipt and postage prepaid where applicable; or (d) sent by facsimile transmission (receipt verified and a copy promptly sent by another permissible method of providing notice described in clauses (a), (b) or (c) above), to address for a Party set forth below, or such other address for a Party as may be specified in writing by like notice:

To Agios:

Agios Pharmaceuticals, Inc. 88 Sidney Street Cambridge, MA 02139 Attention: Chief Executive Officer

Telephone: 617-649-8600

Facsimile: [**]

With a copy to:

Agios Pharmaceuticals, Inc. 88 Sidney Street Cambridge, MA 02139 Attention: Legal Department Telephone: (617) 649-8600

Facsimile: [**]

and

WilmerHale 60 State Street Boston, MA 02109

Attention: Steven D. Singer Telephone: (617) 526-6410 Facsimile: (617) 526-5000

To Celgene Corp. or Celgene RIVOT:

Celgene Corporation 86 Morris Avenue Summit, NJ 07901

Attention: Senior Vice President Business

Development

Telephone: (908) 673-9000

Facsimile: [**]

With a copy to:

Celgene Corporation 86 Morris Avenue Summit, NJ 07901

Attention: Legal Department Telephone: (908) 673-9000

Facsimile: [**]

and

Celgene RIVOT Ltd. Aon House 30 Woodbourne Avenue Pembroke HM 08

Bermuda

Phone: 441-296-4803

and

Dechert LLP 1900 K St. NW Washington, DC 20006 Attention: David E. Schulman Telephone: (202) 261-3440

Facsimile: [**]

Any such notices shall be effective upon receipt by the Party to whom it is addressed.

- 12.7 <u>Waiver</u>. Except as otherwise expressly provided in this Agreement, any term of this Agreement may be waived only by a written instrument executed by a duly authorized representative of the Party waiving compliance. The delay or failure of either Party at any time to require performance of any provision of this Agreement shall in no manner affect such Party's rights at a later time to thereafter enforce such provision. No waiver by either Party of any condition or term in any one or more instances shall be construed as a further or continuing waiver of such condition or term or of another condition or term.
- 12.8 Severability. If any provision of this Agreement should be held invalid, illegal or unenforceable in any jurisdiction, the Parties shall negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties and all other provisions of this Agreement shall remain in full force and effect in such jurisdiction and shall be liberally construed in order to carry out the intentions of the Parties hereto as nearly as may be possible. If the Parties cannot agree upon a substitute provision, the invalid, illegal or unenforceable provision of this Agreement shall not affect the validity of this Agreement as a whole, unless the invalid, illegal or unenforceable provision is 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 provision.
- 12.9 Entire Agreement. This Agreement (including the Schedules and Appendices attached hereto, including the form of each Development & Commercialization Agreement) constitutes the entire agreement between the Parties relating to its subject matter, and supersedes all prior and contemporaneous agreements, representations or understandings, either written or oral, between the Parties with respect to such subject matter, including the 2010 Agreement (including Section 3.7 thereof) solely with respect to the [**] Program and the [**] Program. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties relating to the subject matter hereof other than as set forth herein and therein.
- 12.10 <u>Modification</u>. No modification, amendment or addition to this Agreement, or any provision hereof, shall be effective unless reduced to writing and signed by a duly authorized representative of each Party. No provision of this Agreement shall be varied, contradicted or explained by any oral agreement, course of dealing or performance or any other matter not set forth in an agreement in writing and signed by a duly authorized representative of each Party.

- 12.11 <u>Independent Contractors; No Intended Third Party Beneficiaries</u>. Nothing contained in this Agreement is intended or shall be deemed or construed to create any relationship of employer and employee, agent and principal, partnership or joint venture between the Parties. Each Party is an independent contractor. Neither Party shall assume, either directly or indirectly, any liability of or for the other Party. Neither Party shall have any express or implied right or authority to assume or create any obligations on behalf of, or in the name of, the other Party, nor to bind the other Party to any contract, agreement or undertaking with any Third Party. There are no express or implied third party beneficiaries hereunder, except for the indemnitees identified in Sections 10.1 and 10.2.
- 12.12 <u>Interpretation; Construction</u>. The captions to the several Articles and Sections of this Agreement are included only for convenience of reference and shall not in any way affect the construction of, or be taken into consideration in interpreting, this Agreement. In this Agreement, unless the context requires otherwise, (a) the word "including" shall be deemed to be followed by the phrase "without limitation" or like expression, whether or not followed by the same; (b) references to the singular shall include the plural and vice versa; (c) references to masculine, feminine and neuter pronouns and expressions shall be interchangeable; (d) the words "herein" or "hereunder" relate to this Agreement; (e) "or" is disjunctive but not necessarily exclusive; (f) the word "will" shall be construed to have the same meaning and effect as the word "shall"; and (g) all references to "dollars" or "\$" herein shall mean U.S. Dollars. Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provisions.

12.13 Performance by Affiliates.

- 12.13.1 A Party may perform any obligation this Agreement imposes on such Party through any of such Party's Affiliates. To the extent that this Agreement imposes obligations on Affiliates of a Party, such Party agrees to cause its Affiliates to perform such obligations.
- 12.13.2 The Parties hereby acknowledge and agree that (a) Celgene Corp. is the party to this Agreement with respect to all rights and obligations (including payment obligations) under this Agreement in the United States; and (b) Celgene RIVOT is the party to this Agreement with respect to all rights and obligations (including payment obligations and the right to enter into any Development & Commercialization Agreement) under this Agreement outside of the United States.
- 12.14 Counterparts. This Agreement may be executed in two (2) counterparts, each of which shall be deemed an original, and both of which together shall constitute one and the same instrument. Any such counterpart, to the extent delivered by means of a fax machine or by .pdf, .tif, .gif, .jpeg or similar attachment to electronic mail (any such delivery, an "Electronic Delivery") shall be treated in all manner and respects as an original executed counterpart and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person. No Party hereto shall raise the use of Electronic Delivery to deliver a signature or the fact that any signature or agreement or instrument was transmitted or communicated through the use of Electronic Delivery as a claim or defense with respect to the formation of a contract, and each Party forever waives any such claim or defense, except to the extent that such claim or defense relates to lack of authenticity.

- 12.15 <u>Equitable Relief.</u> Notwithstanding anything to the contrary herein, the Parties shall be entitled to seek equitable relief, including injunction and specific performance, as a remedy for any breach of this Agreement. Such remedies shall not be deemed to be the exclusive remedies for a breach of this Agreement but shall be in addition to all other remedies available at law or equity.
- 12.16 <u>Further Assurances</u>. Each Party shall execute, acknowledge and deliver such further instruments, and do all such other acts, as may be necessary or appropriate in order to carry out the expressly stated purposes and the clear intent of this Agreement.

[Signature Page Follows]

IN WITNESS WHEREOF, and intending to be legally bound hereby, the Parties have caused this Master Research and Collaboration Agreement to be executed by their respective duly authorized officers as of the Effective Date.

CELGENE CORPORATION

By: <u>/s/ Mark Alles</u> Name: Mark Alles

Title: Chief Executive Officer

[Signature Page to Master Research and Collaboration Agreement]

IN WITNESS WHEREOF, and intending to be legally bound hereby, the Parties have caused this Master Research and Collaboration Agreement to be executed by their respective duly authorized officers as of the Effective Date.

Solely with respect to the rights and obligations under this Master Research and Collaboration Agreement outside of the United States (subject to Section 12.13):

CELGENE RIVOT LTD.

By: /s/ Kevin Mello

Name: Kevin Mello Title: Director

[Signature Page to Master Research and Collaboration Agreement]

IN WITNESS WHEREOF, and intending to be legally bound hereby, the Parties have caused this Master Research and Collaboration Agreement to be executed by their respective duly authorized officers as of the Effective Date.

AGIOS PHARMACEUTICALS, INC.

By: <u>/s/ David P. Schenkein</u>
Name: David P. Schenkein
Title: President and Chief Executive Officer

[Signature Page to Master Research and Collaboration Agreement]

APPENDIX A

FORM OF CO-DEVELOPMENT AND CO-COMMERCIALIZATION AGREEMENT

A-1

APPENDIX A

FORM OF CO-DEVELOPMENT AND CO-COMMERCIALIZATION AGREEMENT

CO-DEVELOPMENT AND CO-COMMERCIALIZATION AGREEMENT

by and among

AGIOS PHARMACEUTICALS, INC.

and

[AGIOS EX-US]

and

CELGENE CORPORATION

and

CELGENE RIVOT LTD.

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CO-DEVELOPMENT AND CO-COMMERCIALIZATION AGREEMENT

This Co-Development and Co-Commercialization Agreement (this "Agreement") is entered into as of [●] (the "Execution Date"), by and between Agios Pharmaceuticals, Inc., a Delaware corporation ("Agios Pharmaceuticals") and Celgene Corporation, a Delaware corporation ("Celgene Corp."), with respect to all rights and obligations under this Agreement in the United States, and [AGIOS Ex-US ("Agios Ex-US")] and Celgene RIVOT Ltd., a Bermuda company ("Celgene RIVOT"), with respect to all rights and obligations under this Agreement outside of the United States (Agios Pharmaceuticals and [Agios Ex-US], together, "Agios," and Celgene RIVOT and Celgene Corp. together, "Celgene"). Celgene and Agios are each referred to herein by name or as a "Party", or, collectively, as the "Parties".

INTRODUCTION

- 1. Agios and Celgene are parties to the Master Research and Collaboration Agreement, dated as of May 17, 2016 (the "Master Agreement").
- 2. Pursuant to the Master Agreement, Agios has discovered and has been developing the compound(s) identified on <u>Exhibit A</u>, each of which the Parties believe to be a potent [inhibitor/activator] *[select the applicable one before signing]* of the metabolic target identified on <u>Exhibit A</u>.
- 3. The Parties have agreed that the further Development and Commercialization of the Compound(s) should be conducted collaboratively by the Parties pursuant to the terms of this Agreement and that all further such activities related to such Compound(s) should cease under the Master Agreement, except as contemplated herein.

NOW, THEREFORE, in consideration of the respective representations, warranties, covenants and agreements contained herein, and for other valuable consideration, the receipt and adequacy of which are hereby acknowledged, Agios and Celgene hereby agree as follows:

Article I Definitions

When used in this Agreement, each of the following terms shall have the meanings set forth in this Article I. Terms used but not defined herein shall have the meaning set forth in the Master Agreement.

Section 1.1 "Agios Co-Co Collaboration Intellectual Property," "Agios Co-Co Collaboration Know-How" and "Agios Co-Co Collaboration Patents" means, respectively, the Co-Co Collaboration Intellectual Property Controlled by Agios, the Co-Co Collaboration Know-How Controlled by Agios, and the Co-Co Collaboration Patents Controlled by Agios.

Section 1.2 "Agios Intellectual Property" means Agios Know-How and Agios Patents, collectively.

- Section 1.3 "Agios Know-How" means any Know-How that is (a) Controlled by Agios as of the Execution Date or during the Term, and (b) necessary or useful for the Development, Manufacture or Commercialization of the Compounds or Licensed Products, but excluding Co-Co Collaboration Know-How.
- Section 1.4 "<u>Agios Patents</u>" means any Patents that (a) are Controlled by Agios as of the Execution Date or during the Term, and (b) Cover, or are useful for, the Development, Manufacture or Commercialization of the Compounds or Licensed Products (including the composition of matter, manufacture or any use thereof); but excluding Co-Co Collaboration Patents. Agios Patents as of the Execution Date are as set forth on <u>Exhibit B</u> to this Agreement.
- Section 1.5 "Agios Profit or Loss Allocation" means (a) fifty percent (50%) if this Agreement is for a Shared 50/50 Program as indicated in Exhibit A or (b) thirty-five percent (35%) if this Agreement is for a Shared 65/35 Program as indicated in Exhibit A.
- Section 1.6 "<u>Calendar Quarter</u>" means a calendar quarter ending on the last day of March, June, September or December; <u>provided, however, that</u> the first Calendar Quarter shall begin on the Effective Date and end on the last day of the calendar quarter during which the Effective Date occurs.
- Section 1.7 "<u>Calendar Year</u>" means a period of time commencing on January 1 and ending on the following December 31; <u>provided, however, that</u> the first Calendar Year shall begin on the Effective Date and end on December 31 of the calendar year during which the Effective Date occurs.
- Section 1.8 "<u>Celgene Collaboration Intellectual Property</u>" means Celgene Collaboration Know-How and Celgene Collaboration Patents, collectively.
- Section 1.9 "<u>Celgene Collaboration Know-How</u>" means, collectively, (a) Know-How within Celgene Collaboration Intellectual Property (as defined in the Master Agreement) and (b) Co-Co Collaboration Know-How Controlled by Celgene that is necessary or useful for the Development, Manufacture and/or Commercialization of any Compounds or Licensed Products.
- Section 1.10 "Celgene Collaboration Patents" means, collectively, (a) Patents within Celgene Collaboration Intellectual Property (as defined in the Master Agreement) and (b) Co-Co Collaboration Patents Controlled by Celgene that are necessary or useful for the Development, Manufacture and/or Commercialization of any Compounds or Licensed Products. Celgene Collaboration Patents as of the Execution Date are as set forth on Exhibit B to this Agreement.
 - Section 1.11 "Celgene Intellectual Property" means Celgene Know-How and Celgene Patents, collectively.
- Section 1.12 "Celgene Know-How" means any Know-How that is (a) Controlled by Celgene as of the Effective Date or during the Term; (b) necessary or useful for the Development, Manufacture or Commercialization of the Compounds or Licensed Products; and (c) contributed by Celgene, in Celgene's sole discretion, for use in the Collaboration, as evidenced by written notice from Celgene to Agios; but excluding Celgene Collaboration Know-How.

- Section 1.13 "<u>Celgene Patents</u>" means any Patents that (a) are Controlled by Celgene as of the Effective Date or during the Term; (b) Cover the Compounds or Licensed Products; and (c) are contributed by Celgene, in Celgene's sole discretion, for use in the Collaboration, as evidenced by written notice from Celgene to Agios; but excluding Celgene Collaboration Patents. Celgene Patents as of the Execution Date are as set forth on <u>Exhibit B</u> to this Agreement.
- Section 1.14 "<u>Celgene Profit or Loss Allocation</u>" means (a) fifty percent (50%) if this Agreement is for a Shared 50/50 Program as indicated in <u>Exhibit A</u> or (b) sixty-five percent (65%) if this Agreement is for a Shared 65/35 Program as indicated in <u>Exhibit A</u>.
- Section 1.15 "<u>Clinical Trial</u>" means a Phase I Study, a Phase II Study, a Phase III Study, a Pivotal Clinical Trial, a Phase IV Study or a combination of any of the foregoing studies.
 - Section 1.16 "Code" means the United States Internal Revenue Code of 1986, as amended.
- Section 1.17 "<u>Co-Co Collaboration Intellectual Property</u>" means Co-Co Collaboration Know-How and Co-Co Collaboration Patents, collectively.
- Section 1.18 "Co-Co Collaboration Know-How" means any Know-How or interest therein that is developed or generated on or after the Execution Date, either (a) solely by or on behalf of Celgene and/or its Affiliates, (b) solely by or on behalf of Agios and/or its Affiliates or (c) jointly by or on behalf of Persons described in the foregoing clauses (a) and (b), in the conduct of the Collaboration activities pursuant to this Agreement, including Joint Inventions.
- Section 1.19 "<u>Co-Co Collaboration Patents</u>" means any Patents or interest therein that are, on or after the Execution Date, Controlled solely by Celgene or Agios or Controlled jointly by any of such Persons and that Cover Co-Co Collaboration Know-How, including Joint Patents.
- Section 1.20 "<u>Collaboration</u>" means the activities performed or to be performed by a Party or Parties, as the case may be, relating to the Development, Manufacturing and Commercialization of the Licensed Products under this Agreement or the Master Agreement.
- Section 1.21 "<u>Companion Diagnostic</u>" means a biomarker or diagnostic test that is developed by a Party or jointly by the Parties in the course of the Collaboration as a companion diagnostic for use with a Licensed Product in accordance with the Regulatory Approval(s) therefor to generate a result for the purposes of diagnosing a disease or condition, or to facilitate the application of the Licensed Product in the cure, mitigation, treatment, or prevention of disease, including a biomarker or diagnostic test used to diagnose the likelihood that a specific patient will contract a certain disease or condition or to predict which patients are suitable candidates for a specific form of therapy using a Compound or Licensed Product.
- Section 1.22 "<u>Compound</u>" means (a) any compound that is listed on <u>Exhibit A</u> and (b) to the extent Active (as defined in the Master Agreement) against the Target, any salt, fluorinated derivative, free acid, free base, clathrate, solvate, hydrate, hemihydrates, anhydride, ester, chelate, conformer, congener, crystal form, crystal habit, polymorph, amorphous solid, isomer, stereoisomer, enantiomer, racemate, prodrug, isotopic or radiolabeled equivalent, metabolite, conjugate, complex or mixture, of such chemical entity of any such compound identified in the foregoing clause (a) or in this clause (b).

- Section 1.23 "<u>Confidential Information</u>" means (a) all confidential or proprietary information relating to the Collaboration, and (b) all other confidential or proprietary documents, technology, Know-How or other information (whether or not patentable) actually disclosed by one Party to the other pursuant to this Agreement or the Master Agreement[, or, solely with respect to information relating to the [[**] Program/[**] Program], previously disclosed prior to the Execution Date,] [bracketed clause to be included if relevant] relating to the Licensed Products and all proprietary biological materials of a Party.
- Section 1.24 "<u>Data</u>" means any and all research data, results, pharmacology data, medicinal chemistry data, preclinical data, market research, clinical data (including investigator reports (both preliminary and final), statistical analysis, expert opinions and reports, safety and other electronic databases), in any and all forms, including files, reports, raw data, source data (including patient medical records and original patient report forms, but excluding patient-specific data to the extent required by applicable Laws) and the like, in each case directed to, or used in, the Development, Manufacture or Commercialization of the Licensed Products.
- Section 1.25 "<u>Development Plan</u>" means a development plan and the related Development Budget approved by the JSC, as amended from time to time pursuant to Section 3.1(a).
- Section 1.26 "<u>Effective Date</u>" means the date on or after the Execution Date that is the Implementation Date (as defined in the Master Agreement) with respect to this Agreement.
- Section 1.27 "Executive Officers" means Celgene's Chief Executive Officer (or the officer or employee of Celgene then serving in a substantially equivalent capacity) or his designee and Agios' Chief Executive Officer (or the officer or employee of Agios then serving in a substantially equivalent capacity) or his designee; <u>provided that</u> any such designee must have decision-making authority on behalf of the applicable Party.
 - Section 1.28 "Existing Third Party Agreement" means any agreement listed on Exhibit C to this Agreement.
 - Section 1.29 "Field" means the treatment, control, mitigation, prevention or cure or diagnosis of any Indications.
- Section 1.30 "<u>First Commercial Sale</u>" means the first commercial sale of a Licensed Product by a Party, its Affiliates, distributors or agents in a country in an arms' length transaction to a Third Party following receipt of applicable Regulatory Approval of such product in such country. Sales for test marketing or clinical trial purposes shall not constitute a First Commercial Sale.

Section 1.31 "[**]" means [**].

Section 1.32 "<u>Generic Competition</u>" means, with respect to a Licensed Product in a given country in a given Calendar Year, that, during such Calendar Year one or more Generic Products shall be commercially available in such country.

Section 1.33 "Generic Product" means, as to a Licensed Product, any product (including a "generic product" approved by way of an Abbreviated New Drug Application by the FDA (or equivalent regulatory mechanism for another Regulatory Authority), "biogeneric," "follow-on biologic," "follow-on biological product," "follow-on protein product," "similar biological medicinal product," or "biosimilar product") that, in each case, (a) is sold by a Third Party that is not a sublicensee of the royalty-paying Party or any of its Affiliates and that has not otherwise been authorized by the royalty-paying Party or any of its Affiliates under a Regulatory Approval granted by a Regulatory Authority to such Third Party that is based upon or relies upon the Regulatory Approval granted by such Regulatory Authority for such Licensed Product; and (b) in the United States, is "therapeutically equivalent," "comparable," "biosimilar," or "interchangeable," as evaluated by the FDA, applying the definition of "therapeutically equivalent" set forth in the preface to the then-current edition of the FDA publication "Approved Drug Products With Therapeutic Equivalence Evaluations" or any other definitions set forth in the US Code, FDA regulations, or other source of US Law and, outside the United States, meets such equivalent determination by the applicable Regulatory Authorities (including a determination that the product is "comparable," "interchangeable," "bioequivalent," or "biosimilar" with respect to the Licensed Product), in each case, as is necessary to permit a pharmacist or other individual authorized to dispense pharmaceuticals under Law to substitute one product for another product in the absence of specific instruction from a physician or other authorized prescriber under Law.

Section 1.34 "[**]" means [**].

Section 1.35 "Joint Collaboration IP" means, collectively:

"Joint Collaboration Know-How" which means all Know-How, including physical embodiments of Compound(s), Licensed Product(s) and Companion Diagnostic(s), that is discovered, generated or invented by or on behalf of both Parties or their respective Affiliates, whether solely or jointly with any Third Party, pursuant to the conduct of activities under the Collaboration at any time during the Term, including Joint Inventions; and

"Joint Collaboration Patents" which means Patents that Cover any Joint Collaboration Know-How, including Joint Patents.

Section 1.36 "<u>Lead Party</u>" means, with respect to the US Territory, the Lead US Party, and, with respect to the ROW Territory, Celgene. Notwithstanding the foregoing, Celgene shall be the Lead Party for the entire Territory from and after the Agios Opt-Out Date, if any.

Section 1.37 "<u>Lead US Party</u>" means (a) Celgene, if this Agreement is for a Shared 65/35 Program, as indicated on <u>Exhibit A</u>, or (b) the Party designated as the Lead US Party in <u>Exhibit A</u> if this Agreement is for a Shared 50/50 Program, as indicated on Exhibit A.

Section 1.38 "<u>Licensed Product Data</u>" means all relevant data included in the Know-How Controlled by either Party or its Affiliates in relation to Licensed Products and/or Companion Diagnostics for use in the Field either: (a) as of the Effective Date; or (b) generated from activities conducted by or on behalf of a Party under the Development Plan or that otherwise specifically relates to Licensed Products and/or Companion Diagnostics and in each case is necessary or useful for applications for Regulatory Approval, or Regulatory Approvals, for Licensed Products in the Field and in the Territory.

Section 1.39 "<u>Licensed Products</u>" means (a) a Compound, and (b) any product that contains a Compound as an active ingredient.

Section 1.40 "<u>Licensee Partner</u>" means any Third Party to whom a Party or any of its Affiliates or any other Licensee Partner grants a sublicense or license with respect to the Development, Manufacture or Commercialization of Licensed Products in the Field under the rights to Agios Intellectual Property, Celgene Intellectual Property, Celgene Collaboration Intellectual Property, Agios Co-Co Collaboration Intellectual Property or Joint Collaboration IP, as the case may be, granted to such Party or Affiliate hereunder, in each case excluding (a) Third Party Contractors and (b) wholesale distributors or any other Third Party that purchases Licensed Product in an arm's-length transaction, where such Third Party does not have a sublicense to Develop, Manufacture or Commercialize the Licensed Product except for a limited sublicense to the extent required to enable such Third Party to perform final packaging for such Licensed Product for local distribution.

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Section 1.41 "Major [**]" means [**].
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Section 1.42 "Major Market" means [**].

Section 1.43 "<u>Manufacturing Technology</u>" means copies of all Celgene Know-How, Agios Know-How, Celgene Collaboration Know-How, Agios Co-Co Collaboration Know-How or Joint Collaboration Know-How, as applicable, which are necessary or useful for Manufacturing preclinical, clinical or commercial supply, as applicable, of the Licensed Products, including specifications, assays, batch records, quality control data, and transportation and storage requirements.

Section 1.44 "<u>NDA</u>" means an application submitted to a Regulatory Authority for the marketing approval of a Licensed Product, including (a) a New Drug Application, Product License Application or Biologics License Application (as such capitalized terms are used in C.F.R Title 21) filed with FDA or any successor applications or procedures, (b) a foreign equivalent of a US New Drug Application, Product License Application or Biologics License Application or any successor applications or procedures, including a Marketing Authorization Application in the European Union, and (c) all supplements and amendments that may be filed with respect to the foregoing.

Section 1.45 "Non-Supplying Party" means with respect to Agios Clinical-Scale Manufacturing Responsibilities, Agios Commercial-Scale Manufacturing Responsibilities, Celgene Clinical-Scale Manufacturing Responsibilities and Celgene Commercial-Scale Manufacturing Responsibilities, the Party other than the Responsible Supply Party.

- Section 1.46 "Phase IV Study" means a human clinical trial of a product which is (a) conducted to satisfy a requirement of a Regulatory Authority in order to maintain a Regulatory Approval or (b) conducted voluntarily after Regulatory Approval of the product has been obtained from an appropriate Regulatory Authority for enhancing marketing or scientific knowledge of an approved Indication.
- Section 1.47 "<u>Profit or Loss Allocation</u>" means the Agios Profit or Loss Allocation or the Celgene Profit or Loss Allocation, as applicable.
- Section 1.48 "Regulatory Documentation" means, with respect to the Collaboration, all INDs, NDAs and other regulatory applications submitted to any Regulatory Authority, Regulatory Approvals, pre-clinical and clinical data and information, regulatory materials, drug dossiers, master files (including Drug Master Files, as defined in 21 C.F.R. 314.420 and any non-United States equivalents), and any other data, reports, records, regulatory correspondence and other materials relating to Development or Regulatory Approval of the Licensed Products, or required to Manufacture, distribute or sell the Licensed Products, including any information that relates to pharmacology, toxicology, chemistry, Manufacturing and controls data, batch records, safety and efficacy, and any safety database.
- Section 1.49 "Regulatory Exclusivity" means, with respect to a Licensed Product in a country, that the Licensed Product has been granted marketing exclusivity afforded approved drug products, or approved biological products if applicable, pursuant to (a) Sections 505(c), 505(j), and 505A of the FDCA, and the regulations promulgated thereunder, as amended from time to time, or similar laws enacted to apply to biological products, and the regulations promulgated thereunder, as amended from time to time, or their equivalent in a country other than the United States, (b) the orphan drug exclusivity afforded approved drugs designated for rare diseases or conditions under Sections 526 and 527 of the FDCA, and the regulations promulgated thereunder, as amended from time to time, or its equivalent in a country other than the United States, or (c) any future Law.
- Section 1.50 "<u>Reimbursable Back-up Expenses</u>" means, if, prior to the Execution Date, [**] conduct of specified Development activities with respect to Compound(s) in addition to the initially designated Development Candidate (as defined in the Master Agreement) that are [**]. The amount of the Reimbursable Back-up Expenses, if any, is set forth on Annex I to Exhibit A.
- Section 1.51 "<u>Reimbursable Manufacturing Expenses</u>" means, if, prior to the Execution Date, [**]. The amount of the Reimbursable Manufacturing Expenses, if any, is set forth on Annex I to Exhibit A.
- Section 1.52 "<u>Responsible Supply Party</u>" means Agios, with respect to Agios Clinical-Scale Manufacturing Responsibilities and Agios Commercial-Scale Manufacturing Responsibilities, and Celgene, with respect to Celgene Clinical-Scale Manufacturing Responsibilities.
- Section 1.53 "<u>Right of Reference or Use</u>" means a "Right of Reference or Use" as that term is defined in 21 C.F.R. §314.3(b), and any non-United States equivalents.
 - Section 1.54 "ROW Territory" means all countries in the world other than the US Territory.

- Section 1.55 "Supply Failure" means (a) a failure by the Responsible Supply Party to comply with its obligations to supply relating to, with respect to Agios, Agios Clinical-Scale Manufacturing Responsibilities or Agios Commercial-Scale Manufacturing Responsibilities, and with respect to Celgene, Celgene Clinical-Scale Manufacturing Responsibilities or Celgene Commercial-Scale Manufacturing Responsibilities under the Supply Agreement, including failure to [**], to be defined under the Supply Agreement in terms of [**], on the Non-Supplying Party or its Affiliates or Licensee Partners, and such failure is not cured in all material respects within a commercially reasonable period of time, or (b) insolvency of the Responsible Supply Party; provided that a Supply Failure excludes any event (or anticipated event) to the extent attributable to the [**].
 - Section 1.56 "Target" means the metabolic target set forth on Exhibit A.
 - Section 1.57 "Territory" means the US Territory and the ROW Territory.
- Section 1.58 "<u>Third Party Agreement</u>" means (a) each Existing Third Party Agreement and (b) any other Third Party agreement that either Party may enter into, during the Term in accordance with the terms of this Agreement, to acquire or license Third Party Patents or Know-How that are necessary or useful for the Development, Manufacture or Commercialization of the Compounds or Licensed Products.
- Section 1.59 "<u>Third Party Rights</u>" means, with respect to a Party, any rights of, and any limitations, restrictions or obligations imposed by, Third Parties pursuant to any Third Party Agreements.
 - Section 1.60 "US Territory" means the United States of America, including its territories, possessions and Puerto Rico.
- Section 1.61 "<u>Valid Claim</u>" means (a) a claim of any issued, unexpired patent that has not been revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no appeal can be taken, or with respect to which an appeal is not taken within the time allowed for appeal, and that has not been disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise, or (b) a patent application or subject matter of a claim thereof filed by a Person in good faith that has not been cancelled, withdrawn or abandoned, nor been pending for more than [**] from the earliest filing date to which such patent application or claim is entitled.
- Section 1.62 <u>Additional Definitions</u>. Each of the following definitions is set forth in the section of this Agreement indicated below:

35 U.S.C. § 102(c) Patent
[**]
Accounting Standards
Acquirer Program
Additional Revenue

Section 10.7 Section 8.6(b)(iii) Exhibit D Section 8.6(b)(v)(D) Exhibit D **DEFINITION SECTION**

Additional Study Section 3.3 Additional Study Approval Section 3.3(c) Advertising and Market Research Expenses Exhibit D

Affiliate Master Agreement Preamble Agios

Agios Clinical-Scale Manufacturing Responsibilities Section 4.1(a) Agios Commercial-Scale Manufacturing Responsibilities Section 4.1(a) Agios Indemnified Parties Section 13.1(a) Agios Opt-Out Notice Section 2.3(a) Agios Opt-Out Date Section 2.3(b) Agios Pharmaceuticals Preamble

Agios Program Assets Section 12.4 Preamble Agreement Annual Net Sales Exhibit D

Antitrust Law Master Agreement Audit Team Section 9.8(a) Audit Rights Holder Section 9.8(e)

Auditee Section 9.8(e) Bankruptcy Code Section 8.8

Business Day Master Agreement Preamble Celgene Celgene Corp. Preamble Celgene RIVOT Preamble

Celgene Indemnified Parties Section 13.2(a) Celgene Clinical-Scale Manufacturing Responsibilities Section 4.1(c) Celgene Commercial-Scale Manufacturing Responsibilities Section 4.1(c)

Celgene Manufacturing Responsibilities Section 4.1(c)

Challenge Section 14.3(d) Challenging Party Section 14.3(d) Co-Co Buy-In Section 3.4 **Combination Product** Exhibit D

Commercialization/Commercialize Master Agreement

Exhibit D Commercialization Expenses Commercialization Budget Section 6.2(a)(i) Commercialization Plan Section 6.2(a)(i) Commercially Reasonable Efforts Master Agreement Competitive Infringement Section 10.3(b)

Competitive Program Section 8.6(b)(iv) Competitive Program Party Section 8.6(b)(iv) Control/Controlled Master Agreement Cooperating Party Section 11.3(b)(iii) Cover/Covering/Covered Master Agreement

CPI Exhibit D Cure Period Section 14.3(b)(i)

Damages Master Agreement

Deemed Buy-In Section 3.3(c) Develop/Development Master Agreement Development Budget Section 3.1(a) **Development Costs** Exhibit D **Disclosing Party** Section 11.1 Section 15.1 Dispute **Distribution Costs** Exhibit D **Earlier Patent** Section 10.7 Section 15.16 Electronic Delivery

FDA Master Agreement
FDCA Master Agreement
force majeure event Section 15.7
FTE Exhibit D

Preamble

Execution Date

FTE Exhibit D
FTE Costs Exhibit D
FTE Rate Exhibit D
Global Safety Database Section 5.3
Health Care Reform Fees Exhibit D

IND

[**]

Section 9.9(b)(i)

Indication

Master Agreement Indication **Initial Enforcement Party** Section 10.3(b) **Invalidity Claim** Section 10.4(b) Joint Inventions Section 10.1(c) Joint Patents Section 10.1(c) JPC Designee Section 2.2(e) Know-How Master Agreement Law Master Agreement

Licensed Branding
Licensed Branding
Section 6.4(c)
Licensing Party
Section 8.5(c)
Loss
Exhibit D
Lump Sum
Section 3.3(c)
Manufacture/Manufacturing
Master Agreement

Manufacturing CostsExhibit DManufacturing Scale-Up CostsExhibit DMarketing ActivitiesSection 6.3(a)Marketing ExpensesExhibit DMarketing Management ExpensesExhibit D

Marketing Management ExpensesExhibit DMaster AgreementIntroductionMaterial BreachSection 14.3(b)(i)

Medical Education Expenses Exhibit D

Matchelia Torret

Master A greener

Metabolic Target Master Agreement
Net Sales Exhibit D

Non-Proposing Party

Nongoing Clinical Trial

Section 3.3

Section 3.1(c)

Other Commercialization Costs
Out-of-Pocket Costs

Party or Parties

Patent and Trademark Prosecution and Enforcement Costs

Patent Prosecution Expenses

Patents
Payee Party
Paying Party
Person

Pharmacovigilance Agreement

Phase I Study Phase II Study Phase III Study

Phase IV Study Expenses

Pivotal Clinical Trial

PPACA

Product Liabilities Product Trademarks

Profit

Profit or Loss
Proposing Party
Prosecuting Party
Prosecution/Prosecute

Publication
Pursuing Party
Recall Expenses
Receiving Party
Redacted Version
Regulatory Approval
Regulatory Authority
Regulatory Interactions
Regulatory Expenses

Regulatory Maintenance Costs

Requesting Party Royalty Rate Royalty Term

SEC

Selling Expenses

Sole

Step-In Enforcement Party

Subsequent Third Party Agreement

Supply Agreement Supply Plan Term

Therapeutic Modality

Exhibit D

Exhibit D
Preamble
Exhibit D

Section 10.2(c) Master Agreement

Section 9.9(b)(i) Section 9.9(b)(i) Master Agreement

Section 5.3

Master Agreement Master Agreement Master Agreement

Exhibit D

Master Agreement

Exhibit D
Exhibit D
Section 6.4(a)
Exhibit D
Exhibit D
Exhibit D
Section 3.3
Section 10.2(d)(i)
Master Agreement

Master Agreement
Master Agreement
Section 14.3(d)
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Section 11.1
Section 11.3(b)(i)
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Master Agreement
Master Agreement
Section 5.1(b)
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Exhibit D

Section 11.3(b)(iii) Section 9.5(a) Section 9.5(b) Section 11.3(b)(i) Exhibit D Master Agreement

Section 10.3(d) Section 9.6(b)(ii) Section 4.1(g) Section 4.1(e) Section 14.1 Section 8.6(a)

Third Party Contractors

Third Party Infringement

Section 8.2(a)(ii)

Section 10.3(a)

Third Party Infringement Action

Third Party Patent Costs

Third Party Products Liability Action

Section 13.4(a)

Article II Governance; Collaboration

- Section 2.1 <u>Certain Interactions with and Effects on the Master Agreement</u>. Upon and after the Effective Date, notwithstanding anything to the contrary in the Master Agreement:
- (a) During the Term, the Committees shall remain established as set forth in Article IV of the Master Agreement to perform the functions set forth therein with respect to the Parties' activities under this Agreement.
- (b) Except as otherwise set forth in this Agreement, all activities regarding Development and Manufacturing of a Compound or a Licensed Product shall cease under the Master Agreement and all future such activities shall be conducted solely under this Agreement.
- (c) None of the Parties' activities performed in accordance with this Agreement (including those activities specifically permitted upon and after termination) shall be deemed a violation of Section 5.2 of the Master Agreement.

Section 2.2 <u>Decision Making</u>.

- (a) <u>Committee Voting</u>. All decisions of a Committee with respect to the Parties' activities under this Agreement shall be attempted to be made by unanimous vote, with each Party's representatives collectively having one (1) vote, and each such decision (if made) shall be set forth in minutes approved by both Parties' representatives on the Committee. Upon [**] prior written notice, either Party may convene a special meeting of a Committee for the purpose of resolving any failure to reach agreement on a matter within the scope of the authority and responsibility of such Committee. No Committee shall have the authority to resolve any dispute involving the breach or alleged breach of this Agreement or to amend or modify this Agreement or the Parties' respective rights and obligations hereunder.
- (b) <u>Referrals from JDC or JCC to JSC</u>. If the JDC or JCC is unable to decide, by unanimous vote, on any matter so referred to it for resolution by one or both Parties within [**] after the matter is so referred to it, the chairperson of the JDC or JCC, as applicable, shall refer such matter to the JSC for attempted resolution by unanimous vote.
- (c) <u>Referrals from the JSC to Executive Officers</u>. If the JSC is unable to decide, by unanimous vote, on any such matter referred to it by the JDC or the JCC or on any other matter specified in this Agreement to be decided by the JSC, within [**] after the matter is referred to it or first considered by it, the chairperson of the JSC shall submit such matter for attempted resolution by agreement of the Executive Officers.

- (d) <u>Decision-Making Authority</u>. If the Executive Officers are unable to resolve any matter referred to them by the chairperson of the JSC within [**] after the matter is referred to them, then, subject to Section 2.2(f):
- (i) if the unresolved matter relates to the Development of the Compounds and Licensed Products, [**] during Development and Regulatory Interactions in a geography until Regulatory Approval for such geography: (A) the Lead US Party shall have the right to decide any such unresolved matter that relates solely to the US Territory except for the matters specified in subsection (ii)(B) below, (B) Celgene shall have the right to decide any such unresolved matter that relates solely to the ROW Territory, and (C) if Agios is the Lead US Party and such unresolved matter relates to both the US Territory and the ROW Territory, Agios shall have the right to decide such unresolved matter with respect to the US Territory and Celgene shall have the right to decide such unresolved matter with respect to the ROW Territory; provided that, in each case ((A), (B) and (C)), the resolving Party shall give due consideration to any comments or preferences expressed by the other Party with respect to such matter.
- (ii) if the unresolved matter relates to Manufacturing of the Licensed Products for Commercialization, (A) if the unresolved matter relates to Agios Commercial-Scale Manufacturing Responsibilities, then Agios shall have final decision-making rights with respect to such matter, and (B) if the unresolved matter relates to Celgene Manufacturing Responsibilities, then Celgene shall have final decision-making rights with respect to such matter, <u>provided that</u> such resolving Party shall give due consideration to any comments or preferences expressed by the other Party with respect to such matter; and
- (iii) if the unresolved matter relates to Commercialization of the Licensed Products: (A) subject to Section 6.3(f), the Lead US Party shall have the right to decide the unresolved matter for the US Territory except for the matters specified in subsection (ii)(B) above and (B) Celgene shall have the right to decide the unresolved matter for the ROW Territory; provided that the resolving Party shall give due consideration to any comments or preferences expressed by the other Party with respect to such matter.
- (e) <u>JPC</u>. If the JPC is unable to decide, by unanimous vote, on any matter within [**] after the matter is first raised with the JPC, then the matter will be referred to the [**] of Celgene and the [**] of Agios (each, a "<u>JPC Designee</u>") for resolution. If such matter is not resolved by such JPC Designees of the Parties within [**] after the matter was referred to them, then the applicable Prosecuting Party (as set forth in Article X) may decide the matter. Notwithstanding the foregoing, if at any time the Party who has decision-making rights for such matter under Article X reasonably believes that the delay in decision resulting from such procedure will create a risk that any rights to Know-How or Patents will be lost or otherwise diminished, then such Party may exercise such decision-making rights immediately, <u>provided that</u> such resolving Party shall give due consideration to any comments or preferences expressed by the other Party with respect to such matter.

(f) Exceptions.

(i) This Section 2.2 is subject to the applicable terms and conditions of Article IV of the Master Agreement.

(ii) Notwithstanding anything to the contrary contained herein, the Parties understand and agree that, from and after the date that Agios provides the Agios Opt-Out Notice, the Committees shall no longer have any decision-making authority, but shall continue to function for information sharing purposes.

Section 2.3 Agios Opt-Out.

- (a) Opt-Out Notice. Without it being a breach of Article VII, Agios shall have the right to elect to opt-out of its Development, Manufacturing and Commercialization rights and the sharing of Development Costs and Profit or Loss under this Agreement by written notice to Celgene (such notice, the "Agios Opt-Out Notice"); provided, however, that Agios may not, without consent of Celgene, provide any such notice (x) within [**] after any Regulatory Authority or the other Party has provided to any Committee or Agios any notification [**] with respect to any Licensed Product or (y) within [**] after any Committee or Agios receives [**]. After Agios provides such Agios Opt-Out Notice, Celgene shall have sole discretion with respect to any matters regarding further Development, Manufacturing and Commercialization (including any sales force activities and designation of sales representatives) hereunder, provided that, during the period between such Agios Opt-Out Notice and the applicable Agios Opt-Out Date, Celgene shall use Commercially Reasonable Efforts to continue such activities in accordance with the plans and budgets therefor in effect as of such Agios Opt-Out Notice.
- (b) Opt-Out Date. Agios' opt-out shall be effective [**] after the Agios Opt-Out Notice is given; provided that, if Agios exercises its right to opt-out at any time during the [**] period prior to [**] of any Licensed Product, then such notice period shall commence on the date of the Agios Opt-Out Notice and continue until [**] after the [**] of such Licensed Product [**] (the "Agios Opt-Out Date").
 - (c) Effects of Agios Opt-Out Notice or Agios Opt-Out Date. Following the Agios Opt-Out Notice:
- (i) the license and sublicense granted to Agios under Section 8.1(b) shall terminate effective as of the Agios Opt-Out Date and all licenses granted by Agios to Celgene under Section 8.1(a) with respect to the Licensed Product(s) that are the subject of the applicable breach by Celgene shall convert to worldwide licenses as if Celgene were the Lead Party worldwide and otherwise remain in effect, and, from and after such termination;
- (ii) effective as of the Agios Opt-Out Date, Celgene shall become (if it is not then already) the Lead Party with respect to the entire Territory and, in accordance with Section 2.2(f)(ii), all decisions that a Committee would have made relating to Development, Manufacturing or Commercialization shall be made solely by Celgene; provided that Celgene shall perform such functions in a manner consistent with a commitment of Commercially Reasonable Efforts to the Development and Commercialization of the Licensed Products;
- (iii) neither Party shall have any further obligations under the Development Plan or Commercialization Plan effective as of the Agios Opt-Out Date;

- (iv) effective as of the Agios Opt-Out Date, Celgene (but not Agios) shall continue to have obligations under Section 7.1(b) and Section 7.2, but neither Party shall have any obligations under Section 7.1(a);
- (v) Celgene shall be solely responsible for all Development Costs and Commercialization Expenses for the Licensed Products incurred after the Agios Opt-Out Date, except as provided in clause (vi) immediately below and as provided in Section 5.4, Section 13.3 and Section 13.4:
- (vi) effective as of the Agios Opt-Out Date, Agios shall cease to conduct any further Development or Commercialization activities (including Marketing Activities) with respect to any Licensed Products, cease to have any obligations to use Commercially Reasonable Efforts with respect to Article III (Development) and Article VI (Commercialization), and cease to incur any further Development Costs or Commercialization Expenses except as approved by Celgene or as provided in Section 5.4, Section 13.3 and Section 13.4;
- (vii) within [**] after the Agios Opt-Out Date, Agios shall provide to Celgene a reasonably detailed accounting of all Development Costs and Commercialization Expenses incurred by Agios under the Collaboration prior to the Agios Opt-Out Date for the purpose of calculating a final reconciliation of shared costs through the Agios Opt-Out Date in accordance with Section 9.2 and Section 9.4;
- (viii) within [**] after the Agios Opt-Out Notice, Agios shall provide to Celgene a reasonably detailed summary of Development and Commercialization activities undertaken by Agios under the Collaboration, including any Clinical Trials committed but not yet completed as of such date;
- (ix) within [**] after the Agios Opt-Out Date, Agios shall provide to Celgene an update to the summary provided pursuant to subsection (viii) above;
- (x) Agios shall undertake, and coordinate with Celgene with respect to, any wind-down or transitional activities reasonably necessary to transfer to Celgene all Development, Manufacturing (including all Agios Clinical-Scale Manufacturing Responsibilities) and Commercialization responsibility for the Licensed Products throughout the Territory, at [**] expense, including those activities referenced in Section 14.4(b)(vii), and Agios shall use Commercially Reasonable Efforts to complete such activities before the Agios Opt-Out Date; provided that the Parties shall reasonably cooperate in seeking to minimize the costs of such wind-down or transitional activities; provided further that, (A) if [**] requests that any contracts or agreements that extend beyond the Agios Opt-Out Date be terminated, [**] all costs associated with such termination, and, (B) if [**] requests that any such contract or agreement remain in effect, [**] shall be responsible for all Development Costs and Commercialization Expenses incurred under such contract or agreement following the Agios Opt-Out Date or, if [**] requests assignment of such contract or agreement prior to the Agios Opt-Out Date, incurred following such assignment (whichever is earlier);

- (xi) Celgene shall have the option to obtain Agios' inventory of the Licensed Products and their active pharmaceutical ingredients at a price equal to [**]% of Agios' Manufacturing Costs;
- (xii) in the event Agios is utilizing a Third Party manufacturer to Manufacture the Licensed Products or their active pharmaceutical ingredients, to the extent permitted by the terms of such contract, Agios shall, if requested by Celgene, promptly assign to Celgene the manufacturing agreements with such Third Party with respect to such products and ingredients (it being understood that Agios shall remain fully responsible for its share of obligations thereunder arising with respect to periods prior to such assignment in accordance with the terms and conditions of this Agreement);
- (xiii) Agios shall transfer, or have transferred, to Celgene or its designee, pursuant to a technology transfer plan to be mutually agreed by the Parties promptly after the Agios Opt-Out Notice, all Manufacturing Technology Controlled by Agios within Agios Intellectual Property that is necessary to Manufacture the Licensed Products or their active pharmaceutical ingredients as Manufactured by or on behalf of Agios and its Affiliates, and Agios shall provide reasonable assistance in connection with the transfer of such Manufacturing Technology to Celgene or its designee, all of which shall be deemed Development Costs and Agios shall use Commercially Reasonable Efforts to complete such activities before the Agios Opt-Out Date;
- (xiv) effective as of the Agios Opt Out Date, each Licensed Product shall be subject to the royalty provisions of Section 9.5 from and after the Agios Opt-Out Date, in lieu of the sharing of Development Costs under Section 9.2 and Profit or Loss under Section 9.4; and
- (xv) as quickly as reasonably possible, [**] shall transition to [**] Prosecution and enforcement responsibilities (if any) with respect to Agios Patents, Agios Co-Co Collaboration Patents, Joint Inventions and Joint Collaboration Patents, which transition Agios shall use Commercially Reasonable Efforts to complete prior to the Agios Opt-Out Date, and provide reasonable assistance to [**] and cooperation in connection therewith, including execution of such documents as may be necessary to effect such transition, provided that [**] shall retain step-in rights (in the event that [**] elects not to Prosecute) on Prosecution matters relating to Joint Collaboration Patents, Agios Patents and Agios Co-Co Collaboration Patents that are not Joint Collaboration Patents comparable to [**].
- (d) <u>No Reversion</u>. For purposes of clarity, except as provided in this Agreement, after the Agios Opt-Out Date, Celgene shall be responsible for all costs and expenses for the Program and Agios shall not have any option or right to buy back into any co-Development or co-Commercialization rights.

Article III Development

Section 3.1 <u>Development of Licensed Products.</u>

- (a) <u>Development Plan and Changes</u>. Subject to Section 2.2 and Section 2.3, Development of Licensed Products shall be governed by the Development Plan for each of the US Territory and the ROW Territory that, collectively, describe the Development activities to be undertaken with respect to the Licensed Products in the Territory, which shall include an annual budget of Development Costs pursuant to Section 3.1(b) ("Development Budget") and anticipated timelines for performance. Promptly after the Effective Date, but in any event within [**] thereafter, the Lead US Party (with respect to Development of the Licensed Products in the United States) and Celgene (with respect to Development of the Licensed Product in the ROW Territory) shall each prepare and submit to the JSC for review and approval its applicable portion (for the territory in which it is the Lead Party) of an initial global Development Plan for Licensed Products. The JDC will establish the required form and contents of the Development Plan, and will review and approve each Development Plan in accordance with Section 3.1(e). The JDC may propose changes to the Development Plan to the JSC. The Development Plan may be amended from time to time by agreement between the Parties, or by the Lead Party (including without limitation in the event of any failure by the JSC to approve the initial Development Plan proposal by such Lead Party, or any amendment or update) for the relevant portion of the Territory, provided that (subject to the terms and conditions of this Agreement), the Parties agree that the Development Plan shall incorporate any reasonable comments made by either Party in relation to the Development of Licensed Products either within or outside such Party's territory. Subject to Article IV of the Master Agreement and Section 3.3 of this Agreement, the Lead Party may not make any amendments, without agreement of the other Party, that would impose any obligations on the other Party beyond those for which the other Party is responsible, or diminish the other Party's rights, under this Agreement and/or the then-current Development Plan and/or Development Budget (including by increasing the other Party's financial obligations hereunder).
- (b) Development Budgets. Promptly after the Effective Date, but in any event within [**] thereafter, and concurrently with the preparation of the Development Plan pursuant to Section 3.1(a), the Parties shall cooperate to prepare the initial Development Budget, which shall be reviewed and approved by the JDC (provided that, in the event that the JDC is unable to agree upon and approve the initial Development Budget proposal, the applicable Lead Party shall be entitled to approve such proposed Development Budget for its respective portion of the Territory). The Lead US Party shall be responsible for the preparation of the budget for the Development activities for, including all Clinical Trials to support Regulatory Approval of Licensed Products in, the United States, and Celgene shall be responsible for the preparation of the portion of the budget for the Development activities, including all Clinical Trials to support Regulatory Approval of Licensed Products in, the ROW Territory. For Development Costs to be incurred from and after the Effective Date, the JDC will review and approve the Development Budget reasonably in advance of the applicable Development Costs being incurred (with the intent being to obtain such approval at least [**] in advance of such costs being incurred, where practicable). Thereafter, the JDC will update and provide the JSC sufficiently in advance of the next Calendar Year so as to provide the Parties with an opportunity to budget accordingly, but in any event no later than [**] of each Calendar Year during the Term. The JSC will review and approve any such update or any other amendment to the Development Budget. In addition, either Party may request at any time that the JDC consider, and the JSC approve, other updates to the Development Budget. The

Development Budget may be amended from time to time either by agreement between the Parties through the JSC or by the Lead Party in the event that the JSC is unable to agree upon and approve any such amendment or updates for its respective portion of the Territory, provided that, subject to the terms and conditions of this Agreement, the Parties agree that each Party shall consider any reasonable comments made by either Party in relation to the Development of Licensed Products either within or outside the territory for which such Party is the Lead Party. The Parties understand and agree that, if the Non-Proposing Party does not elect to participate in an Additional Study as set forth in Section 3.3, the Proposing Party shall have the sole right to amend the Development Budget to account for the costs of such Additional Study (but, for clarity, shall not have the right to impose any additional payment obligations on the Non-Proposing Party for expenses related to such Additional Study, unless and until a Co-Co Buy-In occurs as set forth in Section 3.4, or a Deemed Buy-In occurs pursuant to Section 3.3(c)), after which time any changes to the Development Budget shall be run through the procedures described in this Section 3.1(b).

(c) Ongoing Clinical Trials. Notwithstanding the foregoing:

- (i) if Agios was conducting a Clinical Trial(s) as part of Pre-Exercise Phase I Development (as defined in the Master Agreement), excluding any expansion cohorts in such Clinical Trial(s) that are not part of Pre-Exercise Phase I Development, anywhere in the world with respect to any Compound and/or Licensed Product under the Collaboration which has not been completed as of the Effective Date ("Ongoing Clinical Trial"), then, at Celgene's sole election, Agios will continue to be responsible for the performance of such Ongoing Clinical Trial, at Agios' expense, in accordance with the Development Plan, and in accordance with the terms of the applicable Clinical Trial protocol until completion thereof, and notwithstanding Section 5.3, Agios will be responsible for adverse drug experiences reporting with respect to such Ongoing Clinical Trial until its completion; and
- (ii) if Agios was responsible for supply of Compound and/or Licensed Product for any Ongoing Clinical Trial(s) that have not been completed as of the Effective Date, then Agios will continue to be responsible at its cost for supplying such Compound and/or Licensed Product for such Ongoing Clinical Trial(s) (in the relevant dosage strength, formulation and presentation).
- (d) <u>Development Responsibilities</u>. Each Party shall use Commercially Reasonable Efforts to perform the activities assigned to it in accordance with the specifications, timelines and budgets indicated in the Development Plan.
- (e) <u>General Development Principles</u>. It is the intent of the Parties that Development of the Licensed Products will be conducted in accordance with the following principles, except to the extent (if any) otherwise expressly provided in the then-current Development Plan. The JDC (or the JSC or the Executive Officers as applicable) shall take into account and attempt to implement the following principles in its decision-making, including preparation, review and approval of any updates to and amendments of the Development Plan:
- (i) Regardless of the specific division of responsibility between the Parties for particular activities at any particular time, the JDC (and JSC) shall serve as a conduit for sharing information, knowledge and expertise relating to the Development of the Licensed Products.

- (ii) Clinical Development of the Licensed Products should be performed according to a single, integrated global program (with, for the avoidance of doubt, allowance of Additional Studies as provided in Section 3.3).
- (iii) The Development Plan should include an allocation of responsibilities between the Parties reasonably determined after taking into consideration each Party's expertise, capabilities, staffing and available resources to take on such activities.
- (iv) After receipt of Regulatory Approval of a Licensed Product in any Major Market, the Development Plan should (absent special circumstances or significant changes in circumstances) include pursuit of Regulatory Approval for such Licensed Product in the other Major Markets, Japan, and such other countries as the JSC deems appropriate.
- (f) <u>Coordination and Reports</u>. Each Party shall coordinate with, and keep the JDC informed with respect to, activities assigned to such Party under the Development Plan, including the conduct of any applicable Clinical Trials. Each Party shall provide the JDC with regular quarterly written reports on such Party's Development activities relating to the Collaboration, including a summary of results, information, and data generated, any activities planned with respect to Development going forward (including, for example, updates regarding regulatory matters and Development activities for the next Calendar Quarter), challenges anticipated and updates regarding intellectual property issues (including a disclosure of Collaboration Intellectual Property developed or generated since the last written report) relating to the Collaboration. Such written reports may be discussed by telephone or video-conference, or may be provided at each JDC meeting; <u>provided that</u>, reasonably in advance of the meeting of the JDC, the Party providing the written report will deliver to the JDC an agenda setting forth what will be discussed during the meeting. The Party receiving such written report shall have the right to reasonably request, and to receive in a timely manner at or after the JDC meeting, clarifications and answers to questions with respect to such reports.
- Section 3.2 <u>Development Costs</u>. The Parties will share all Development Costs incurred from and after the Execution Date in accordance with Section 9.2.
- Section 3.3 Additional Development Activities. If, following the Effective Date, a Party (the "[**]") wishes (i) to conduct a Clinical Trial or other study (including to repeat any Clinical Trial previously conducted under the Development Plan that failed to meet its primary endpoints) of Licensed Products not contemplated by the Development Plan, (ii) to Develop Licensed Products for a territory for which it is the Lead Party for any Indication in the Field other than an Indication for which such Licensed Products are being Developed pursuant to the Development Plan, (iii) to Develop a dosage form or formulation of Licensed Products for a territory for which the [**] is the Lead Party other than that being studied in the Development Plan, or (iv) to conduct any other Clinical Trial of a Licensed Product in the Field for a territory for which the [**] is the Lead Party that the [**] believes may have utility to support Regulatory Approval in the [**] territory, including any Phase IV Study or any combination of pharmaceutical products (each such study or activity in (i)-(iv) not already included in a

Development Plan, an "[**]"), then (A) the [**] shall first provide the proposed trial design and protocol for such Additional Study to the other Party (the "[**]"), through its members of the JDC, for review and approval as to the clinical and regulatory aspects of such Additional Study, and shall incorporate reasonable comments from the [**] Party's JDC members into such Additional Study design and protocol, and (B) following such review by the [**] Party's JDC members, provide the final proposed design and projected costs of such Additional Study to the [**] Party's JSC members. In any such case the following shall apply:

- (a) If the [**], through its members of the JSC, [**] to [**] such Additional Study, the Parties shall amend the Development Plan and the Development Budget to [**] such Additional Study, and the [**] of such Additional Study shall [**] in the Development Cost share in accordance with Section 9.2.
- (b) If [**] to include costs incurred with respect to such proposed Additional Study within the Development Cost share, the [**] may proceed with such Additional Study and shall [**] for the conduct and [**] of such study. In such case, the [**] would have [**] to use any resulting data (including any Licensed Product Data), except as set forth in Section 3.6(b) with respect to safety information required to be filed with the applicable Regulatory Authorities, in any such filings with Regulatory Authorities in the territory for which such [**] is the Lead Party, unless and until a [**] occurs as set forth in Section 3.4, or a [**] occurs pursuant to Section 3.3(c).
- (c) If (i) the [**] an Additional Study, [**] Additional Study as Development Costs or exercise a [**] with respect to such Additional Study pursuant to Section 3.4 prior to the initiation of the earlier of (A) a [**] or (B) a [**] and (ii) the [**] (each, an "Additional Study Approval"), such [**] shall be deemed to have elected to buy in to such Additional Study (a "[**]"), and shall pay to the [**] for such Additional Study a lump sum payment ("Lump Sum") equal to [**] percent ([**]%) of the costs that otherwise would have been apportioned to the [**] as Development Costs had such [**] originally opted-in, to conduct such Additional Study prior to the [**]. For example, in the case of the Shared 65/35 Program, where Celgene bears sixty-five percent (65%) of the Development Cost share and Agios bears thirty-five percent (35%) of the Development Cost share, if Agios were the [**] and Celgene incurred \$[**] in Development Costs prior to the [**], then Agios would be required to pay \$[**] (which represents [**] percent ([**])%) of the thirty-five percent (35%) share that Agios otherwise would have been required to pay under the Development Cost share pursuant to Section 9.2). The [**] shall pay to the [**] the [**] amounts set forth in this Section 3.3(c) within [**] after the [**] notifies the [**] in writing that the [**] has received Additional Study Approval.
- (d) If the Non-Proposing Party elects to co-fund an Additional Study, or elects to exercise a Co-Co Buy-In pursuant to Section 3.4, or is subject to a Deemed Buy-In as set forth in Section 3.3(c), then following such Non-Proposing Party's decision to co-fund, or following such Co-Co Buy-In, or Deemed Buy-In, as applicable, all data resulting from such Additional Study (including any Licensed Product Data) shall be available for use by (i) the Non-Proposing Party [**] and (ii) both Parties in the Territory to perform activities allocated to each such Party in the Development Plan or otherwise as set forth in this Agreement.

(e) For clarity, the [**] of any such Additional Study shall [**] in the Development Cost share pursuant to Section 9.2 unless and until (i) the [**] agrees to [**] pursuant to Section 3.3(a); (ii) a [**] occurs pursuant to Section 3.4; or (iii) a [**] occurs pursuant to Section 3.3(c).

Section 3.4 <u>Buy-In Right.</u> Notwithstanding Section 3.3(b) above, and subject to Section 3.3(c), at any time prior to the initiation of the earlier of (a) a [**] or (b) a [**], the [**] would have the right to elect by written notice to the [**] to include within the Development Cost share the costs of such Additional Study (the "[**]"). In such case, (x) the Parties shall share any Development Costs from the day of such notice onward incurred by the [**] to conduct such Additional Study after the [**] in accordance with their respective Profit or Loss Allocations, and (y) the [**] shall reimburse the [**] an amount equal to [**] percent ([**]") of the costs that otherwise would have been apportioned to the [**] as Development Costs had such [**] originally opted-in, to conduct such Additional Study prior to the [**]. For example, in the case of the Shared 65/35 Program, where Celgene bears sixty-five percent (65%) of the Development Cost share and Agios bears thirty-five percent (35%) of the Development Cost share, if [**] were the [**] and [**] incurred \$[**] in Development Costs prior to the [**], then [**]would be required to pay \$[**] (which represents [**]% of the thirty-five percent (35%) share that [**]otherwise would have been required to pay under the Development Cost share). Upon any such [**], the Parties shall have the rights with respect to such Clinical Trial or studies and the data arising therefrom as set forth in Section 3.3(d) and Section 3.6. If the [**] elects a [**], it shall pay to the [**] the [**] amounts set forth in subsection (y) within [**] after the [**] notifies the [**] in writing that the [**] is exercising its right to effect the [**] pursuant to this Section 3.4 and, for clarity, from and after any [**], the ongoing costs incurred for such Additional Study shall be included in the Profit or Loss and borne by the Parties in accordance with the Parties' applicable Profit or Loss Allocations.

Section 3.5 <u>Retained Rights for Certain Development Activities</u>. Notwithstanding anything to the contrary contained herein, (a) [**] retains the right to conduct Development of Licensed Products in the ROW Territory (when it is the Lead US Party), (b) [**] retains the right to conduct Development of Licensed Products in the United States (whether or not [**] is the Lead US Party), in each case of (a) and (b) solely to the extent necessary or useful to support Regulatory Approval for or conduct post-marketing studies of such Licensed Product in connection with the Lead US Party's Commercialization of Licensed Product in the US Territory, or [**] Commercialization of Licensed Product in the ROW Territory, as applicable, and (c)(i) [**] retains the right in the ROW Territory (when it is the Lead US Party), and (ii) [**] retains the right in the United States (whether or not [**] is the Lead US Party), to Manufacture and have Manufactured Compounds and Licensed Products to the extent reasonably required to support, in the case of the Lead US Party, such Party's Development and Commercialization of Compounds and Licensed Products within the ROW Territory, in each case to the extent such Party has the right to conduct such Manufacturing. If either Party plans to undertake such activities, it shall so notify the other Party. The rights retained by the Parties in this Section 3.5 [**] to use or enroll patients in association with any Clinical Trial(s) or other Development study(ies) of Licensed Products, or Companion Diagnostics in the ROW Territory (in the case of [**], when it is the Lead US Party) and in the United States (in the case of either [**] or [**]), notwithstanding anything to the contrary in Article IV of the Master Agreement.

Section 3.6 Rights to Use Licensed Product Data.

- (a) Each Party, in a given country for Development of Compounds and Licensed Products in such country, shall keep accurate records of all Licensed Product Data generated as a result of all activity by or on behalf of such Party in performing Development and Commercialization in relation to Compounds, Licensed Products and Companion Diagnostics, including any data generated pursuant to the Party's activities under Section 3.3. Except as provided in Section 3.3(b), each Party shall provide the other Party with copies of all such Licensed Product Data Controlled by the Party during the Term that is necessary for or reasonably related to the Development and Commercialization of Compounds, Licensed Products and Companion Diagnostics promptly following the generation of such Licensed Product Data. Licensed Product Data Controlled by Celgene (other than that to which Agios does not have rights pursuant to Section 3.3(b)) shall be included in the license grant to Agios pursuant to Section 8.1(b), and Licensed Product Data Controlled by Agios (other than that to which Celgene does not have rights pursuant to Section 3.3(b)) shall be included in the Agios Know-How and licensed to Celgene pursuant to Section 8.1(a).
- (b) Notwithstanding anything to the contrary in this Agreement, each Party shall promptly provide to the other Party, free of charge, copies of and rights of reference to and use of all Licensed Product Data that is Controlled by such Party, and that are relevant to or necessary to address issues relating to: (i) the safety of Licensed Products in the Territory, including data that is related to adverse effects experienced with Compounds or Licensed Products, and/or (ii) all activities relating to CMC regarding Compounds or Licensed Products, and in each of (i) and (ii), that are required to be reported or made available to Regulatory Authorities in the Territory, when and as such data become available.

Section 3.7 <u>Companion Diagnostics</u>.

- (a) <u>Development of Companion Diagnostic</u>. The Parties may mutually agree to Develop or Commercialize a Companion Diagnostic for use with the Licensed Products; <u>provided that</u>, in the event the Parties do not agree to jointly Develop or Commercialize a Companion Diagnostic, the Lead Party shall be entitled to Develop or Commercialize a Companion Diagnostic for use with Licensed Products in its applicable portion of the Territory. The Parties will use a Third Party Contractor reasonably acceptable to both Parties to perform all Development and Commercialization for the Companion Diagnostic. In such event, (i) the definition of "Licensed Product" shall and hereby does include the Companion Diagnostic for purposes of defining Agios Patents, Celgene Patents, Celgene Collaboration Patents, Agios Co-Co Collaboration Patents and Joint Collaboration Patents, and each of the licenses granted to a Party under Section 8.1; and (ii) all costs and profits with respect to such Development or Commercialization of the Companion Diagnostic (as Developed and Commercialized in accordance with this Section 3.7(a)) shall be shared by the Parties in accordance with their respective Profit or Loss Allocation percentages pursuant to a mechanism agreed to by the Parties at the time the Third Party Contractor is appointed.
- (b) <u>Separate Obligations</u>. No payments shall be owed by Celgene to Agios pursuant to Section 9.3 or Section 9.5 or by Agios to Celgene pursuant to Section 14.4(a)(i) with respect to a Companion Diagnostic. Upon termination of this Agreement, or reversion of

rights to a Party with respect to the Licensed Products, in addition to the effects of such termination or reversion set forth in Section 14.4, separate transitional activities shall be undertaken with respect to the Companion Diagnostic to ensure that the appropriate Regulatory Approvals, Manufacturing Technology or other Know-How or Patents necessary for the Development, Manufacture or Commercialization of such Companion Diagnostic shall be transferred to the Party to whom the rights to the Licensed Products are transferred to the same extent as Regulatory Approvals, Manufacturing Technology or other Know-How or Patents otherwise associated with such Licensed Products are transferred.

(c) <u>No Other Diagnostics</u>. For purposes of clarity, unless otherwise mutually agreed by the Parties, neither Party shall have any right, under the licenses granted to such Party pursuant to Section 8.1 and notwithstanding the definition of "Field" hereunder, to Develop, Manufacture or Commercialize any biomarker or diagnostic product for use with the Licensed Products, other than a Companion Diagnostic pursuant to this Section 3.7.

Section 3.8 Records; Tech Transfer.

- (a) Maintenance of Records. Each Party shall maintain in all material respects, and shall require its Third Party Contractors to maintain in all material respects, complete and accurate records in segregated books of all Development work conducted in furtherance of the Collaboration and all results, data and developments made in conducting such activities. Such records shall be complete and accurate and shall fully and properly reflect all such work done and results achieved in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes. Each Party shall require the applicable study sites to maintain original source documents from Clinical Trials of the Licensed Products for at least [**] (or such longer period as is commercially reasonable under the circumstances, taking into account maintenance requirements under applicable Law) following completion of the Development activities undertaken by such Party or its Third Party Contractors; provided that Celgene or Agios shall be entitled to obtain copies of such source documents at the end of such [**] period.
- (b) <u>Inspection</u>. 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 or its Third Party Contractors, as applicable, maintained in connection with the work done and results achieved in the performance of Development activities under the Collaboration, but solely to the extent access to such records is necessary for such Party to exercise its rights under this Agreement.
- (c) <u>Tech Transfer</u>. As soon as reasonably practical after the Effective Date and thereafter upon Celgene's reasonable request during the Term, Agios shall transfer to Celgene, at no cost to Celgene, copies of all Agios Know-How, Agios Co-Co Collaboration Know-How and Agios' interest in the Joint Collaboration Know-How related to the Licensed Product, to the extent not previously transferred to Celgene. Upon Agios' reasonable request during the Term, Celgene shall transfer to Agios, at no cost to Agios, copies of all Celgene Know-How, Celgene Collaboration Know-How and Celgene's interest in the Joint Collaboration Know-How related to the Licensed Product, to the extent not previously transferred to Agios. In addition, each Party shall provide reasonable assistance, including

making its personnel reasonably available for meetings or teleconferences to answer questions and provide technical support to the other Party with respect to the use of such transferred Know-How in the Development, Manufacture and Commercialization of Licensed Products. The costs and expense incurred by either Party in connection with such assistance shall constitute Development Costs.

Article IV Manufacture and Supply

Section 4.1 Pre-Clinical, Clinical and Commercial Supply.

- (a) <u>Agios Responsibilities</u>. Subject to the Supply Agreement, if any, Agios shall be responsible for Manufacturing, or having Manufactured by its designee, (i) all pre-clinical supply of Licensed Products, (ii) all active pharmaceutical ingredients for all Clinical Trials (collectively, items (i) and (ii), the "<u>Agios Clinical-Scale Manufacturing Responsibilities</u>"), and (iii) all active pharmaceutical ingredients for Commercialization of Licensed Products (the "<u>Agios Commercial-Scale Manufacturing Responsibilities</u>").
- (b) Agios Commercial-Scale Manufacturing Responsibilities. Subject to the Supply Agreement, if any, Agios or its Affiliate may have any Third Party conduct on behalf of Agios any of the Agios Commercial-Scale Manufacturing Responsibilities, provided that, from the period commencing on the Effective Date and ending on the first to occur of (i) the first date [**], and (ii) a [**], Agios shall notify Celgene at least [**] prior to the time at which it anticipates it will engage a Third Party to conduct such activities, and the Parties thereafter shall discuss the selection of the Third Party, provided that Celgene may, in its discretion, indicate that it is interested in undertaking the applicable Agios Commercial-Scale Manufacturing Responsibilities, in which event the Parties shall discuss that as well. Agios retains the right to determine whether a Third Party or Celgene shall conduct the applicable Agios Commercial-Scale Manufacturing Responsibilities, and the terms thereof, provided that such manufacturing still conforms to the requirements of this Section 4.1(b). Agios shall fulfill a substantial portion of the Agios Commercial-Scale Manufacturing Responsibilities from within, and ship all such active pharmaceutical ingredients to Celgene from, [**] for purposes of Section 954(d) of the Code and Section 1.954-3(a)(2) of the Treasury Regulations (or any other similar provision of the Code or Treasury Regulations in effect as of any time); provided that Agios may obtain raw materials from any country as determined by Agios for use in connection with the Agios Commercial-Scale Manufacturing Responsibilities, and provided further that if [**].
- (c) <u>Celgene Responsibilities</u>. As of the Effective Date, Celgene shall be responsible for all drug product manufacturing and processing and filling of Licensed Products for all Clinical Trials ("<u>Celgene Clinical-Scale Manufacturing Responsibilities</u>") and for Commercialization of Licensed Products (the "<u>Celgene Commercial-Scale Manufacturing Responsibilities</u>") (Celgene Clinical-Scale Manufacturing Responsibilities and Celgene Commercial-Scale Manufacturing Responsibilities, collectively, the "<u>Celgene Manufacturing Responsibilities</u>"). Celgene shall fulfill a substantial portion of the Celgene Commercial-Scale Manufacturing Responsibilities from [**] for purposes of Section 954(d) of the Code and Section 1.954-3(a)(2) of the Treasury Regulations (or any other similar provision of the Code or Treasury Regulations in effect as of any time); <u>provided that</u> Celgene may obtain raw materials from any country as determined by Celgene for use in connection with the Celgene Manufacturing Responsibilities, and provided further that [**].

- (d) <u>Lead Party Responsibilities</u>. As to each of the US Territory and the ROW Territory, the respective Lead Party shall be responsible for Manufacturing, or having Manufactured by its designee, all supply of Licensed Products not included within Agios Clinical-Scale Manufacturing Responsibilities, Agios Commercial-Scale Manufacturing Responsibilities and Celgene Manufacturing Responsibilities, including drug product packaging, labeling, shipping and storage.
- (e) The JDC with respect to clinical supply and the JCC with respect to commercial supply may from time to time each agree on a supply plan consistent with the Supply Agreement, if any, (each, a "Supply Plan") to set forth the details regarding the Parties' supply of active pharmaceutical ingredients, drug product and Licensed Product. Each Supply Plan shall include customary terms such as forecasting procedures and a definition of "supply failure" in terms of failure to provide adequate and/or timely supply.
- (f) <u>Manufacturing Costs</u>. Manufacturing Costs associated with clinical supply of the Licensed Products shall be shared in accordance with Section 9.2. Manufacturing Costs associated with commercial supply of the Licensed Products shall constitute Commercialization Expenses.
- (g) The Parties intend to enter into an agreement that will govern the terms of manufacture and supply of Licensed Products for the Collaboration (a "Supply Agreement"). Notwithstanding the foregoing, the Parties understand and agree (1) that the following principles do not set forth all of the material terms and conditions of any such Supply Agreement, and (2) the Parties shall not be obligated to enter into any Supply Agreement unless pursuant to definitive terms and conditions that the Parties shall mutually agree upon. If the Parties decide to enter into a Supply Agreement, such Supply Agreement shall incorporate the following principles, and other material terms such as pricing, as the Parties shall mutually agree upon:
- (i) The Supply Agreement shall contain reasonable and customary provisions to minimize the risk of supply interruptions, including, if agreed by the Parties, the establishment of backup Manufacturing capabilities for Agios Clinical-Scale Manufacturing Responsibilities, Agios Commercial-Scale Manufacturing Responsibilities, Celgene Clinical-Scale Manufacturing Responsibilities and Celgene Commercial-Scale Manufacturing Responsibilities at Third Party facilities; and
- (ii) If a Supply Failure occurs, the Non-Supplying Party shall have the right to step in and manufacture or procure its own supply of the applicable Licensed Product and the Responsible Supply Party will transfer to the Non-Supplying Party (A) a copy of all Agios Know-How or Celgene Know-How, as applicable, that is Controlled by and in the possession of the Responsible Supply Party or its Affiliates and that is necessary or useful to enable the Manufacture of Licensed Product in accordance with the applicable specifications, and by making available its or its Affiliates' qualified technical personnel during normal business hours on a reasonable basis to consult with the Non-Supplying Party with respect to

such Know-How and (B) at Non-Supplying Party's request and cost, any materials then in the Responsible Supply Party's or its Affiliates' possession and Control that has been specifically designated to be used by the Responsible Supply Party or its Affiliates or Third Party Contractors in the Manufacture of such Licensed Product. Such Know-How and material transfer will be conducted pursuant to a technology transfer plan developed by the Parties for the purpose of ensuring the complete and timely transfer of such Know-How and materials. The Non-Supplying Party and its Third Party manufacturer may only use the Know-How and materials provided to the Non-Supplying Party pursuant to this Section 4.1(g)(ii) in support of Manufacturing Licensed Product and solely in accordance with this Agreement, and will not use any such Know-How and materials for any other reason or for any other product or product candidate (or intermediate or component thereof). All Manufacturing for Commercialization under this Section 4.1(g)(ii) will be located in [**] for purposes of Section 954(d) of the Code and Section 1.954-3(a)(2) of the Treasury Regulations (or any other similar provision of the Code or Treasury Regulations in effect as of any time)).

Section 4.2 <u>Third Party Manufacturers</u>. For each Third Party that a Party uses to fulfill its Manufacturing obligations or rights under Section 4.1 with respect to a primary source or under Section 4.4 with respect to a secondary source for any supply to be used in any Development or Commercialization activities under the Collaboration, the Third Party and the terms of the agreement with such Third Party must be approved by the JDC or JCC, as applicable, in each case subject to Section 2.2.

Section 4.3 <u>Transfer of Manufacturing Responsibility</u>. In order to assist Celgene to perform the Celgene Manufacturing Responsibilities or, if selected by Agios pursuant to Section 4.1(b), the Agios Commercial-Scale Manufacturing Responsibilities, Agios shall (a) transfer, or have transferred, to Celgene or its designee, pursuant to a technology transfer plan to be mutually agreed by the Parties, all Manufacturing Technology Controlled by Agios and used in Manufacturing Licensed Products at the time of such transfer to the extent relevant to the Celgene Manufacturing Responsibilities or, if selected by Agios pursuant to Section 4.1(b), the Agios Commercial-Scale Manufacturing Responsibilities, and (b) provide reasonable assistance in connection with the transfer of such Manufacturing responsibility to Celgene or its designee. Costs incurred by either Party in such transfer shall be Development Costs.

Section 4.4 <u>Manufacturing Efforts</u>. The Party that is responsible for Manufacturing hereunder shall use Commercially Reasonable Efforts to ensure adequate manufacturing capacity to meet forecast demand for the applicable Licensed Product, including the possible establishment of an alternative supply source. The Party that is responsible for Manufacturing hereunder shall also use Commercially Reasonable Efforts to ensure adequate pre-clinical, clinical and commercial supply of the applicable Licensed Product for both Parties to Develop or Commercialize, as applicable, such Licensed Products as contemplated under the applicable Development Plan or Commercialization Plan.

Article V Regulatory Matters

Section 5.1 <u>Lead Responsibility for Regulatory Interactions</u>. Except as may otherwise be mutually agreed by the Parties or the JSC, JDC or JCC, as applicable, and subject to oversight by the JSC, JDC or JCC:

(a) Lead Responsibility.

- (i) <u>US Territory</u>. The Lead US Party shall have lead responsibility for all Regulatory Interactions with Regulatory Authorities in the US Territory for the applicable Licensed Product (including after any transfer set forth in Section 5.1(c)).
- (i i) <u>ROW Territory</u>. Celgene shall have the lead responsibility for all Regulatory Interactions with Regulatory Authorities in the ROW Territory with respect to each Licensed Product.
- (b) <u>Regulatory Interactions Defined</u>. For purposes of this Agreement, "<u>Regulatory Interactions</u>" means (i) monitoring and coordinating all regulatory actions, preparing, submitting and coordinating all communications and filings with, and submissions to, all Regulatory Authorities with respect to the Licensed Products and (ii) interfacing, corresponding and meeting with the Regulatory Authorities with respect to the Licensed Products.
- (c) <u>Transfer of Regulatory Responsibility</u>. Celgene shall become the Lead Party for Regulatory Interactions for any Licensed Product upon an Agios Opt-Out Notice being delivered to Celgene.
- (d) <u>Regulatory Responsibilities</u>. Upon and after such time that Celgene becomes the Lead Party for Regulatory Interactions for any Licensed Product pursuant to Sections 5.1(a) or 5.1(c):
- (i) Agios shall (A) at Celgene's option, either close or inactivate Agios' IND(s) for such Licensed Product, or transfer such IND(s) to Celgene, and (B) with Celgene input, complete all relevant activities related to such IND as required for Celgene to assume regulatory ownership, as applicable, all within [**] after Celgene's notice;
- (ii) Celgene shall be responsible for the preparation and filing of all regulatory filings with respect to any subsequent Development, Manufacturing or Commercialization for Licensed Products after such activities described in clause (i) above are completed; and
- (iii) Agios shall provide Celgene with all relevant clinical and non-clinical data reasonably requested by Celgene or a Regulatory Authority, including CMC, pharmacology and toxicology generated by Agios with respect to the subject Licensed Product.

Section 5.2 Participation Rights.

(a) <u>Review of Regulatory Documentation</u>. Each Party shall keep the JDC reasonably informed in connection with all Regulatory Interactions, preparation of all Regulatory Documentation, Regulatory Authority review of Regulatory Documentation,

Regulatory Approvals, annual reports, including annual safety reports to the respective health authorities, annual re-assessments, and any subsequent variations and changes to labeling, in each case with respect to the Licensed Products. Each Party shall respond within a reasonable time frame to all reasonable inquiries by the other Party with respect to any information provided pursuant to this Section 5.2(a) (and sufficiently promptly for the other Party to provide meaningful input with respect to responses to Regulatory Authorities).

- (b) <u>Participation in Meetings</u>. The Party not having the lead responsibility for Regulatory Interactions in a country with respect to the Licensed Products shall have the right to have two senior, experienced employees reasonably acceptable to the responsible Party participate as an observer in material or scheduled face-to-face meetings, video conferences and any teleconferences with the applicable Regulatory Authority, and shall be provided with advance access to the responsible Party's material documentation prepared for such meetings.
- (c) <u>Review</u>. Prior to submission of material correspondence to any Regulatory Authority with respect to the Licensed Products, the Party having the lead responsibility for Regulatory Interactions shall, sufficiently in advance for the other Party to review and comment, provide the other Party any material correspondence with the Regulatory Authority related to such meetings. The responsible Party shall also provide the other Party with copies of any material correspondence with Regulatory Authorities relating to Development of, or the process of obtaining Regulatory Approval for, the Licensed Products in such Party's territory, and respond within a reasonable time frame to all reasonable inquiries by the other Party with respect thereto.
- Section 5.3 Global Safety Database; Pharmacovigilance Agreement. At a time to be mutually agreed by the Parties, the Parties shall establish, hold and maintain a single electronic system for the collection and storage of all safety information for the Licensed Products (the "Global Safety Database"). Such database shall comply in all material respects with all Laws reasonably applicable to pharmacovigilance anywhere where the Licensed Products are being or have been Developed or Commercialized. Unless the Parties otherwise agree in the Pharmacovigilance Agreement, the Lead US Party shall initially be responsible for the Global Safety Database for the Licensed Products, and the other Party shall assume control on a Licensed Product-by-Licensed Product basis following the transfer, if any, of lead responsibility for Regulatory Interactions in the US Territory for such Licensed Product to the other Party. The Party not maintaining the Global Safety Database may hold and maintain a parallel safety database for the Licensed Products as needed or required according to applicable Laws. The Parties will use Commercially Reasonable Efforts to negotiate a pharmacovigilance agreement (the "Pharmacovigilance Agreement") to govern cooperation among the Parties that will enable each of them to comply with its respective obligations under applicable Laws and to satisfy its duty of care with respect to the Licensed Products, including with regard to ownership of the Global Safety Database, adverse event data collection, analysis and reporting. The Pharmacovigilance Agreement will be entered among the Parties no later than [**] following the Effective Date.

Section 5.4 Recalls, Market Withdrawals or Corrective Actions.

- (a) In the event that any Regulatory Authority issues or requests a recall, market withdrawal or similar action in connection with a Licensed Product in any portion of the Territory, or in the event either Party determines that an event, incident or circumstance has occurred that may result in the need for a recall, market withdrawal or similar action in any portion of the Territory, the Party notified of such recall, market withdrawal or similar action, or the Party that desires such recall, market withdrawal or similar action, shall within [**] advise the other Party thereof by telephone or facsimile. The Lead Party shall, after reasonable consultation with the other Party, decide whether to conduct a recall, market withdrawal or similar action in its applicable portion of the Territory and the manner in which any such recall, market withdrawal or similar action shall be conducted. Each Party will make available to the other Party, upon request, all of such Party's (and its Affiliates') pertinent records that such other Party may reasonably request to assist such other Party in effecting any recall, market withdrawal or similar action.
- (b) The costs and expenses incurred before the Agios Opt-Out Date relating to a recall, market withdrawal or similar action of any Licensed Product(s) in the Territory shall be taken into account in determining Profit or Loss as, and to the extent, provided in Exhibit D. The costs and expenses incurred after the Agios Opt-Out Date for any recall, market withdrawal or similar action of any Licensed Product(s) in the Territory shall be borne solely by Celgene if and only to the extent (i) such recall, market withdrawal or similar action was caused by the occurrence after the Agios Opt-Out Date of the event, incident or circumstance that led to the recall, market withdrawal or similar action and (ii) the event, incident or circumstance and the costs and expenses for such recall, market withdrawal or similar action are not the subject of an indemnity obligation of Agios under Section 13.2. The costs and expenses incurred after the Agios Opt-Out Date relating to any recall, market withdrawal or similar action of any Licensed Product(s) in the Territory shall be borne by the Parties in accordance with their respective Profit or Loss Allocation percentages to the extent (A) such recall, market withdrawal or similar action was caused by the occurrence before the Agios Opt-Out Date of the event, incident or circumstance that led to the recall, market withdrawal or similar action and (B) such event, incident or circumstance and such costs and expenses are not the subject of an indemnity obligation of either Party under Section 13.1 or Section 13.2. If Agios is invoiced for its portion of such costs and expenses incurred after the Agios Opt-Out Date, payment is due within [**] of receipt of invoice.

Article VI Commercialization

Section 6.1 <u>Commercialization Responsibilities for Licensed Products.</u>

(a) <u>Responsibility</u>. Subject to oversight by the JCC and to Section 2.2, Section 2.3 and Section 6.3(f), each Party shall have the responsibilities for the Commercialization of Licensed Products as specified in the Commercialization Plan. Subject to the foregoing and the remainder of this Article VI, the applicable Lead Party in each of the US Territory and the ROW Territory shall have primary responsibility for Commercialization of Licensed Products in the US Territory and the ROW Territory, respectively.

(b) <u>Sales</u>. The applicable Lead Party will book all sales of the Licensed Products in the US Territory and the ROW Territory, respectively, and will have the sole responsibility for the processing of orders, invoicing, terms of sale, and distribution of the Licensed Products throughout the US Territory and the ROW Territory, respectively, associated therewith.

Section 6.2 Commercialization Plan.

(a) Initial Commercialization Plan.

- (i) Subject to Section 2.2 and Section 2.3, Commercialization of Licensed Products shall be governed by a Commercialization Plan (the "<u>Commercialization Plan</u>"), for each of the US Territory and the ROW Territory that, collectively, describe the Commercialization activities (including pre-launch and launch activities, if applicable) to be undertaken with respect to the Licensed Products in the Territory, which shall include an annual budget of Commercialization Expenses ("<u>Commercialization Budget</u>") and anticipated timelines for performance.
- (ii) Commencing no later than [**] prior to the anticipated First Commercial Sale of each Licensed Product in the US Territory and the ROW Territory, the applicable Lead Party shall prepare the initial Commercialization Plan covering the first [**] after First Commercial Sale of each Licensed Product in the US Territory or the ROW Territory, with input and guidance from the JDC and the JCC. Such Commercialization Plans shall describe Commercialization activities to be undertaken by the Parties in the US Territory and the ROW Territory, respectively.
- (b) <u>JCC Approval; Amendments</u>. The JCC shall approve the first Commercialization Plan for each Licensed Product in each of the US Territory and the ROW Territory no later than [**] prior to the anticipated First Commercial Sale of the first such Licensed Product in the US Territory and the ROW Territory, respectively. Thereafter, the JCC shall review and approve the Commercialization Plan(s) (for the current Calendar Year and the next succeeding Calendar Year) each Calendar Year (provided that, in the event the JCC is unable to agree on such proposed plan, the Lead Party in the applicable Territory shall have the final say for its portion of the proposed Commercialization Plan). Either Party may also develop and submit to the JCC for review from time to time other proposed amendments to the applicable Commercialization Plan(s). The initial Commercialization Plan(s), and any amendments and updates to the Commercialization Plan(s), shall be effective upon the approval of the JCC.

Section 6.3 Field-Based Marketing Activities.

(a) <u>General</u>. The JCC shall determine the type and scope of field-based marketing efforts to be used for Commercialization of each Licensed Product in the Territory (*e.g.*, [**]) (collectively, "<u>Marketing Activities</u>"), and the Commercialization Plan(s) for each Licensed Product in the Territory shall set forth such Marketing Activities for each Indication which is marketed in the Territory.

- (b) Allocation of Activities. The Commercialization Plan(s) will allocate to each Party its portion of the total Marketing Activities for each Licensed Product in the Territory; provided that, unless otherwise agreed to by the Parties, each Party will be allocated a percentage of the Marketing Activities in the [**] equal to its respective Profit or Loss Allocation, wherein such percentages refer to the total number of FTEs devoted to an activity when applicable. The Commercialization Plan will attempt to provide that Marketing Activities are distributed geographically within the [**] in a manner reasonably consistent with the distribution of the population in the [**] and that each Party's detailing effort, if applicable, will be directed to physicians of similar prescribing potential but shall take into account the competitive situation of the Licensed Product. In overseeing the Marketing Activities, the JCC will take into account the Licensed Product's [**] for the Licensed Product. Notwithstanding anything to the contrary contained herein, the non-Lead Party (itself or by or through any others, including any Affiliates or Licensee Partners), will not take any action regarding the Commercialization of Licensed Products in the countries for which it is not the Lead Party (except as contemplated by this Agreement) unless mutually agreed in writing, described in the Commercialization Plan, or otherwise approved by the JCC.
- (c) <u>Sales Force</u>. To the extent the Marketing Activities include detailing efforts, the JCC shall determine the number of sales representatives needed to carry out the required Marketing Activities in the [**] for each Licensed Product. 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 Agios and Celgene sales forces in promoting the Licensed Products will be organized under the supervision of the JCC 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(s); <u>provided that</u> the Commercialization Plan(s) shall identify the portion of the detailing effort to be undertaken by each Party in the [**] no later than [**] before the planned date of the NDA submission in, as applicable, the [**]. The following provisions shall apply to the activities of sales representatives with respect to Commercialization of Licensed Products:
- (i) Each Party will be solely responsible for recruiting, hiring and maintaining its sales force of sales representatives for promotion of Licensed Product in accordance with its standard procedures, the requirements of this Agreement and the minimum qualifications set forth on Schedule 6.3. Each Party will be responsible for the activities of its sales representatives, including compliance by its sales representatives with training and detailing requirements. In particular, each Party will provide its sales representatives assigned to promote the Licensed Product in the [**] with the level of oversight, management, direction and sales support with respect to the promotion of Licensed Product necessary to effectively and efficiently promote the Licensed Product in accordance with the terms of this Agreement and applicable Law. Each Party agrees that none of its sales representatives involved in the promotion of the Licensed Product will have any legal or regulatory disqualifications, bars or sanctions. [**].

- (ii) Notwithstanding the foregoing, neither Party will have the right to use any Third Party contract sales force to fulfill its obligations under this Agreement in the [**], except during the first [**] following First Commercial Sale in such portion of the Territory.
- (iii) The Commercialization Plan will set forth (A) the precise number of each Party's sales representatives for Licensed Product in the [**], consistent with the foregoing, (B) policies and processes for the creation of marketing and promotional materials, (C) planning for conferences, (D) the number, type (e.g., first position, second position, etc.) and frequency of details to be conducted by sales representatives for Licensed Products in each Calendar Year, (E) the allocation of sales details between the Parties, (F) development of sales forecasts, and (G) coordinating strategies for compensation packages for sales representatives.
- (iv) If either Party does not provide in the [**] at any particular time, for any reason, the number of sales representatives specified in the Commercialization Plan to be provided for the [**], then the other Party will have the right to make up such shortfall using its sales representatives until such time as the non-fulfilling Party is able to provide its agreed upon number of sales representatives, and, for clarity, all costs incurred by the other Party related to making up such shortfall shall be included in the calculation of the Profit or Loss Allocation.
- (v) The calculation of costs of engaging sales representatives for purposes of calculating the Profit or Loss Allocation shall be based on the FTE Rate, and such FTE Rate shall be used by both Parties for promotion of Licensed Product in the [**].
- (d) Training Materials and Sessions. The JCC will develop product-specific training materials and arrange for provision of such materials to each Party's sales forces, if applicable, for use in the [**]. The JCC will develop a sales training program directed towards the Licensed Products for use in the [**]. Unless otherwise mutually agreed by the Parties, Celgene and Agios sales representatives will participate in a launch meeting(s) (which may be held together or separately) for each Licensed Product, which shall include training sessions of product-specific sales skills with respect to the approved Indications for the Licensed Products. Each Party will train and instruct their respective sales representatives to make only those statements and claims regarding the Licensed Product, including as to efficacy and safety, that are consistent with the Licensed Product labeling and accompanying inserts and the approved promotional materials. Subsequent to launch, Celgene and Agios shall periodically hold meetings with Agios 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 in the [**]. As requested by the applicable Lead Party, the other Party shall make its management, marketing, training and other personnel reasonably available to participate in the Lead Party's national and regional sales meetings and Licensed Product training events for the [**], as applicable. For clarity, all marketing and promotional materials used in the [**] must be approved by the applicable Lead Party prior to use.
- (e) Other Obligations. Subject to Section 2.3, in conducting the Marketing Activities in the [**], the Parties will comply with all applicable Laws, applicable industry professional standards and compliance policies of the Lead Party that have been previously furnished to the other Party, as the same may be updated from time to time and provided to the other Party and not in violation of any applicable Law. Each Party will reasonably assist the

other Party in training sales representatives in such standards. Neither Party shall make any claims or statements with respect to the Licensed Products that are not strictly consistent with the product labeling and the sales and marketing materials approved for use pursuant to the Commercialization Plan(s) or otherwise approved by the JCC.

(f) <u>Termination of Marketing Activities</u>. (i) To the extent Agios is not the Lead US Party, Agios shall have the right to terminate its Marketing Activities obligations in the US Territory, and (ii) Agios shall have the right to terminate its Marketing Activities obligations in the [**], with respect to any Licensed Product by providing at least [**] prior written notice to Celgene (or sooner as Celgene may determine, in its sole discretion). Upon exercise of such termination right, effective upon the expiration of such [**] (or, if applicable, shorter) notice period, Agios' obligations to perform Marketing Activities under this Section 6.3 in the US Territory or [**], as applicable, shall terminate. Further, if Agios exercises this right with respect to the US Territory, then Celgene shall have final decision-making authority over all matters regarding Commercialization with respect to the US Territory.

Section 6.4 <u>Trademarks</u>.

- (a) <u>Selection of Trademarks</u>. The JCC shall select the trademark(s) to be used in connection with the marketing and sale of the Licensed Products in the Territory (such marks, together will registrations, applications for registration and common law rights therein, collectively, "<u>Product Trademarks</u>"). Any dispute over the selection of a Product Trademarks shall be presented to the JSC for resolution. The Parties shall adhere to the use of the Product Trademark(s) in their Commercialization of the Licensed Products in the Territory hereunder, to the extent permitted by Law.
- (b) Ownership. The [**] shall own all Product Trademarks for any Licensed Product in the Territory. Effective as of the Agios Opt-Out Date, if Agios is the [**] under this Agreement, it hereby assigns to Celgene all right, title and interest in and to the Product Trademarks in the Territory that are owned by Agios free and clear of any liens and encumbrances. Agios will execute and deliver any further document reasonably requested by Celgene to further document or record such assignment.
- (c) <u>Branding</u>. At such time as the JCC deems appropriate, the Parties shall discuss in good faith any branding and/or co-branding of the Licensed Products (the "<u>Licensed Branding</u>"), and the Parties will enter into appropriate trademark licensing agreements to achieve the foregoing. For the avoidance of doubt, nothing in this Agreement shall be construed to grant either Party any rights in or to any of the other Party's trademarks, tradenames, logos, or other marks (other than Product Trademarks), including use thereof, absent a separate trademark licensing agreement entered into in accordance with this Section 6.4(c). Notwithstanding the foregoing, subject to any restrictions on the form or content of the Licensed Branding imposed by any Regulatory Authority, unless the Parties mutually agree otherwise in writing, the Licensed Branding used with respect to Licensed Products shall feature the logos of Agios and Celgene with approximately equal sizing and similar prominence, with the Lead Party's name first, on all packaging and materials used for Commercialization of such Licensed Products, to the extent permitted by applicable Law.

Article VII Diligence

Section 7.1 Collaboration Activities.

- (a) <u>General</u>. Each Party shall use Commercially Reasonable Efforts to perform all Development, Manufacturing and Commercialization activities for which such Party is responsible hereunder in compliance with the applicable Development Plan or Commercialization Plan, including any budget(s) and timeframe(s) set forth therein and including making available those resources set forth in any applicable Development Plan or Commercialization Plan, and the terms of this Agreement.
 - (b) Compliance with Laws. Each Party shall:
 - (i) perform its obligations under this Agreement in a scientifically sound and workmanlike manner; and
- (ii) carry out all work done in the course of the Collaboration in compliance with all applicable Laws governing the conduct of such work.

Section 7.2 <u>Diligence Obligations</u>.

- (a) In addition to the diligence obligations set forth in Section 7.1, the Parties (directly or through one or more Affiliates or Licensee Partners) shall use Commercially Reasonable Efforts to Develop and achieve Regulatory Approval for the Licensed Products in each of the [**] and, following such Regulatory Approval, to Commercialize such Licensed Products in each of the [**].
- (b) A breach of the diligence obligations set forth in this Section 7.2 shall be deemed a material breach and shall be subject to termination under Article XIV. Notwithstanding the foregoing, the Parties acknowledge that it might be commercially reasonable, under certain circumstances, for the Lead Party for a given [**] to determine not to launch a Licensed Product in such [**], and failure under such circumstances to launch such Licensed Product shall not be a breach of this Agreement.
- Section 7.3 <u>Day-to-Day Responsibility</u>. Each Party shall be responsible for day-to-day implementation of the Development, Manufacturing and Commercialization activities for which it (or its Affiliate) has or otherwise is assigned responsibility under this Agreement or the applicable Development Plan or Commercialization Plan and shall keep the other Party reasonably informed as to the progress of such activities, as determined by the JDC and JCC.

Article VIII Grant of Rights; Exclusivity

- Section 8.1 <u>License Grants</u>. Subject to the terms and conditions of this Agreement:
 - (a) <u>License Granted to Celgene</u>. Agios hereby grants to Celgene:

- (i) a non-transferable (except as set forth in (a)), exclusive right and license in each country of the Territory for which Celgene is the Lead Party (subject to the rights of Agios and its Affiliates to Develop, Manufacture and Commercialize Compounds, Licensed Products and Companion Diagnostics as specifically set forth in this Agreement, including to Develop and Manufacture in such country(ies) to support Development, Manufacture and Commercialization in the US Territory if Agios is the Lead US Party), with the right to grant sublicenses as set forth in Section 8.2(a) and Section 8.2(b), under Agios' rights in Agios Intellectual Property, Agios Co-Co Collaboration Intellectual Property and Agios' interest in the Joint Collaboration IP and Manufacturing Technology, to Develop, Manufacture or Commercialize Compounds, Licensed Products and Companion Diagnostics; provided that, as to Companion Diagnostics, such license grant shall be limited to Developing, Manufacturing and Commercializing Companion Diagnostics for use as companion diagnostics with Licensed Products under this Agreement;
- (ii) a non-transferable (except as set forth in Section 15.4), non-exclusive right and license in each country of the Territory for which Celgene is not the Lead Party under Agios' rights in Agios Intellectual Property, Agios Co-Co Collaboration Intellectual Property and Agios' interest in the Joint Collaboration IP and Manufacturing Technology, to Develop and Manufacture Compounds, Licensed Products and Companion Diagnostics in such countries to support Development, Manufacture and Commercialization in the ROW Territory; provided that, as to Companion Diagnostics, such license grant shall be limited to Developing, Manufacturing and Commercializing Companion Diagnostics for use as companion diagnostics with Licensed Products under this Agreement; and
- (iii) a non-transferable (except as set forth in Section 15.4), non-exclusive right and license in the Territory under Agios' rights in Agios Intellectual Property, Agios Co-Co Collaboration Intellectual Property and Agios' interest in the Joint Collaboration IP and Manufacturing Technology, solely to permit Celgene to perform its obligations under the Development Plans and Commercialization Plans.

(b) <u>License Granted to Agios</u>. Celgene hereby grants to Agios:

(i) if Agios is the Lead US Party, a non-transferable (except as set forth in (a)), exclusive right and license in the US Territory (subject to the rights of Celgene and its Affiliates to Develop, Manufacture and Commercialize Compounds, Licensed Products and Companion Diagnostics as specifically set forth in this Agreement, including to Develop and Manufacture in the US Territory to support Development, Manufacture and Commercialization in the ROW Territory), with the right to grant sublicenses as set forth in Section 8.2(a) and Section 8.2(b), under Celgene's rights in Celgene Intellectual Property, Celgene Collaboration Intellectual Property and Celgene's interest in the Joint Collaboration IP and Manufacturing Technology, to Develop, Manufacture or Commercialize Compounds, Licensed Products and Companion Diagnostics; provided that, as to Companion Diagnostics, such license grant shall be limited to Developing, Manufacturing and Commercializing Companion Diagnostics for use as companion diagnostics with Licensed Products under this Agreement;

- (ii) a non-transferable (except as set forth in Section 15.4), non-exclusive right and license in each country of the Territory for which Agios is not the Lead Party under Celgene's rights in Celgene Intellectual Property, Celgene Collaboration Intellectual Property and Celgene's interest in the Joint Collaboration IP, to Develop and Manufacture Compounds, Licensed Products and Companion Diagnostics in such countries to support Development, Manufacture and Commercialization in the United States; provided that, as to Companion Diagnostics, such license grant shall be limited to Developing, Manufacturing and Commercializing Companion Diagnostics for use as companion diagnostics with Licensed Products under this Agreement; and
- (iii) a non-transferable (except as set forth in Section 15.4), non-exclusive right and license in the Territory under Celgene's rights in Celgene Intellectual Property, Celgene Collaboration Intellectual Property and Celgene's interest in the Joint Collaboration IP and Manufacturing Technology, solely to permit Agios to perform its obligations under the Development Plans and Commercialization Plans.
 - Section 8.2 <u>Sublicense Rights</u>. Subject to Section 8.3, the Parties have the following sublicensing rights.
- (a) <u>Sublicenses to Affiliates and Subcontractors</u>. Each Party shall have the right to grant sublicenses within the scope of the licenses and sublicense under Section 8.1:
 - (i) to such Party's Affiliates; and
- (ii) to Third Parties for the purpose of (X) [**] any Compound, Licensed Product or related Companion Diagnostic or (Y) engaging Third Parties as contract research organizations, contract manufacturers, contract sales forces, consultants, academic researchers and the like ("Third Party Contractors") in connection with Development, Manufacturing or Commercialization activities throughout the Territory on behalf of such Party or its Affiliates with respect to the Collaboration under this Agreement, subject to the following:
- (A) unless otherwise mutually agreed by the Parties, each Party shall require any such Third Party to whom such Party discloses Confidential Information to enter into an appropriate written agreement obligating such Third Party to be bound by obligations of confidentiality and restrictions on use of such Confidential Information that are no less restrictive than the obligations set forth in Article XI, including requiring such Third Party to agree in writing not to issue any Publications except in compliance with the terms of this Agreement (including approval by the JDC or JCC, as applicable, pursuant to the approved publication plan, and the obligations set forth in Section 11.4, except that Publications by academic collaborators shall be permitted (without JDC or JCC consent, as applicable) if the academic collaborator (i) provides an advance copy of the proposed Publication (under the same time periods as described in Section 11.4(a)), which may be shared with the other Party, (ii) agrees to delay such Publication sufficiently long enough to permit the timely preparation and filing of a patent application, and (iii) upon the request of either Party, removes from such Publication any Confidential Information of such Party);
- (B) unless otherwise mutually agreed by the Parties, each Party will obligate such Third Party to agree in writing to assign ownership of, or grant an exclusive, royalty-free, worldwide, perpetual and irrevocable license (with the right to grant sublicenses) to,

any inventions arising under its agreement with such Third Party to the extent related to Development, Manufacturing or Commercialization with respect to the Compounds or Licensed Products in the Field; and such Party shall structure such assignment or exclusive license so as to enable such Party to sublicense such Third Party inventions to the other Party pursuant to Section 8.1 (including permitting such other Party to grant further sublicenses); provided that, in connection with any academic collaborator performing research work with respect to the Target, Compounds or Licensed Products that is not reasonably expected by the applicable Party to result in inventions related to composition of matter or methods of use, it shall be sufficient for such Party to obtain a non-exclusive, worldwide, royalty-free, perpetual license (with the right to grant sublicenses) to, and a right to negotiate for an exclusive license, with the right to grant sublicenses, to, any inventions resulting from such research work, which sublicensing rights must permit sublicensing to the other Party pursuant to Section 8.1 (including permitting such other Party to grant further sublicenses);

- (C) each Party shall notify the JDC or JCC, as applicable, at a regular meeting of the JDC or JCC, as applicable, of the execution any such agreement with such Third Party and, if requested, shall provide the other Party with a copy of such agreement, which copy may be redacted with respect to matters that do not relate to the Collaboration; and
- (D) unless otherwise mutually agreed by the Parties, each Party will require any such Third Party to grant to the other Party access to all confidential protocols and data generated by such Third Party's work with respect to the Licensed Products to the same extent as such other Party's licenses under Section 8.1, and grant the other Party the right to audit the records of such Third Party.
- (b) Other Sublicenses. Except as provided in Section 8.2(a), any other sublicense by either Party under the licenses and sublicense set forth in Section 8.1 shall require the prior written approval of the other Party.
- Section 8.3 <u>Sublicense Requirements</u>. Any sublicense granted by a Party pursuant to this Agreement shall be subject to the following:
- (a) each sublicense granted hereunder by a Party or its Affiliates shall be consistent with the requirements of this Agreement;
- (b) any transfer of rights between a Party and its Affiliates shall not be deemed a sublicense by such Party but shall be deemed a direct license by the other Party to such Party's Affiliate; <u>provided that</u> such Party shall remain responsible for the activities of its Affiliate;
- (c) a Party's or its Affiliates' Licensee Partners shall have no right to grant further sublicenses without the other Party's prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed;
- (d) such Party shall be primarily liable for any failure by its Affiliates and Licensee Partners to comply with all relevant restrictions, limitations and obligations in this Agreement; and

(e) such sublicense must be granted pursuant to a written sublicense agreement and, with respect to any sublicense other than a sublicense by a Party to an Affiliate of such Party, such Party must provide the other Party with a copy of any sublicense agreement entered into under Section 8.2 above within [**] after the execution of such sublicense agreement; provided that any such copy may be reasonably redacted to remove any confidential, proprietary or competitive information, but such copy shall not be redacted to the extent that it impairs the other Party's ability to ensure compliance with this Agreement. Such sublicense agreement shall be treated as Confidential Information of the sublicensing Party and no copies are required with respect to sublicense agreements with Third Party Contractors.

Section 8.4 <u>Affiliates and Third Party Contractors</u>. Either Party may exercise its rights and perform its obligations hereunder itself or through its Affiliates and sublicensees. Each Party shall be primarily liable for any failure by its Affiliates and sublicensees (including Third Party Contractors) to comply with all relevant restrictions, limitations and obligations in this Agreement. If either Party desires to use any Person to conduct any of its Development, Commercialization or other Collaboration activities hereunder, such Party must comply with the obligations of Section 8.2(a)(ii)(A) through (D), even to the extent no sublicense of rights is granted to such Third Party.

Section 8.5 Third Party Agreements.

- (a) <u>Acknowledgement</u>. Except as provided in Section 8.5(b) and Section 9.6, each Party acknowledges that Agios is responsible for the fulfillment of its obligations under each Existing Third Party Agreement, and each Party is responsible for the fulfillment of its obligations under any Subsequent Third Party Agreement that it enters into, and each Party agrees to fulfill the same obligations, including any provisions necessary to maintain in effect any rights sublicensed to the other Party hereunder and the exclusive or non-exclusive nature of such rights, as applicable, subject to the other Party's compliance with its obligations hereunder.
- (b) Incorporation of Certain Provisions. Each Party agrees and acknowledges that Agios is required to provide to licensors under the Existing Third Party Agreements, and either Party may be required to provide to licensors under any Subsequent Third Party Agreements, periodic reports relating to the gross sales and Net Sales of Licensed Products. Each Party shall keep true and accurate records and books of account, and open such books and records for inspection by such licensors, for a duration of [**] from the date of origination of such books or records. Furthermore, each Party acknowledges that the other Party may be required to share certain reports and copies of sublicense agreements provided hereunder with any licensor under an Existing Third Party Agreement or Subsequent Third Party Agreement, and each Party consents to the sharing of such reports and such copies of such sublicense agreements to the extent required under such Existing Third Party Agreement or Subsequent Third Party Agreement to the same extent as disclosures are permitted under Section 11.3(b) hereunder; provided that any such copies of sublicense agreements must be redacted to the extent permitted under such Existing Third Party Agreement or Subsequent Third Party Agreement. In addition, each Party acknowledges that the Prosecution, enforcement and other intellectual property management rights under this Agreement with respect to Patents and other intellectual property licensed under Existing Third Party Agreements or Subsequent Third Party Agreements shall be subject to the terms and conditions of the applicable Existing Third Party

Agreements or Subsequent Third Party Agreements and, in the case of Existing Third Party Agreements or Subsequent Third Party Agreements in which the licensor is an academic institution, other provisions of such Existing Third Party Agreements or Subsequent Third Party Agreements that are customarily required to be imposed on sublicensees in academic licenses (in no event to include any exclusivity covenant).

- (c) <u>Covenants Regarding Third Party Agreements</u>. Each Party that has entered into an Existing Third Party Agreement or Subsequent Third Party Agreement (the "<u>Licensing Party</u>") agrees that during the Term:
- (i) The Licensing Party shall not modify or amend any Existing Third Party Agreement or Subsequent Third Party Agreement in any way that adversely affects the other Party's rights hereunder without the other Party's prior written consent;
- (ii) The Licensing Party shall not terminate any Existing Third Party Agreement or Subsequent Third Party Agreement, in whole or in part, without the other Party's prior written consent;
- (iii) Subject to Section 9.6, the Licensing Party shall be solely responsible for, and shall make, all royalty payments, milestone payments, yearly fees, sublicensee fees, Prosecution fees, and all other payments owed to any licensor under and pursuant to any Existing Third Party Agreement or Subsequent Third Party Agreement;
- (iv) The Licensing Party shall not exercise or fail to exercise any of its rights, or fail to perform any of its obligations, under any Existing Third Party Agreement or Subsequent Third Party Agreement that relates to the other Party's rights hereunder without the prior written consent of the other Party, including rights with respect to including improvements within the licenses granted under such Existing Third Party Agreement or Subsequent Third Party Agreement; and, at the reasonable request of the other Party, the Licensing Party shall exercise such rights and make such requests that relate to the other Party's rights hereunder as are permitted under such Existing Third Party Agreement or Subsequent Third Party Agreement;
- (v) The Licensing Party shall promptly furnish the other Party with copies of all reports and other communications that the Licensing Party furnishes to any licensor under any Existing Third Party Agreement or Subsequent Third Party Agreement to the extent that such reports relate to this Agreement;
- (vi) The Licensing Party shall promptly furnish the other Party with copies of all reports and other communications that the Licensing Party receives from any licensor under any Existing Third Party Agreement or Subsequent Third Party Agreement that relate to the subject of this Agreement (including notices relating to improvements under such Existing Third Party Agreement or Subsequent Third Party Agreement);
- (vii) The Licensing Party shall furnish the other Party with copies of all notices received by the Licensing Party relating to any alleged breach or default by the Licensing Party under any Existing Third Party Agreement or Subsequent Third Party Agreement within [**] after the Licensing Party's receipt thereof; in addition, if the Licensing Party should at any time breach an Existing Third Party Agreement or subsequent Third Party Agreement or become unable to timely perform its obligations thereunder, the Licensing Party shall immediately notify the other Party; and

- (viii) If the Licensing Party cannot or chooses not to cure or otherwise resolve any alleged breach or default under any Existing Third Party Agreement or Subsequent Third Party Agreement, (A) the Licensing Party shall so notify the other Party within [**] of such decision, which shall not be less than [**] prior to the expiration of the cure period under such Existing Third Party Agreement or Subsequent Third Party Agreement; provided that the Licensing Party shall use Commercially Reasonable Efforts to cure any such breach or default; and (B) the other Party, in its sole discretion, shall be permitted (but shall not be obligated), on behalf of the Licensing Party, to cure any breach or default under such Existing Third Party Agreement or Subsequent Third Party Agreement in accordance with the terms and conditions of such Existing Third Party Agreement or Subsequent Third Party Agreement or otherwise resolve such breach directly with the applicable licensor(s) under such Existing Third Party Agreement or Subsequent Third Party Agreement; and (C) if the other Party pays any such licensor any amounts owed by the Licensing Party under such Existing Third Party Agreement or Subsequent Third Party Agreement, then, provided that such amounts have not arisen as a result of the other Party's failure to comply with the terms and conditions of such Existing Third Party Agreement or Subsequent Third Party Agreement within the categories described in Section 8.5(b) applicable to the other Party as a sublicensee, the other Party may deduct the Licensing Party's share of such amounts from payments the other Party is required to make thereafter to the Licensing Party hereunder or, at the other Party's election, may otherwise seek reimbursement of such amounts from the Licensing Party.
- (d) <u>Survival of Rights Following Termination of Third Party Agreement</u>. The Parties agree that in the event of any termination of any Existing Third Party Agreement or Subsequent Third Party Agreement with respect to any intellectual property rights licensed to a Party hereunder, such Party shall have any rights available under such Existing Third Party Agreement or Subsequent Third Party Agreement to become a direct licensee of the Third Party licensor(s) under such Existing Third Party Agreement or Subsequent Third Party Agreement and the Licensing Party shall use Commercially Reasonable Efforts to assist the other Party in exercising such rights; <u>provided that</u> the other Party has not breached this Agreement, or breached the applicable Third Party Rights under such Existing Third Party Agreement or Subsequent Third Party Agreement. In addition, notwithstanding the foregoing, in the event of such termination, the other Party may in any event approach any licensor under any Existing Third Party Agreement or Subsequent Third Party Agreement for a direct license.
- (e) Termination of Third Party Agreements. The Parties agree that termination, without both Parties' prior written consent, of any Existing Third Party Agreement or Subsequent Third Party Agreement with respect to any Patent or Know-How that is necessary to Develop, Manufacture or Commercialize the Licensed Products shall be deemed a breach of this Agreement by the Licensing Party; provided that (i) if the other Party's breach of this Agreement results in a breach of any Existing Third Party Agreement or Subsequent Third Party Agreement, Celgene agrees to use Commercially Reasonable Efforts to assist the Licensing Party in curing such breach of such Existing Third Party Agreement or Subsequent Third Party Agreement, and (ii) if the other Party's breach of this Agreement results in a termination of any Existing Third Party Agreement or Subsequent Third Party Agreement, such termination of such Existing Third Party Agreement or Subsequent Third Party Agreement shall not be deemed a breach by the Licensing Party of this Agreement.

Section 8.6 Exclusivity.

(a) Exclusivity Obligations. From the Effective Date until the end of the Term, the Parties and, subject to Section 15.4, their Affiliates shall not, directly or indirectly, Develop, Manufacture or Commercialize [**] for application in [**] that [**] the Target through direct binding to the Target with [**], except for (i) Licensed Products (including those activities specifically permitted following termination of this Agreement) and (ii) Programs (as defined in the Master Agreement) directed to the Target (A) that are being conducted pursuant to the Master Agreement, (B) to which Celgene has exercised its Option (as defined in the Master Agreement) under the Master Agreement or (C) the rights to which have reverted to Agios in accordance with Section 2.12 of the Master Agreement.

(b) Exceptions.

- (i) <u>Incidental Discoveries</u>. A Party shall be deemed not to be, directly or indirectly (whether such activities are conducted internally or with or through a Third Party), Developing, Manufacturing or Commercializing in violation of the provisions of Section 8.6(a) as a result of conducting a research program or discovery effort (or manufacturing or commercializing a [**] resulting from such research program or discovery effort) that has as its specified and primary goal, as evidenced by items such as laboratory notebooks or other relevant documents contemporaneously kept, taken as a whole, to discover or Develop compounds that [**] through direct binding to a target other than the Target.
- (ii) <u>Celgene Exception</u>. It is agreed and understood by the Parties that any Celgene research, discovery and commercialization activities existing as of the effective date of the Master Agreement, whether such activities are undertaken by Celgene alone or in conjunction with one or more partners, licensors, licensees, and/or collaborators, are expressly excluded from the provisions of this Section 8.6. In particular and without limitation, Celgene research, discovery, and commercialization activities related to (i) [**]; (ii) [**]; (iii) [**]; (iv) [**]; (v) [**]; or (vi) [**], are expressly excluded from the provisions of this Section 8.6.
- (iii) Academic Collaborations. Notwithstanding the provisions of Section 8.6(a), and without limiting Section 8.2(a)(ii), each Party shall be permitted to perform any of the activities that would otherwise be prohibited under Section 8.6(a) in relation to the Target, if such activities are (A) the subject of an existing agreement between such Party and an academic institution or academic collaborator entered into prior to the effective date of the Master Agreement, provided that such Party shall not be permitted to amend any such agreement unless such amendment contains provisions consistent with the terms and conditions of such agreement in effect as of the effective date of the Master Agreement with respect to (1) [**], or (B) the subject of a new agreement entered into between such Party and an academic institution or academic collaborator that contains terms and conditions with respect to the [**] consistent with the terms and conditions of [**]; provided that, if any [**] of an amendment described in (A) or an agreement described in (B) would not be [**] the agreements between such Party and an academic institution or academic collaborator entered into prior to the effective date of the Master Agreement, such Party [**].

(iv) Competitive Programs. Section 8.6(a) shall not apply if, during the [**], any Party or its Affiliates (other than in a Change of Control transaction with respect to such Party) merges or consolidates with, or otherwise acquires, a Third Party that is then engaged in activities that would otherwise constitute a breach of this Section 8.6 by any Party or its Affiliates (a "Competitive Program"); it being understood and agreed that, unless the Parties agree otherwise in writing, such Party that is engaged in a Competitive Program (the "Competitive Program Party") shall, within [**] after the date of such merger, consolidation or acquisition, notify the other Party that it intends to either: (A) terminate, or cause its relevant Affiliate to terminate, the Competitive Program or (B) divest, or cause its relevant Affiliate to divest, whether by license or otherwise, the Competitive Program. If the Competitive Program Party notifies the other Party within such [**] period that it intends to [**], such Competitive Program, the Competitive Program Party or its relevant Affiliate, shall (X) terminate such Competitive Program as quickly as possible, and in any event within [**] (unless applicable Law requires a longer termination period) after the Competitive Program Party delivers such notice to the other Party; and (Y) confirm to the other Party when such termination has been completed, and the Competitive Program Party's continuation of the Competitive Program during such [**] (or, as required by applicable Law, longer) period shall not constitute a breach of the Competitive Program Party's exclusivity obligations under Section 8.6(a). If the Competitive Program Party notifies the other Party within such [**] period that it intends to divest such Competitive Program, the Competitive Program Party or its relevant Affiliate shall use all reasonable efforts to effect such divestiture as quickly as possible, and in any event within [**] after the Competitive Program Party delivers such notice to the other Party, and shall confirm to the other Party when such divestiture has been completed. If the Competitive Program Party or its relevant Affiliate fails to complete such divestiture within such [**] period, but has used reasonable efforts to effect such divestiture within such [**] period, then, unless otherwise required by applicable Law, such [**] period shall be extended for such additional reasonable period thereafter as is necessary to enable such Competitive Program to be in fact divested, not to exceed an additional [**]; provided that such additional [**] period shall be extended for such period as is necessary to obtain any governmental or regulatory approvals required to complete such divestiture if the Competitive Program Party or its relevant Affiliate is using good faith efforts to obtain such approvals. The Competitive Program Party's continuation of the Competitive Program during such divestiture period shall not constitute a breach of the Competitive Program Party's exclusivity obligations under Section 8.6(a).

(v) Certain Permitted Activities.

(A) The [**] shall not constitute a breach of Section 8.6(a). Each Party shall report to the JSC on a [**] basis [**] and that would otherwise breach Section 8.6(a). For clarity, [**] without violation of Section 8.6(a) [**] shall not constitute [**] in violation of such Party's exclusivity obligations under this Section 8.6 as long as [**].

(B) The [**] shall not constitute a breach of Section 8.6(a); <u>provided that</u> [**] shall be subject to Section 8.6(a) and shall not be permitted under this Section 8.6(b)(v).

- (C) The restrictions set forth in Section 8.6(a) shall not be deemed to prevent either Party or its respective Affiliates from (1) fulfilling its obligations under this Agreement, or (2) engaging any subcontractors in accordance with Section 8.2(a)(ii) of this Agreement.
- (D) If [**] occurs with respect to either Party with a Third Party and the Third Party already is conducting or is planning to conduct activities that would cause a Party or an Affiliate to violate Section 8.6(a) (an "Acquirer Program"), then such Third Party [**]; provided that (1) [**] in any Acquirer Program, (2) [**] in any Acquirer Program, and (4) [**] to such Acquirer Program, including by [**] the activities under this Agreement, and the activities covered under such Acquirer Program (except that this requirement shall not apply to [**] activities under such Acquirer Program).
- (vi) <u>Clinical Combinations</u>. Notwithstanding anything to the contrary in this Agreement, for purposes of this Section 8.6, either Party shall, at all times, have the right to conduct clinical Development of Licensed Products, alone or with Third Parties, in which the [**]'s regulatory filings for purposes of enabling such Party and such Third Party to include the relevant use of Licensed Products in combination with such other therapeutic product in the approved label for such Licensed Products and/or such other therapeutic product, respectively, provided that [**] may grant to any such Third Party the right to sell, offer for sale and otherwise commercially exploit such Licensed Products.

Section 8.7 Retained Rights.

- (a) No Implied Licenses or Rights. Except as expressly provided in Section 8.1, and subject to Section 8.6, all rights in and to the Agios Intellectual Property, Agios' and its Affiliates' interests in Agios Co-Co Collaboration Intellectual Property, Joint Collaboration IP and any other Patents or Know-How of Agios and its Affiliates, are hereby retained by Agios and its Affiliates. Except as expressly provided in Section 8.1, and subject to Section 8.6, all rights in and to the Celgene Intellectual Property, Celgene's and its Affiliates' interests in Celgene Collaboration Intellectual Property and any other Patents or Know-How of Celgene and its Affiliates, are hereby retained by Celgene and its Affiliates.
- (b) Other Retained Rights. The Parties acknowledge that the licenses granted hereunder are subject to any rights retained by any licensor under any Existing Third Party Agreement pursuant to any provision of such Existing Third Party Agreement, as identified in Exhibit C; provided that, upon Celgene's reasonable request, Agios shall cooperate fully in requesting and obtaining any waiver with respect to the requirement, if applicable under such agreements, that the Licensed Products used or sold in the United States be manufactured substantially in the United States.
- Section 8.8 Section 365(n) of the Bankruptcy Code. All rights and licenses granted under or pursuant to any section of this Agreement are and will otherwise be deemed to be for purposes of Section 365(n) of the United States Bankruptcy Code (Title 11, US Code), as amended (the "Bankruptcy Code"), licenses of rights to "intellectual property" as defined in Section 101(35A) of the Bankruptcy Code. The Parties will retain and may fully exercise all of their respective rights and elections under the Bankruptcy Code. The Parties agree that each

Party, as licensee of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the Bankruptcy Code or any other provisions of applicable law outside the United States that provide similar protection for "intellectual property." The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a Party under the Bankruptcy Code or analogous provisions of applicable Law outside the United States, the Party that is not subject to such proceeding will be entitled to a complete duplicate of (or complete access to, as appropriate) such intellectual property and all embodiments of such intellectual property, which, if not already in the non-subject Party's possession, will be promptly delivered to it upon the non-subject Party's written request thereof. Any agreements supplemental hereto will be deemed to be "agreements supplementary to" this Agreement for purposes of Section 365(n) of the Bankruptcy Code.

Article IX Financial Provisions

Section 9.1 <u>Upfront Option Payment</u>. In consideration of Agios' discovery and initial Development under the Master Agreement of the Compound(s) and the rights and licenses granted hereunder, Celgene shall make an initial, non-refundable payment to Agios equal to the applicable Upfront Option Payment set forth in paragraph 4 and Annex I of <u>Exhibit A</u>, within [**] following the Effective Date.

Section 9.2 <u>Sharing of Development Costs.</u> Subject to Section 2.3 and Section 3.3:

- (a) The Development Costs to be shared by the Parties under this Agreement are those (i) Development Costs that are incurred after the Execution Date and (ii) Manufacturing Costs associated with clinical supply of Licensed Products incurred after the Execution Date, and, in either case, that are within [**] percent ([**]%) of the approved Development Budget under the Development Plan, if any, applicable to such Development Costs, as measured on a Party-by-Party basis (such that the [**]% limit is applicable to each Party's allocated activities and budgeted amounts under the Development Plan and Development Budget). Any Development Costs in excess of [**] percent ([**]%) of the approved portion of the Development Budget allocated to such Party under the Development Plan shall be borne solely by the Party incurring such costs unless such Party has received the other Party's written approval to share such excess costs. Celgene shall be responsible for a percentage of the Development Costs allocated to this Agreement equal to the Celgene Profit or Loss Allocation and Agios shall be responsible for a percentage of such Development Costs equal to the Agios Profit or Loss Allocation.
- (b) Within [**] following the beginning of the last month of each Calendar Quarter, each Party shall prepare and deliver to the JCC a quarterly report detailing its and its Affiliates' Development Costs incurred during the first two (2) months of such Calendar Quarter, estimated to be incurred during the last month of such Calendar Quarter, and actually incurred in the last month of the immediately preceding Calendar Quarter which are required to be shared pursuant to this Section 9.2. Each Party shall submit any supporting information or clarifications reasonably requested by the other Party related to such Development Costs included in such Party's report within [**] after the other Party's receipt of such request. The Parties, with the assistance of the JCC, shall conduct a reconciliation of Development Costs for

the subject Calendar Quarter within [**] after receipt of all such supporting information, and an invoice shall be issued to the Party (if any) that has not paid for its full share of the Development Costs for such Calendar Quarter. Such reconciliation shall balance the actual amount of Development Costs incurred during the last month of the immediately preceding Calendar Quarter (to correct for any differences between the estimates and actual amount of such costs) together with the amounts incurred during the first two (2) months of such Calendar Quarter and those estimated to be incurred during the last month of such Calendar Quarter. The paying Party shall pay all amounts payable under any such invoice within [**] after its receipt of such invoice.

Section 9.3 <u>Milestone Payments</u>.

(a) <u>Development and Regulatory Milestones</u>. Celgene shall pay Agios the following amounts after the first achievement by or on behalf of the Parties or their respective Affiliates or Licensee Partners of the corresponding development and regulatory milestone events set forth below with respect to the first Licensed Product to achieve such milestone events.

Milestones	Amount for Shared 65/35 Program (as indicated on Exhibit A)	Amount for Shared 50/50 Program (as indicated on <u>Exhibit A</u>)
[**]	US \$25,000,000 (Twenty-Five Million US Dollars)	US \$20,000,000 (Twenty Million US Dollars)
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]

⁽i) For purposes of determining the occurrence of milestones under items (2) and (3) in the table above, (A) the [**] shall be deemed a single [**] for purposes of determining whether the [**] and (B) achievement of such milestones with respect to the [**] shall be deemed to have occurred only if [**] have been obtained. For purposes of clarity, no milestone amount shall be payable to Agios under item (3) if [**], but Celgene shall pay Agios the milestone amount set forth in item (3) upon receipt of [**] as applicable, than the [**] for purposes of item (3).

⁽ii) The milestone payments under items (2), (3) and (4) shall be paid at [**] percent ([**]%) of the specified amounts upon the [**] of the applicable milestone event by a Licensed Product for a different Indication than the Indication for which such Licensed Product first achieved such milestone event. For the avoidance of doubt, each distinct histology shall qualify as a distinct Indication for purposes of this Section 9.3. For the further avoidance of doubt, if a Licensed Product achieves a milestone for an Indication and subsequently achieves the same milestone for an earlier line setting in the same Indication, no milestone payments shall be due for such earlier line setting (e.g., if a Licensed Product [**], no milestone payments

would be due if such Licensed Product later [**]). For the further avoidance of doubt, for purposes of this Section 9.3, if a Licensed Product achieves a milestone for an Indication as part of a monotherapy or combination therapy and subsequently achieves the same milestone in the same Indication as part of a combination therapy or monotherapy, respectively, no milestone payments shall be due for such subsequent milestone.

- (iii) Each milestone payment under this Section 9.3 shall be made within [**] after the achievement of the applicable milestone by Celgene or any of its Affiliates or sublicensees (or, if achievement of such milestone is within the control of Agios, within [**] following Celgene's receipt of written notice of the achievement of such milestone).
- (iv) For clarity, except as set forth in subsection (ii), the milestone payments set forth in the table above in this Section 9.3 (to the extent payable) shall be paid only once, regardless of the number of Licensed Products to achieve the applicable milestone event and regardless of the number of Indications for which the milestone event may be achieved.

Section 9.4 <u>Profit or Loss</u>. Subject to Section 2.3:

- (a) <u>Profit or Loss</u>. The Parties shall share in Profit or Loss as follows: Agios shall bear (and be entitled to) a percentage of Profit or Loss equal to the Agios Profit or Loss Allocation, and Celgene shall bear (and be entitled to) a percentage of Profit or Loss equal to the Celgene Profit or Loss Allocation. Each Party may include Commercialization Expenses in the Profit or Loss incurred by such Party that are within [**] percent ([**]%) of the approved portion of the Commercialization Budget allocated to such Party under the Commercialization Plan (and, for clarity, Commercialization activities are measured on a Party-by-Party basis, such that the [**]% limit is applicable to each Party's allocated activities and budgeted amounts under the Commercialization Plan and Commercialization Budget). Any Commercialization Expenses in excess of [**] percent ([**]%) of the budgeted amount in the approved Commercialization Budget under the Commercialization Plan shall be borne solely by the Party incurring such costs and not included in Profit or Loss unless such Party has received the other Party's written approval to share such excess costs.
- (b) Quarterly Reconciliation and Payments. Unless the Parties otherwise agree within [**] following the end of each Calendar Quarter, each Party shall prepare and deliver to the JCC a quarterly report detailing its Net Sales made and Commercialization Expenses incurred, and other amounts necessary to calculate Profit or Loss, during such Calendar Quarter, with respect to which the Parties share Profit or Loss pursuant to this Section 9.4. Each Party shall submit any supporting information reasonably requested by the other Party related to such Net Sales, Commercialization Expenses and such other amounts included in such Party's reconciliation report within [**] after the other Party's receipt of such request. The Parties, with the assistance of the JCC, shall conduct a reconciliation of Profit or Loss for the full Calendar Quarter within [**] after receipt of all such supporting information, and an invoice shall be issued to the Party (if any) that owes the other Party a payment to accomplish the sharing, in accordance with the Profit or Loss Allocations, of the Profit or Loss identified in such reconciliation for such Calendar Quarter by the other Party. The paying Party shall pay all amounts payable under any such invoice within [**] after its receipt of such invoice.

Section 9.5 Royalty Payments Following Agios Opt-Out. Following any Agios Opt-Out Date:

(a) <u>Royalty Rate</u>. Subject to Section 9.5(b), Celgene shall pay to Agios royalties on worldwide Annual Net Sales of Licensed Products following any Agios Opt-Out Date at the applicable royalty rate set forth below (each, a "<u>Royalty Rate</u>") on a Licensed Product-by-Licensed Product basis (in no event to include Companion Diagnostics):

Worldwide Annual Net Sales of Licensed Products from a Shared 50/50 Program	Royalty Rate
On the tranche of worldwide Annual Net Sales occurring until aggregate worldwide Annual Net Sales reaches [**] US Dollars (US\$[**])	[**]%
On the tranche of worldwide Annual Net Sales occurring so long as aggregate worldwide Annual Net Sales is equal to or greater than [**] US Dollars (US\$[**]) and less than [**] US Dollars (US\$[**])	[**]%
On the tranche of worldwide Annual Net Sales occurring upon and after aggregate worldwide Annual Net Sales equals [**] US Dollars (US\$[**])	[**]%

Worldwide Annual Net Sales of Licensed Products from a Shared 65/35 Program	Royalty Rate
On the tranche of worldwide Annual Net Sales occurring until aggregate worldwide Annual Net Sales reaches [**] US Dollars (US\$[**])	[**]%
On the tranche of worldwide Annual Net Sales occurring so long as aggregate worldwide Annual Net Sales is equal to or greater than [**] US Dollars (US\$[**]) and less than [**] US Dollars (US\$[**])	[**]%
On the tranche of worldwide Annual Net Sales occurring upon and after aggregate worldwide Annual Net Sales equals [**] US Dollars (US\$[**])	[**]%

Each Royalty Rate set forth in the tables above will apply only to that portion of the worldwide Annual Net Sales of a given Licensed Product in the Territory during a given Calendar Year that falls within the indicated tranche.

For example, if worldwide Annual Net Sales of a given Licensed Product in the Territory by Celgene and its Affiliates and Licensee Partners was \$[**] and such Licensed Product was under a Shared 50/50 Program, then the royalties payable with respect to such worldwide Annual Net Sales, subject to adjustment as set forth in this Section 9.5(a), would be:

[**].

- (b) <u>Royalty Term</u>. Royalties payable under this Section 9.5 shall be paid by Celgene on a Licensed Product-by-Licensed Product and country-by-country basis from the later of (i) the Agios Opt-Out Date and (ii) the date of First Commercial Sale of each Licensed Product in a country with respect to which royalty payments are due, until the latest of:
- (i) the last to expire of any Valid Claim of Agios Patents, Celgene Collaboration Patents or Agios Co-Co Collaboration Patents (including Joint Collaboration Patents), in each case Covering such Licensed Product in such country;
 - (ii) [**] following the date of First Commercial Sale in such country; and
 - (iii) the expiration of Regulatory Exclusivity for such Licensed Product in such country;

(each such term with respect to a Licensed Product and a country, a "Royalty Term").

- (iv) Notwithstanding the foregoing, (A) in the event that the Royalty Term for a Licensed Product in a country continues solely due to Section 9.5(b)(ii) above (*i.e.*, the Licensed Product is not Covered by a Valid Claim of Agios Patents, Celgene Collaboration Patents or Agios Co-Co Collaboration Patents (including Joint Collaboration Patents) in the applicable country, and such Licensed Product is not subject to Regulatory Exclusivity in such country) or (B) in the event that, and for so long as, Generic Competition for a Licensed Product occurs in a country, then, in either such event, the royalty rate in such country will be reduced to [**] percent ([**]%) of the applicable rate in Section 9.5(a) in such country.
- (v) Upon the expiration of the Royalty Term with respect to a Licensed Product in a country, the license granted by Agios to Celgene pursuant to Section 8.1(a) shall be deemed to be fully paid-up, irrevocable and perpetual with respect to such Licensed Product in such country; provided that, notwithstanding Section 9.6(a), Celgene shall assume and be solely responsible (without deduction under Section 9.5(c)) for any amounts payable to Third Party licensors and Celgene shall be responsible for complying with the terms of any license agreements with such Third Party licensors, in each case, with respect to Celgene's exercise of such rights as to such Licensed Product in such country following the expiration of the Royalty Term.
- (c) <u>Deduction for Third Party Payments after Agios Opt-Out</u>. In the event that, following an Agios Opt-Out Date, royalties are payable by Celgene to Agios with respect to any Licensed Product under this Section 9.5, the Parties shall continue to be responsible for amounts payable to Third Party licensors under Existing Third Party Agreements as set forth in Section 9.6 (which amounts shall not be deductible from royalties as set forth in this Section 9.5(c))

and Celgene shall have the right to deduct from royalty payments otherwise due and payable by Celgene to Agios under this Section 9.5, on a Licensed Product-by-Licensed Product and country-by-country basis, a maximum of [**] percent ([**]%) of any royalties or other amounts actually paid by Celgene to a Third Party from and after the Agios Opt-Out Date with respect to any Subsequent Third Party Agreement, but only to the extent that the Patents or Know-How licensed under such Subsequent Third Party Agreement are necessary (i) to [**] the Target to which the applicable Licensed Product is directed or (ii) for the Development, Manufacture or Commercialization of such Licensed Product in a country(ies); provided that, on a Licensed Product-by-Licensed Product basis, any royalty deductions that are not credited against royalties for the Calendar Quarter in which they were accrued due to the limitation in the preceding proviso shall be carried forward and credited against royalties payable in subsequent Calendar Quarter(s) hereunder until such royalty credits are completely expended.

- (d) Royalty Reports; Payments. Within [**] after the end of each Calendar Quarter following the Agios Opt-Out Date, Celgene with respect to each Licensed Product shall provide Agios with a report stating the sales in units and in value of such Licensed Product made by Celgene, its Affiliates, and Licensee Partners, as applicable, on a country-by-country basis, together with the calculation of the royalties due to Agios, including the method used to calculate the royalties, the exchange rates used, and itemized deductions. Payments of all amounts payable under this Section 9.5 shall be made by Celgene to the bank account indicated by Agios concurrently with the delivery of such report.
- (e) <u>Cumulative Effect of Royalty Reductions</u>. In no event shall the royalty reductions described in this Section 9.5, alone or together, reduce the royalties payable by Celgene for a Licensed Product in a country in any given Calendar Quarter to less than [**] percent ([**]%) of the amounts otherwise payable by Celgene for such Calendar Quarter. Celgene may carry over and apply any such royalty reductions, which are incurred or accrued in a Calendar Quarter and are not deducted in such Calendar Quarter due to the limitation set forth above in this Section 9.5(e), to any subsequent Calendar Quarter(s) and shall begin applying such reduction to such royalties as soon as practicable and continue applying such reduction on a Calendar Quarterly basis thereafter until fully deducted, in all cases subject to the limitation set forth above in this Section 9.5(e).

Section 9.6 Third Party Payments.

(a) Existing Third Party Agreements. All royalties payable under the Existing Third Party Agreements, in the aggregate, on or after the Effective Date that (i) directly relate to a Licensed Product and (ii) in no event exceed [**] percent ([**]%) of worldwide Net Sales in the aggregate shall be shared as Development Costs if paid prior to the First Commercial Sale of such Licensed Product or Commercialization Expenses if paid thereafter and, for clarity, all royalties payable under the Existing Third Party Agreements in excess of [**] percent ([**]%) of worldwide Net Sales in the aggregate, and all non-royalty amounts payable under such Existing Third Party Agreements shall be paid by Agios (and in no event shall be included in the Profit or Loss Allocation).

- (b) Additional Agreements. After the Effective Date, if Celgene at any time or Agios before an Agios Opt-Out Notice believes that a license under Third Party Patents or Third Party Know-How, other than an Existing Third Party Agreement, could be necessary or useful to Develop, Manufacture or Commercialize the Licensed Products, then such Party shall notify (A) the JDC if such notice is provided during Development or Manufacturing of Licensed Products for Development or (B) the JCC if such notice is provided during Commercialization.
- (i) If the JDC or JCC, as applicable, agrees by unanimous vote to obtain such license, and if so, which of the Parties will do so, then the Parties will proceed as determined by the JDC or JCC, as applicable. If the JDC or JCC, as applicable, cannot agree on whether to obtain such license or which Party will do so, then the matter will be escalated to the JSC for resolution in accordance with Section 2.2; provided that, if the JSC cannot agree on which Party should obtain such license, then the Lead Party in the applicable Territory shall have the first right to obtain such license and if the applicable Lead Party does not promptly exercise such right then the other Party shall have the right to do so; provided, further, that, after an Agios Opt-Out Notice, Celgene shall have the sole right to obtain such license throughout the Territory.
- (ii) The costs of each such license (each, a "<u>Subsequent Third Party Agreement</u>") to the extent the costs directly relate to the Licensed Products shall be shared as Development Costs if paid prior to the First Commercial Sale of a Licensed Product or Commercialization Expenses if paid thereafter and, in the event of an Agios Opt-Out Date, shall be borne solely by Celgene to the extent incurred after the Agios Opt-Out Date, subject to deduction from royalties in accordance with Section 9.5(c).
- (iii) For purposes of this Agreement, the Third Party Patents and Third Party Know-How licensed pursuant to this Section 9.6(b) shall be deemed "Co-Co Collaboration Intellectual Property" of the Party obtaining such license.
- (iv) (1) The Party designated to pursue the Subsequent Third Party Agreement shall keep the other Party fully informed of the status of the negotiations with the Third Party and provide the other Party with copies of all draft agreements; (2) the other Party may provide comments and suggestions with respect to the negotiation of the agreement with the Third Party, and the Party seeking the Subsequent Third Party Agreement shall reasonably consider all comments and suggestions reasonably recommended by the other Party; and (3) the Party seeking the Subsequent Third Party Agreement shall obtain a license that is sublicensable to the other Party in accordance with the terms of this Agreement, treating (unless otherwise agreed by the Parties) the Third Party intellectual property as Co-Co Collaboration Intellectual Property hereunder and treating the agreement licensing such Third Party intellectual property in the same way as the Existing Third Party Agreement (including as provided in Section 8.5), except for payment obligations, which will be treated as provided in this Section 9.6.
- Section 9.7 <u>Financial Records</u>. The Parties shall keep, and shall require their respective Affiliates and sublicensees to keep, complete and accurate books and records in accordance with the applicable Accounting Standards. The Parties shall keep, and shall require their respective Affiliates and sublicensees to keep, such books and records for at least [**] following the end of the Calendar Year to which they pertain. Such books of accounts shall be kept at the principal place of business of the financial personnel with responsibility for preparing and maintaining such records. With respect to royalties, such records shall be in sufficient detail to support calculations of royalties due to Agios. Celgene and Agios shall also keep, and require

their respective Affiliates and sublicensees to keep, complete and accurate records and books of accounts containing all data reasonably required for the calculation and verification of Development Costs, including internal FTEs utilized by either Party, Profit or Loss and, if applicable, Annual Net Sales.

Section 9.8 Audits.

- (a) Audit Team. Each Party may, upon request and at its expense (except as provided for herein), cause an internationally recognized independent accounting firm selected by it (except one to whom the Auditee has a reasonable objection) (the "Audit Team") to audit during ordinary business hours the books and records of the other Party and the correctness of any payment made or required to be made to or by such Party, and any report underlying such payment (or lack thereof), pursuant to the terms of this Agreement. Prior to commencing its work pursuant to this Agreement, the Audit Team shall enter into an appropriate confidentiality agreement with the Auditee obligating the Audit Team to be bound by obligations of confidentiality and restrictions on use of such Confidential Information that are no less restrictive than the obligations set forth in Article XI.
- (b) <u>Limitations</u>. In respect of each audit of the Auditee's books and records: (i) the Auditee may be audited [**], (ii) no records for any given year for an Auditee may be audited more than [**]; <u>provided that</u> the Auditee's records shall still be made available if such records impact another financial year which is being audited, and (iii) the Audit Rights Holder shall only be entitled to audit books and records of an Auditee from the [**] prior to the Calendar Year in which the audit request is made.
- (c) <u>Audit Notice</u>. In order to initiate an audit for a particular Calendar Year, the Audit Rights Holder must provide written notice to the Auditee. The Audit Rights Holder exercising its audit rights shall provide the Auditee with notice of one or more proposed dates of the audit not less than [**]prior to the first proposed date. The Auditee will reasonably accommodate the scheduling of such audit. The Auditee shall provide such Audit Team(s) with full and complete access to the applicable books and records and otherwise reasonably cooperate with such audit.
- (d) <u>Payments</u>. If the audit shows any under-reporting or underpayment, or overcharging by any Party, that under-reporting, underpayment or overcharging shall be reported to the Audit Rights Holder and the underpaying or overcharging Party shall remit such underpayment or reimburse such overcompensation (together with interest at the rate set forth in Section 9.11) to the underpaid or overcharged Party within [**] after receiving the audit report. Further, if the audit for an annual period shows an under-reporting or underpayment or an overcharge by any Party for that period in excess of [**] percent ([**]%) of the amounts properly determined, the underpaying or overcharging Party, as the case may be, shall reimburse the applicable underpaid or overcharged Audit Rights Holder conducting the audit, for its respective audit fees and reasonable Out-of-Pocket Costs in connection with said audit, which reimbursement shall be made within [**] after receiving appropriate invoices and other support for such audit-related costs.

(e) <u>Definitions</u>. For the purposes of the audit rights described herein, an individual Party subject to an audit in any given year will be referred to as the "<u>Auditee</u>" and the other Party who has certain and respective rights to audit the books and records of the Auditee will be referred to as the "<u>Audit Rights Holder</u>."

Section 9.9 Tax Matters.

(a) <u>General</u>. The Parties acknowledge that the rights and obligations imposed on each of them pursuant to this Agreement that relate to the sharing of profits from the development and commercialization of the Licensed Products in the [US/ROW] Territory to the Compounds, Licensed Products and Companion Diagnostics and the collaborative relationship formed between them in connection therewith, gives rise to a partnership (whether deemed, constructive, imputed or similar) for US federal (and, to the extent applicable, state) income tax purposes (but not for any non-tax or non-US purpose), and the Parties shall act in accordance with Exhibit G.

(b) Withholding Taxes.

- (i) Each Party shall be entitled to deduct and withhold from any amounts payable under this Agreement (or allocable to another Party pursuant to Article IV of Exhibit G) such taxes as are required to be deducted or withheld therefrom under any provision of applicable Law. The Party that is required to make such withholding (the "Paying Party") will: (A) deduct those taxes from such payment, (B) timely remit the taxes to the proper taxing authority, and (C) send evidence of the obligation together with proof of tax payment to the recipient Party (the "Payee Party") on a timely basis following that tax payment; provided, however, that before making any such deduction or withholding, the Paying Party shall give the Payee Party notice of the intention to make such deduction or withholding (and such notice, which shall set forth in reasonable detail the authority, basis and method of calculation for the proposed deduction or withholding, shall be given at least a reasonable period of time before such deduction or withholding is required, in order for such Payee Party to obtain reduction of or relief from such deduction or withholding). Each Party agrees to cooperate with the other Parties in claiming refunds or exemptions from such deductions or withholdings under any relevant agreement or treaty or other applicable Law which is in effect to ensure that any amounts required to be withheld pursuant to this 9.9(b) are reduced in amount to the fullest extent permitted by applicable Law. In addition, the Parties shall cooperate in accordance with applicable Laws to minimize [**] in connection with this Agreement, as applicable.
- (ii) <u>Tax Documentation</u>. Each Party has provided a properly completed and duly executed IRS Form W-9 or applicable Form W-8 to the other Parties. Each Party and any other recipient of payments under this Agreement shall provide to the other Party, at the time or times reasonably requested by such other Parties or as required by applicable Law, such other properly completed and duly executed documentation as will permit payments made under this Agreement to be made without, or at a reduced rate of, withholding for taxes, and the applicable payment shall be made without (or at a reduced rate of) withholding to the extent permitted by such documentation, as reasonably determined by the Paying Party.

Section 9.10 Currency Exchange; Blocked Payments; Prohibitions on Payments.

- (a) <u>Currency Exchange</u>. Unless otherwise expressly stated in this Agreement, all amounts specified in, and all payments made under, this Agreement shall be in United States Dollars. If any currency conversion shall be required in connection with the calculation of amounts payable under this Agreement, such conversion shall be performed in a manner consistent with the paying Party's normal practices used to prepare its audited financial statements for internal and external reporting purposes. For clarity, Celgene sets currency transaction rates for the month on the last business day of the month prior. Agios has the right to verify that the exchange rates used by Celgene for a given month are within the trading range of the last business day of the month prior.
- (b) <u>Blocked Payments</u>. In the event that, by reason of applicable Law in any country, it becomes impossible or illegal for the paying Party (or any of its Affiliates or Licensee Partners) to transfer, or have transferred on its behalf, payments owed the other Party hereunder, the paying Party will promptly notify the other Party of the conditions preventing such transfer and such payments will be deposited in local currency in the relevant country to the credit of the other Party in a recognized banking institution designated by the other Party or, if none is designated by the other Party within a period of [**], in a recognized banking institution selected by the paying Party or any of its Affiliates or its Licensee Partners, as the case may be, and identified in a written notice given to the other Party.
- (c) <u>Prohibitions on Payments</u>. When in any country in the Territory applicable Law prohibits 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.
- Section 9.11 <u>Late Payments</u>. The paying Party shall pay interest to the receiving Party on the aggregate amount of any payments that are not paid on or before the date such payments are due under this Agreement at a rate per annum equal to the lesser of the [**], or the highest rate permitted by applicable Law, calculated on the number of days such payments are paid after the date such payments are due; <u>provided that</u>, with respect to any disputed payments, no interest payment shall be due until such dispute is resolved and the interest which shall be payable thereon shall be based on the finally-resolved amount of such payment, calculated from the original date on which the disputed payment was due through the date on which payment is actually made.

Article X Intellectual Property Ownership, Protection and Related Matters

Section 10.1 Ownership of Inventions.

(a) <u>Non-Co-Co Collaboration Know-How</u>. Any Know-How developed or generated by Celgene or Agios prior to or outside the Collaboration shall remain the sole property of such Party.

- (b) <u>Sole Inventions</u>. All Co-Co Collaboration Know-How developed or generated solely by employees, agents and consultants of a Party shall be owned exclusively by such Party.
- (c) <u>Joint Inventions</u>. All Co-Co Collaboration Know-How developed or generated jointly by employees, agents and consultants of Celgene, on the one hand, and employees, agents and consultants of Agios, on the other hand, in the conduct of activities under this Agreement ("<u>Joint Inventions</u>" and, any Patents Covering such Joint Inventions, "<u>Joint Patents</u>") shall be owned jointly on the basis of each Party having an undivided interest without a duty to account to the other Party and shall be deemed to be Controlled by each Party. Each Party shall have the right to use such Joint Inventions, or license such Joint Inventions to its Affiliates or any Third Party, or sell or otherwise transfer its interest in such Joint Inventions to its Affiliates or a Third Party, in each case without the consent of the other Party (and, to the extent that applicable Law requires the consent of the other Party, this Section 10.1(c) shall constitute such consent), so long as such use, sale, license or transfer is subject to Section 8.6 and the licenses granted pursuant to this Agreement and is otherwise consistent with this Agreement.
- (d) <u>Notice</u>. Each Party agrees to provide regular quarterly written reports disclosing to the other Party all Co-Co Collaboration Intellectual Property developed or generated by employees, agents and consultants of such Party and all Agios Intellectual Property and Celgene Intellectual Property that becomes subject to this Agreement, which disclosures may be made in connection with the updates made in accordance with Section 3.1(f).
- (e) <u>Inventorship</u>. The determination of inventorship shall be made in accordance with United States patent laws. In the event of a dispute regarding inventorship, if the Parties are unable to resolve the dispute, the Parties shall jointly engage mutually acceptable independent patent counsel not regularly employed by either Party to resolve such dispute. The decision of such independent patent counsel shall be binding on the Parties with respect to the issue of inventorship.
- (f) <u>Further Actions and Assignments</u>. Each Party shall take all further actions and execute all assignments requested by the other Party and reasonably necessary or desirable to vest in the other Party the ownership rights set forth in this Article X.
- Section 10.2 <u>Prosecution of Patents</u>. Subject to the terms and conditions of any Existing Third Party Agreement or Subsequent Third Party Agreement to the extent such agreement applies to the Agios Patents, Agios Co-Co Collaboration Patents, Celgene Patents or Celgene Collaboration Patents, the following provisions shall apply with respect to the Agios Patents, Celgene Patents, Celgene Collaboration Patents, Agios Co-Co Collaboration Patents and Joint Collaboration Patents in the Territory:
- (a) <u>Lead US Party</u>. Subject to the provisions of Section 10.2(f) and coordination with the JPC, the Lead US Party (or, in the event of any Agios Opt-Out, Celgene) shall have the initial right and option to Prosecute the [**]. In the event that the Lead US Party declines to Prosecute such Patents, it shall give the other Party reasonable notice to this effect,

sufficiently in advance to permit the other Party to undertake such Prosecution in any applicable country without a loss of rights, and thereafter the other Party may, upon written notice to the Lead US Party, Prosecute such Patents in the owning Party(ies)'s name(s) subject to coordination with the JPC.

- (b) <u>Celgene</u>. Celgene shall have the sole right and option to Prosecute the [**].
- (c) <u>Costs and Expenses</u>. The Parties shall jointly bear all costs and expenses in Prosecuting Agios Patents, Agios Co-Co Collaboration Patents, Celgene Collaboration Patents and Joint Collaboration Patents (collectively, "<u>Patent Prosecution Expenses</u>") as either Development Costs (to the extent incurred for any country or jurisdiction prior to the First Commercial Sale of the Licensed Product in the country or jurisdiction to which the Patents relate) or Commercialization Expenses (if incurred after First Commercial Sale of the Licensed Product in such country or jurisdiction); <u>provided, however, that</u>, in the event of an Agios Opt-Out Date, all such Patent Prosecution Expenses incurred by Celgene following the Agios Opt-Out Date shall be borne solely by Celgene.
 - (d) Strategy; Failure of JPC to Agree; Diligence and Cooperation.
- (i) The JPC shall attempt to agree upon a strategy (which may be updated from time to time) for Prosecution of Agios Patents, Celgene Collaboration Patents, Agios Co-Co Collaboration Patents and Joint Collaboration Patents, including the scope and priority of the claims to be pursued within such Patents and to maximize the value of such Patents, on a global basis. Any failure by the JPC to agree by unanimous vote with respect to such strategy or any other Prosecution matter will be attempted to be resolved as specified in Section 2.2(e), and if such attempt fails, then the Party conducting Prosecution (the "Prosecuting Party") may resolve such matter. The Prosecuting Party with respect to each such Patent shall follow such strategy in connection with all Prosecution of such Patents unless the JPC approves of a divergence from such strategy (with any failure by the JPC to agree by unanimous vote to be resolved in accordance with Section 2.2(e) and the foregoing sentence).
- (ii) The Prosecuting Party shall be entitled to use patent counsel selected by it and reasonably acceptable to the non-Prosecuting Party (including in-house patent counsel as well as outside patent counsel) for the Prosecution of the Patents Rights subject to Section 10.2(a) and Section 10.2(b). Each Party agrees to cooperate with the other with respect to the Prosecution of such Patents pursuant to this Section 10.2, including (X) executing all such documents and instruments and performing such acts as may be reasonably necessary in order to permit the other Party to undertake any Prosecution of Patents that such other Party is entitled, and has elected, to Prosecute, as provided for in Section 10.2(a) and Section 10.2(b) and (Y) giving consideration to the proper scope of Patents. The Prosecuting Party shall:
- (A) use Commercially Reasonable Efforts to regularly provide the JPC in advance with reasonable information relating to the Prosecuting Party's Prosecution of Patents hereunder, including by providing copies of substantive communications, notices and actions submitted to or received from the relevant patent authorities and copies of drafts of filings and correspondence that the Prosecuting Party proposes to submit to such patent authorities, each of which shall be provided as far in advance as is practicable but with sufficient time for the non-Prosecuting party to provide meaningful input;

- (B) use Commercially Reasonable Efforts to consider in good faith and consult with the non-Prosecuting Party regarding its timely comments with respect to the same;
- (C) 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 reasonably requested by the non-Prosecuting Party; and
- (D) consult with the JPC and non-Prosecuting Party before taking any action that would have a material adverse impact on the scope of claims within the Agios Patents, Celgene Collaboration Patents or Agios Co-Co Collaboration Patents (including the Joint Collaboration Patents), as applicable.
- (iii) The JPC shall determine the countries in which Agios Patents, Celgene Collaboration Patents and Agios Co-Co Collaboration Patents (including Joint Collaboration Patents) shall be Prosecuted, with the understanding that the countries set forth on Exhibit E of this Agreement shall generally form the basis for the overall Prosecution strategy for such Patents and that any failure of the JPC to determine such countries by unanimous vote will be resolved as provided in clause (i) of this Section 10.2(d). Further, the Prosecuting Party shall consult with the JPC well in advance of PCT national phase and Paris Convention deadlines as to additional countries (if any) in which the JPC or non-Prosecuting Party desires that the Agios Patents, Celgene Collaboration Patents and Agios Co-Co Collaboration Patents (including Joint Collaboration Patents) be Prosecuted.
- (iv) The Prosecuting Party agrees not to abandon the subject matter of a claim in an Agios Patent, Celgene Collaboration Patent, Agios Co-Co Collaboration Patent or Joint Collaboration Patent or narrow such claim except in response to an office action from the applicable patent office that, in the Prosecuting Party's reasonable judgment after consultation with the non-Prosecuting Party, requires such abandonment or narrowing; <u>provided that</u>, prior to such abandonment or narrowing, if feasible, the Parties will co-operate to file divisional or continuation applications to separate such claim.
- (e) Third Party Rights. Agios covenants and agrees that it shall not grant any Third Party any right to control the Prosecution of the Agios Patents or Agios Co-Co Collaboration Patents or to approve or consult with respect to any Patents licensed to Celgene hereunder, in any case, that is more favorable to the Third Party than the rights granted to Celgene hereunder or that otherwise conflicts with Celgene's rights hereunder. Celgene covenants and agrees that it shall not grant any Third Party any right to control the Prosecution of the Celgene Collaboration Patents or to approve or consult with respect to the Celgene Collaboration Patents licensed to Agios hereunder, in any case, that is more favorable to the Third Party than the rights granted to Agios hereunder or that otherwise conflicts with Agios' rights hereunder.

- Subsequent Third Party Agreement, the applicable licensor(s) thereunder may retain the right to Prosecute the Agios Patents, Agios Co-Co Collaboration Patents or Celgene Collaboration Patents covered by such agreement; provided that Agios or Celgene, as applicable, may have certain rights to assume Prosecution under such agreement. Agios and Celgene, as applicable, each agrees to keep the other Party fully informed of these rights, as well as provide to the other Party all information and copies of documents received from the licensor(s) under any such Existing Third Party Agreement or Subsequent Third Party Agreement, or their patent counsel, relating to the Agios Patents, Agios Co-Co Collaboration Patents or Celgene Collaboration Patents covered by such agreement. To the extent that Agios or Celgene, as applicable, is permitted to proceed with Prosecution or provide comments or suggestions to patent documents under an Existing Third Party Agreement or Subsequent Third Party Agreement, then the Agios Patents, Agios Co-Co Collaboration Patents or Celgene Collaboration Patents under such Existing Third Party Agreement or Subsequent Third Party Agreement shall be treated in the same manner as other Agios Patents, Agios Co-Co Collaboration Patents or Celgene Collaboration Patents under this Section 10.2, and Agios or Celgene, as applicable, shall exercise all such rights with respect to such Agios Patents, Agios Co-Co Collaboration Patents or Celgene Collaboration Patents pursuant to the instructions of the other Party, if the other Party is given the right to act under this Section 10.2.
- Section 10.3 Third Party Infringement of Agios Patents, Celgene Collaboration Patents and Agios Co-Co Collaboration Patents. Subject to the terms and conditions of any Existing Third Party Agreement or Subsequent Third Party Agreement to the extent such agreement applies to the Agios Patents, Agios Co-Co Collaboration Patents or Celgene Collaboration Patents, the following provisions shall apply with respect to the Agios Patents, Agios Co-Co Collaboration Patents, Celgene Collaboration Patents, Joint Collaboration Patents, Agios Know-How, Agios Co-Co Collaboration Know-How, Celgene Collaboration Know-How and Joint Collaboration Know-How:
- (a) Notice. Each Party shall immediately provide the other Party with written notice reasonably detailing any (i) known or alleged infringement of any Agios Patents, Celgene Patents, Celgene Collaboration Patents, Agios Co-Co Collaboration Patents or Joint Collaboration Patents, or known or alleged misappropriation of any Agios Know-How, Celgene Know-How, Celgene Collaboration Know-How, Agios Co-Co Collaboration Know-How or Joint Collaboration Know-How, by a Third Party, (ii) "patent certification" filed in the United States under 21 U.S.C. §355(b)(2) or 21 U.S.C. §355(j)(2) or similar provisions in other jurisdictions, and (iii) any declaratory judgment, opposition, or similar action alleging the invalidity, unenforceability or non-infringement of any such intellectual property rights (collectively "Third Party Infringement").
- (b) <u>First Right to Initiate Infringement Actions</u>. Each Party shall have the initial right [**], but not the obligation, to initiate a suit or take other appropriate action that such Party believes is reasonably required to protect the Agios Intellectual Property, Celgene Intellectual Property, Celgene Collaboration Intellectual Property, Agios Co-Co Collaboration Intellectual Property or Joint Collaboration IP against the infringement in such part of the Territory, including Third Party Infringement, unauthorized use or misappropriation by a Third Party that relates to a Licensed Product, which, in the case of a Companion Diagnostic, shall

mean Third Party Infringement, unauthorized use or misappropriation in connection with a Companion Diagnostic in the [IO Field/I&I Field] *[identify applicable field prior to execution]* (as defined in the Master Agreement) ("Competitive Infringement"); provided, however, that if [**], Celgene rather than Agios shall have such initial right as to Celgene Intellectual Property [**]. The Party having such initial right under the preceding sentence ("Initial Enforcement Party") shall give the other Party advance notice of the Initial Enforcement Party's intent to file any such suit or take any such action and the reasons therefor, and shall provide the other Party with an opportunity to make suggestions and comments regarding such suit or action. Thereafter, the Initial Enforcement Party shall keep the other Party promptly informed, and shall from time to time consult with the other Party regarding the status of any such suit or action and shall provide the other Party with copies of all material documents (e.g., complaints, answers, counterclaims, material motions, orders of the court, memoranda of law and legal briefs, interrogatory responses, depositions, material pre-trial filings, expert reports, affidavits filed in court, transcripts of hearings and trial testimony, trial exhibits and notices of appeal) filed in, or otherwise relating to, such suit or action. Without limiting the generality of the foregoing, the Parties shall discuss in good faith the Initial Enforcement Party's intended response to a Competitive Infringement.

- (c) <u>Preparation to Enforce</u>. After the First Commercial Sale of a Licensed Product in the US Territory or the ROW Territory, as applicable, subject to coordination with the JPC, the Initial Enforcement Party for such part of the Territory shall use reasonable efforts to prepare for the possibility of suit for Competitive Infringement starting [**] after such First Commercial Sale. Such preparation includes identifying and retaining experts, selecting and retaining outside counsel, having outside counsel conduct a pre-litigation diligence investigation into potential validity and unenforceability arguments, data and document collection and review, and other actions reasonably capable of being conducted before initiation of any such litigation.
- Section 10.3(b) above within [**] after becoming aware of the Competitive Infringement, then the other Party may, in its discretion, provide the Initial Enforcement Party with written notice of such Party's intent to initiate a suit or take other appropriate action to combat such Competitive Infringement. If the Party with such step-in rights under the preceding sentence ("Step-In Enforcement Party") provides such notice and the Initial Enforcement Party fails to initiate a suit or take such other appropriate action within [**] after receipt of such notice from the Step-In Enforcement Party, then the Step-In Enforcement Party shall have the right, but not the obligation, to initiate a suit or take other appropriate action that it believes is reasonably required to protect the applicable Agios Intellectual Property, Celgene Intellectual Property, Celgene Collaboration Intellectual Property, Agios Co-Co Collaboration Intellectual Property or Joint Collaboration IP from Competitive Infringement. The Step-In Enforcement Party shall give the Initial Enforcement Party advance notice of the Step-In Enforcement Party with an opportunity to make suggestions and comments regarding such suit or action. Thereafter, the Step-In Enforcement Party shall keep the Initial Enforcement Party promptly informed and shall from time to time consult with the Initial Enforcement Party regarding the status of any such suit or action and shall provide the Initial Enforcement Party with copies of all material documents (e.g.,

complaints, answers, counterclaims, material motions, orders of the court, memoranda of law and legal briefs, interrogatory responses, depositions, material pre-trial filings, expert reports, affidavits filed in court, transcripts of hearings and trial testimony, trial exhibits and notices of appeal) filed in, or otherwise relating to, such suit or action.

- (e) Conduct of Action; Costs. The Party initiating suit shall have the sole and exclusive right to select counsel for any suit initiated by it under this Section 10.3, which counsel must be reasonably acceptable to the other Party. If required under applicable Law in order for such Party to initiate or maintain such suit, the other Party shall join as a party to the suit. If requested by the Party initiating suit, the other Party shall provide reasonable assistance to the Party initiating suit in connection therewith at no charge to such Party except that the initiating Party shall reimburse the other Party for Out-of-Pocket Costs, other than outside counsel expenses, incurred in rendering such assistance. The Party initiating suit shall assume and pay all of its own Out-of-Pocket Costs incurred in connection with any litigation or proceedings described in this Section 10.3, including the fees and expenses of the counsel selected by it, provided that, prior to the Agios Opt-Out Date, if any, such fees and expenses shall be included in the calculation of Development Costs (if incurred in any country or jurisdiction) or Commercialization Expenses (if incurred after the First Commercial Sale of a Licensed Product in such country or jurisdiction). The other Party shall have the right to participate and be represented in any such suit by its own counsel at its own expense (and which shall not be a Patent and Trademark Enforcement Cost or other cost that is a factor in the calculation of Profit or Loss).
- (f) <u>Recoveries</u>. Any recovery obtained as a result of any proceeding described in this Section 10.3 or from any counterclaim or similar claim asserted in a proceeding described in Section 10.4, by settlement or otherwise, shall be applied in the following order of priority:
- (i) first, the Party initiating the suit or action shall be reimbursed for all previously unreimbursed (or not otherwise included in the calculation of Development Costs or Commercialization Expenses) Out-of-Pocket Costs in connection with such proceeding; and
- (ii) second, any remainder shall be (A) treated as Additional Revenue, if obtained before the Agios Opt-Out Date, if any; or (B) paid [**] percent ([**]%) to the Party initiating the suit or action, and [**] percent ([**]%) to the other Party, if obtained on or after the Agios Opt-Out Date, if any.
- (g) <u>Third Party Agreements</u>. In the event that (i) a Patent covered by an Existing Third Party Agreement or Subsequent Third Party Agreement is at issue in an action under this Section 10.3 or Section 10.4, (ii) Agios or Celgene, as applicable, has a right to enforce the Agios Patents, Agios Co-Co Collaboration Patents or Celgene Collaboration Patents under such Existing Third Party Agreement or Subsequent Third Party Agreement, and (iii) Celgene or Agios, respectively, desires to enforce such Patent in accordance with the procedures under this Section 10.3 or Section 10.4, as applicable, then Agios or Celgene, respectively, shall either (A) obtain the licensor(s)' consent under such Existing Third Party Agreement or Subsequent Third Party Agreement so that Celgene or Agios, respectively, may file such an action in its own name or (B) shall undertake such an action on Celgene's behalf and at Celgene's expense or on Agios' behalf and at Agios' expense, respectively.

Section 10.4 Claimed Infringement; Claimed Invalidity.

- (a) <u>Infringement of Third Party Rights</u>. Each Party shall promptly notify the other Party in writing of any allegation by a Third Party that the activity of either Party or their Affiliates or Licensee Partners under this Agreement infringes or may infringe the intellectual property rights of such Third Party. If a Third Party asserts or files against a Party or its Affiliates any claim of infringement of the intellectual property rights of such Third Party or other action relating to alleged infringement of such intellectual property rights ("<u>Third Party Infringement Action</u>"), then, unless otherwise agreed by the Parties:
- (i) In the event of a Third Party Infringement Action against a single Party, the unnamed Party shall have the right, in the unnamed Party's sole discretion, to participate in the defense of such legal action with legal counsel selected by the unnamed Party and reasonably acceptable to the named Party (the costs of which shall not be a Patent and Trademark Enforcement Cost or other cost that is a factor in the calculation of Profit or Loss). The Party named in such Third Party Infringement Action shall have the right to control the defense of the action, but shall notify and keep the unnamed Party apprised in writing of such action and shall consider and take into account the unnamed Party's reasonable interests and requests and suggestions regarding the defense of such action. In the event of a Third Party Infringement Action against both Parties, the Parties shall attempt to mutually agree as to which Party shall control the defense of such Third Party Infringement Action; provided that, in the event of the failure of the Parties to so mutually agree, [**] in which the suit arises shall have the right to control the defense of such Third Party Infringement Action.
- (ii) The non-controlling Party of a Third Party Infringement Action shall reasonably cooperate with the controlling Party in the preparation and formulation of a defense to such Third Party Infringement Action, and in taking other steps reasonably necessary to respond to such Third Party Infringement Action. The controlling Party shall have the right to select its counsel for the defense to such Third Party Infringement Action, which counsel must be reasonably acceptable to the non-controlling Party if both Parties have been named as defendants in the action. The non-controlling Party shall also have the right to participate and be represented in any such suit by its own counsel at its own expense (and which shall not be a Patent and Trademark Enforcement Cost or other cost that is a factor in the calculation of Profit or Loss). The controlling Party shall not (and shall cause its Affiliates and Licensee Partners not to) either (A) admit infringement, validity or enforceability of the asserted intellectual property rights, (B) pay any amount of money in settlement thereof, unless the controlling Party does not claim the payment as a Patent and Trademark Enforcement Cost or other cost that is a factor in the calculation of Profit or Loss, or (C) enter into a license for the asserted intellectual property rights upon terms that would restrict either Party from fully exploiting such rights consistently with the scope of the rights and obligations of both Parties under this Agreement, in each case (A) through (C), without the written consent of the non-controlling Party, which will not be unreasonably withheld, conditioned or delayed. For the avoidance of doubt, except as provided in the foregoing clause (B), the costs of such defense and settlement (if approved by the non-controlling Party) shall be deemed Patent and Trademark Enforcement Costs that are factored into the calculation of Profit or Loss.

- (iii) If the Party entitled to control the defense under Section 10.4(a)(i) or (ii) fails to proceed in a timely manner with respect to such defense, the other Party shall have the right to control the defense of such claim upon the same conditions set forth therein.
- (iv) If requested by the Party controlling the defense, the Parties shall enter into a joint defense agreement that further outlines their rights and responsibilities consistent with the terms of this Section or as otherwise mutually agreed.
- (b) Patent Invalidity Claim. If a Third Party at any time asserts a claim that any issued Agios Patent, Celgene Collaboration Patent or Agios Co-Co Collaboration Patent (including Joint Collaboration Patents) is invalid or otherwise unenforceable (an "Invalidity Claim"), whether as a defense in an infringement action brought by Agios or Celgene pursuant to Section 10.3(b) or (d), in a declaratory judgment action or in a Third Party Infringement claim brought against Agios or Celgene, the Parties shall cooperate with each other in preparing and formulating a response to such Invalidity Claim; provided that, subject to the terms and conditions of any Existing Third Party Agreement or Subsequent Third Party Agreement to the extent such agreement applies to such Agios Patent, Agios Co-Co Collaboration Patent or Celgene Collaboration Patent, the Party who has (or would have) control over litigation pursuant to Section 10.3(b) or (d) shall have the sole right to control the defense and settlement of any such Invalidity Claim as if it were litigation initiated therein. For the avoidance of doubt, any claim asserted against any Agios Patent, Celgene Collaboration Patent or Agios Co-Co Collaboration Patent before any such Patent is issued is deemed a Prosecution matter that is the subject of Section 10.2.
- Section 10.5 <u>Patent Term Extensions</u>. The JPC shall, as necessary and appropriate, use reasonable efforts to agree upon a joint strategy for obtaining, and cooperate with each other in obtaining, patent term extensions for Agios Patents, Agios Co-Co Collaboration Patents, Celgene Collaboration Patents and Joint Collaboration Patents that Cover Licensed Products. If the JPC is unable to agree upon which of such Patents should be extended, and the matter remains unresolved after the procedure described in Section 2.2(e), then [**] shall have the right to resolve the dispute, subject in each case to the terms and conditions of any Existing Third Party Agreement or Subsequent Third Party Agreement to the extent such agreement applies to such Agios Patent, Agios Co-Co Collaboration Patent or Celgene Collaboration Patent.
- Section 10.6 <u>Patent Marking</u>. Each Party shall comply with the patent marking statutes in each country in which the Licensed Product is Manufactured or Commercialized by or on behalf of a Party or their respective Affiliates or sublicensees, as applicable, hereunder.

Section 10.7 <u>Application of 35 U.S.C. § 102(c)</u> It is agreed and acknowledged that this Agreement establishes a qualifying collaboration within the scope of 35 U.S.C. § 102(c) and, accordingly, shall be deemed to constitute a "Joint Research Agreement" for all purposes under 35 U.S.C. § 102(c). Neither Party shall invoke the provisions of 35 U.S.C. § 102(c), or file this Agreement, in connection with the prosecution of any patent application claiming, in whole or in part, any 35 U.S.C. § 102(c) invention without the prior written consent of the other Party. In the

event that a Party, during the course of prosecuting a patent application claiming a 35 U.S.C. § 102(c) invention (a "35 U.S.C. § 102(c) Patent"), deems it necessary to file a terminal disclaimer to overcome an obviousness type double patenting rejection in view of an earlier filed patent held by the other Party (the "Earlier Patent"), then, if the Parties agree, the Parties shall coordinate the filing of such terminal disclaimer in good faith, and, to the extent required under 35 U.S.C. § 102(c), both Parties shall agree, in such terminal disclaimer, that they shall not separately enforce 35 U.S.C. § 102(c) Patent independently from the Earlier Patent. To this end, to the extent required under 35 U.S.C. § 102(c), following the filing of such terminal disclaimer, the Parties shall, in good faith, coordinate all enforcement actions with respect to 35 U.S.C. § 102(c) Patent.

Article XI Confidentiality

- Section 11.1 <u>Confidential Information</u>. Each Party agrees that a Party (the "<u>Receiving Party</u>") receiving Confidential Information of any other Party (the "<u>Disclosing Party</u>") shall (a) maintain in confidence such Confidential Information using not less than the efforts such Receiving Party uses to maintain in confidence its own proprietary information of similar kind and value, but in no event less than a reasonable degree of effort, (b) not disclose such Confidential Information to any Third Party without the prior written consent of the Disclosing Party, except for disclosures expressly permitted below, and (c) not use such Confidential Information for any purpose except those permitted by this Agreement (it being understood that this clause (c) shall not create or imply any rights or licenses not expressly granted under this Agreement). All Confidential Information of the Disclosing Party shall not be used by the Receiving Party except in performing its obligations or exercising rights explicitly granted under this Agreement, except to the extent that the Confidential Information:
- (a) was known by the Receiving Party or its Affiliates prior to its date of disclosure to the Receiving Party, as established by written evidence; or
- (b) 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) becomes published or generally known to the public 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 such Confidential Information, as established by written records.
 - Section 11.2 <u>Permitted Disclosure</u>. The Receiving Party may provide the Disclosing Party's Confidential Information:
- (a) to the Receiving Party's respective employees, consultants and advisors, and to the employees, consultants and advisors of such Party's Affiliates, who have a need to know such information and materials for performing obligations or exercising rights expressly granted under this Agreement and have an obligation to treat such information and materials as confidential;

- (b) to patent offices in order to seek or obtain Patents or to Regulatory Authorities in order to seek or obtain approval to conduct Clinical Trials or to gain Regulatory Approval with respect to the Licensed Products as contemplated by this Agreement; provided that such disclosure may be made only following reasonable notice to the Disclosing Party and to the extent reasonably necessary to seek or obtain such Patents or Regulatory Approvals; or
- (c) if such disclosure is required by judicial order or applicable Law or to defend or prosecute litigation or arbitration; <u>provided that</u>, prior to such disclosure, to the extent permitted by Law, the Receiving Party promptly notifies the Disclosing Party of such requirement, cooperates with the Disclosing Party to take whatever action it may deem appropriate to protect the confidentiality of the information and furnishes only that portion of the Disclosing Party's Confidential Information that the Receiving Party is legally required to furnish.

Section 11.3 Publicity; Terms of this Agreement; Non-Use of Names.

(a) Public Announcements. Except as required by judicial order or applicable Law (in which case, Section 11.3(b) must be complied with) or as explicitly permitted by this Article XI, neither Party shall make any public announcement concerning this Agreement without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed. The Party preparing any such public announcement shall provide the other Party with a draft thereof at least [**] prior to the date on which such Party would like to make the public announcement (or, in extraordinary circumstances, such shorter period as required to comply with applicable Law). Notwithstanding the foregoing, the Parties shall issue a press release, in the form attached as Exhibit F to this Agreement within [**] after the Effective Date. Neither Party shall use the name, trademark, trade name or logo of the other Party or its employees in any publicity or news release relating to this Agreement or its subject matter, without the prior express written permission of the other Party. For purposes of clarity, either Party may issue a press release or public announcement or make such other disclosure relating to this Agreement if the contents of such press release, public announcement or disclosure (i) (A) does not consist of financial information and has previously been made public other than through a breach of this Agreement by the issuing Party or its Affiliates, (B) is contained in such Party's financial statements prepared in accordance with Accounting Standards, or (C) is contained in the a redacted version of this Agreement, and (ii) is material to the event or purpose for which the new press release or public announcement is made.

(b) Notwithstanding the terms of this Article XI:

(i) Either Party shall be permitted to disclose the existence and terms of this Agreement to the extent required, in the reasonable opinion of such Party's legal counsel, to comply with applicable Laws, including the rules and regulations promulgated by the Securities and Exchange Commission or any other governmental authority. Notwithstanding the foregoing, before disclosing this Agreement or any of the terms hereof pursuant to this Section 11.3(b)(i), the Parties will coordinate in advance with each other in connection with the redaction of certain provisions of this Agreement with respect to any filings with the US Securities and Exchange Commission ("SEC"), London Stock Exchange, the UK Listing Authority, NYSE, the NASDAQ Stock Market or any other stock exchange on which securities issued by a Party or a

Party's Affiliate are traded (the "Redacted Version"), and each Party will use commercially reasonable efforts to seek confidential treatment for such terms as may be reasonably requested by the other Party; provided that the Parties will use commercially reasonable efforts to file redacted versions with any governing bodies which are consistent with the Redacted Version.

- (ii) Notwithstanding Section 11.1, the Receiving Party may disclose Confidential Information belonging to the Disclosing Party, and Confidential Information deemed to belong to both the Disclosing Party and the Receiving Party, to the extent (and only to the extent) such disclosure is reasonably necessary in the following instances:
- (A) subject to Section 11.3(a), complying with applicable Laws (including the rules and regulations of the SEC or any national securities exchange) and with judicial process, if in the reasonable opinion of the Receiving Party's counsel, such disclosure is necessary for such compliance;
- (including attorneys and accountants), (2) subject to Section 11.3(b)(ii)(C), investment bankers, and (3) in each case of (1) and (2), their and each of the Parties' respective directors, employees, contractors and agents; provided that, in all cases of (1), (2) and (3), prior to any such disclosure, each disclosee must be bound by written obligations of confidentiality, non-disclosure and non-use no less restrictive than the obligations set forth in this Article XI (provided, however, that in the case of prospective investment bankers, the term of confidentiality may be [**] from the date of disclosure and in the case of legal advisors, no written agreement shall be required), which for the avoidance of doubt, will not permit use of such Confidential Information for any purpose except those permitted by this Agreement; provided, however, that, in each of the above situations, the Receiving Party shall remain responsible for any failure by any Person who receives Confidential Information pursuant to this Section 11.3(b)(ii)(B) to treat such Confidential Information as required under this Article XI; and
- (C) in the case of any disclosure of this Agreement to any actual or potential acquirer, assignee, licensee, licensor, investment banker, institutional investor, lender or other financial partners, such disclosure shall solely be [**]; it being understood and agreed that, in connection with a proposed [**] with respect to such Party, only [**] this Agreement as applicable, to such Third Party; provided that a Party may also disclose an unredacted version of this Agreement to Third Party attorneys, professional accountants and auditors who are engaged by licensors and lenders and who are under obligations of confidentiality not to disclose the unredacted terms of this agreement to such licensors or lenders for the purpose of confirming such Party's compliance with the terms of its applicable license and loan agreements with such licensors and lenders.
- (iii) [**]. Such disclosures may include achievement of milestones, significant events in the development and regulatory process, commercialization activities and the like. In addition to the initial press release described in Section 11.3(a), a Party (the "Requesting Party") may elect to make any such public disclosure of such achievement of milestones, significant events in the development and regulatory process and commercialization activities, and in such event it shall first notify the other Party (the "Cooperating Party") of such

planned press release or public announcement and provide a draft for review at least [**] in advance of issuing such press release or making such public announcement (or, with respect to press releases and public announcements that are required by applicable Law, or by regulation or rule of any public stock exchange (including NASDAQ), with as much advance notice as possible under the circumstances if it is not possible to provide notice at least [**] in advance); provided, however, that a Party may issue such press release or public announcement without such prior review by the other Party if (A) the contents of such press release or public announcement have previously been made public other than through a breach of this Agreement by the issuing Party and (B) such press release or public announcement does not materially differ from the previously issued press release or other publicly available information. The Cooperating Party may notify the Requesting Party of any reasonable objections or suggestions that the Cooperating Party may have regarding the proposed press release or public announcement, and the Requesting Party shall reasonably consider any such objections or suggestions that are provided in at timely manner. The principles to be observed in such disclosures shall include accuracy, compliance with applicable Law and regulatory guidance documents, reasonable sensitivity to potential negative reactions of the FDA (and its foreign counterparts) and the need to keep investors informed regarding the Requesting Party's business.

- Section 11.4 <u>Publications</u>. The Parties agree that decisions regarding the timing and content of Publications shall be subject to the oversight and approval of the JSC and JPC and neither Party nor its Affiliates shall have the right to make Publications pertaining to the Collaboration except as provided herein. If a Party or its Affiliates desire to make a Publication, such Party must comply with the following procedure:
- (a) <u>JSC Review</u>. The publishing Party shall provide the JSC and the non-publishing Party with an advance copy of the proposed Publication, and the JSC shall then have [**] prior to submission for any Publication ([**] in the case of an abstract or oral presentation) in which to determine whether the Publication may be published and under what conditions, including (i) delaying sufficiently long to permit the timely preparation and filing of a patent application or (ii) specifying changes the JSC reasonably believes are necessary to preserve any Patents or Know-How belonging (whether through ownership or license, including under this Agreement) in whole or in part to the non-publishing Party.
- (b) Removal of Confidential Information. In addition, if the non-publishing Party informs the publishing Party that such Publication, in the non-publishing Party's reasonable judgment, discloses any Confidential Information of the non-publishing Party or could be expected to have a material adverse effect on any Know-How which is Confidential Information of the non-publishing Party, such Confidential Information or Know-How shall be deleted from the Publication.
- (c) <u>Scientific Conferences</u>. Each Party shall have the right to present its Publications approved pursuant to this Section 11.4 at scientific conferences, including at any conferences in any country in the world, subject to any conditions imposed by the JSC in its approval.

- (d) <u>Academic Publications</u>. Notwithstanding the foregoing, the Parties acknowledge that, to the extent that any Publication relates to Agios Intellectual Property that is subject to an Existing Third Party Agreement, the parties to such Existing Third Party Agreement may have retained the right to publish certain information, and nothing in this Section 11.4 is intended to restrict the exercise of such rights; <u>provided that</u>, to the extent that Agios has the right to review and comment on any such publications, Agios shall, to the extent permissible under such Existing Third Party Agreement, exercise such rights after consultation with Celgene.
- (e) <u>Delegation</u>. For purposes of convenience, the JSC may delegate its responsibilities under this Section 11.4 to one or more representatives of Agios and Celgene.
- Section 11.5 <u>Term.</u> All obligations under Sections 11.1, 11.2, 11.3 and 11.6 shall survive termination or expiration of this Agreement and shall expire [**] following termination or expiration of this Agreement.

Section 11.6 Return of Confidential Information.

- (a) <u>Obligations to Return or Destroy</u>. Upon the expiration or termination of this Agreement, the Receiving Party shall return to the Disclosing Party all Confidential Information received by the Receiving Party from the Disclosing Party (and all copies and reproductions thereof). In addition, the Receiving Party shall destroy:
- (i) any notes, reports or other documents prepared by the Receiving Party which contain Confidential Information of the Disclosing Party; and
- (ii) any Confidential Information of the Disclosing Party (and all copies and reproductions thereof) which is in electronic form or cannot otherwise be returned to the Disclosing Party.
- (b) <u>Destruction</u>. Alternatively, upon written request of the Disclosing Party, the Receiving Party shall destroy all Confidential Information received by the Receiving Party from the Disclosing Party (and all copies and reproductions thereof) and any notes, reports or other documents prepared by the Receiving Party which contain Confidential Information of the Disclosing Party. Any requested destruction of Confidential Information shall be certified in writing to the Disclosing Party by an authorized officer of the Receiving Party supervising such destruction.
- (c) <u>Limitation</u>. Nothing in this Section 11.6 shall require the alteration, modification, deletion or destruction of archival tapes or other electronic back-up media made in the ordinary course of business; <u>provided that</u> the Receiving Party shall continue to be bound by its obligations of confidentiality and other obligations under this Article XI with respect to any Confidential Information contained in such archival tapes or other electronic back-up media.

(d) Exceptions. Notwithstanding the foregoing,

(i) the Receiving Party's legal counsel may retain one copy of the Disclosing Party's Confidential Information solely for the purpose of determining the Receiving Party's continuing obligations under this Article XI; and

- (ii) the Receiving Party may retain the Disclosing Party's Confidential Information and its own notes, reports and other documents
- (A) to the extent reasonably required (1) to exercise the rights and licenses of the Receiving Party expressly surviving expiration or termination of this Agreement; or (2) to perform the obligations of the Receiving Party expressly surviving expiration or termination of this Agreement; or
 - (B) to the extent it is impracticable to do so without incurring disproportionate cost.

Notwithstanding the return or destruction of the Disclosing Party's Confidential Information, the Receiving Party shall continue to be bound by its obligations of confidentiality and other obligations under this Article XI.

Article XII Representations and Warranties

- Section 12.1 <u>Mutual Representations</u>. Agios and Celgene each represents, warrants and covenants to the other Party, as of the Execution Date, that:
- (a) <u>Authority</u>. Each Party is duly organized, validly existing and in good standing under the Laws of the jurisdiction of its formation and has full corporate power and authority to enter into this Agreement, and to carry out the provisions hereof or thereof, as applicable.
- (b) <u>Consents</u>. All necessary consents, approvals and authorizations of all government authorities and other Persons required to be obtained by it as of the Execution Date in connection with the execution, delivery and performance of this Agreement, and the performance of its obligations hereunder or thereunder, as applicable, have been obtained, except for authorizations and consents that may be necessary under Antitrust Law.
- (c) No Conflict. Notwithstanding anything to the contrary in this Agreement, the execution and delivery of this Agreement, the performance of such Party's obligations in the conduct of the Collaboration and the licenses and sublicenses to be granted pursuant to this Agreement (i) do not and will not conflict with or violate any requirement of applicable Laws existing as of the Execution Date and (ii) do not and will not conflict with, violate, breach or constitute a default under any agreement or any provision thereof, or any contract, oral or written, to which it is a party or by which it or any of its Affiliates is bound, existing as of the Execution Date.
- (d) <u>Enforceability</u>. This Agreement has been duly executed and delivered on behalf of each Party and is a legal and valid obligation binding upon it and is enforceable in accordance with its terms.
- (e) <u>Employee Obligations</u>. To its knowledge, none of its or its Affiliates' employees who have been, are or will be involved in the Collaboration are, as a result of the nature of such Collaboration to be conducted by the Parties, in violation of any covenant in any contract with a Third Party relating to non-disclosure of proprietary information, noncompetition or non-solicitation.

- Section 12.2 <u>Additional Agios Representations</u>. Agios represents, warrants and covenants to Celgene, as of the Execution Date, as follows: [**]
- (a) Agios has all rights, authorizations and consents necessary to grant all rights and licenses it purports to grant to Celgene under this Agreement, except for authorizations and consents that may be necessary under Antitrust Law.
- (b) Agios has not used, and during the Term will not knowingly use, any Know-How in a Program conducted by Agios that is encumbered by any contractual right of or obligation to a Third Party that conflicts or interferes with any of the rights or licenses granted or to be granted to Celgene hereunder.
- (c) Agios has not granted, and during the Term Agios will not grant, any right or license, to any Third Party relating to any of the intellectual property rights it Controls, that conflicts with or limits the scope of the rights or licenses granted or to be granted to Celgene hereunder.
- (d) There are no claims, litigations, suits, actions, disputes, arbitrations, or legal, administrative or other proceedings or governmental investigations pending or, to Agios' knowledge, threatened against Agios, nor is Agios a party to any judgment or settlement, which would be reasonably expected to adversely affect or restrict the ability of Agios to consummate the transactions contemplated under this Agreement and to perform its obligations under this Agreement, or which would affect the Agios Intellectual Property, or Agios' Control thereof, or any Target or Compound.*
- (e) To Agios' knowledge, the practice of the Agios Intellectual Property as contemplated under this Agreement does not (i) infringe any claims of any Patents of any Third Party, or (ii) misappropriate any Know-How of any Third Party.*
- (f) None of (i) the Agios Patents owned by Agios or both Controlled by and Prosecuted by Agios and (ii) to Agios' knowledge, the Agios Patents Controlled but not Prosecuted by Agios are subject to any pending re-examination, opposition, interference or litigation proceedings.*
- (g) To the knowledge of Agios, the Agios Patents Controlled by Agios or any Affiliate pursuant to any Existing Third Party Agreement were not and are not subject to any restrictions or limitations except as set forth in the Existing Third Party Agreements.
- (h) Agios has and, to Agios' knowledge, the applicable licensor under each Existing Third Party Agreement has, complied with any and all obligations under the Bayh-Dole Act to perfect rights to the applicable Patent Rights or Know-How licensed thereunder.* Neither Agios nor any of its Affiliates has granted any liens or security interests on the Agios Intellectual Property and the Agios Intellectual Property is free and clear of any mortgage, pledge, claim, security interest, covenant, easement, encumbrance, lien or charge of any kind, except in each case with respect to licenses, covenants not to sue, immunities from suit, standstills, releases and options which would not, in the aggregate, fundamentally frustrate the purposes of the Collaboration.

- (i) <u>Schedule 12.2(i)</u> contains a complete and accurate list of all Patents owned by Agios and/or its Affiliates as of the Execution Date that are included in the Patents licensed hereunder, indicating any co-owner(s), if applicable. Except as set forth on <u>Schedule 12.2(i)</u>, Agios and its Affiliates do not own any Patent that is necessary or, to Agios' reasonable belief as of the Execution Date, reasonably useful to research, Develop, Manufacture or Commercialize any Compounds or Licensed Products.
- (j) Schedule 12.2(j) sets forth a complete and accurate list of all Existing Third Party Agreements, true and correct copies of which have been provided to Celgene, and such agreements are in full force and effect and have not been modified or amended. Neither Agios nor, to the knowledge of Agios, any licensor under the Existing Third Party Agreements is in default with respect to a material obligation under, and none of such parties has claimed or has grounds upon which to claim that the other party is in default with respect to a material obligation under, the Existing Third Party Agreements.*
- (k) Except under the Existing Third Party Agreements in effect as of the Execution Date, and except as set forth on Schedule 12.2(j), Agios and its Affiliates are not subject to any payment obligations to Third Parties as a result of the execution or performance of this Agreement.

Section 12.3 Covenants.

- (a) Mutual Covenants. Each Party hereby covenants to the other Party that:
- (i) all employees of such Party or its Affiliates or Third Party subcontractors working under this Agreement will be under appropriate confidentiality provisions at least as protective as those contained in this Agreement and, to the extent permitted under applicable Law, the obligation to assign all right, title and interest in and to their inventions and discoveries, whether or not patentable, to such Party as the sole owner thereof;
- (ii) to its knowledge, such Party will not (A) employ or use, nor hire or use any contractor or consultant that employs or uses, any individual or entity, including a clinical investigator, institution or institutional review board, debarred or disqualified by the FDA (or subject to a similar sanction by any Regulatory Authority outside the United States) or (B) employ any individual who or entity that is the subject of an FDA debarment investigation or proceeding (or similar proceeding by any Regulatory Authority outside the United States), in each of subclauses (A) and (B) in the conduct of its activities under this Agreement
- (iii) neither such Party nor any of its Affiliates shall, during the Term, grant any right or license to any Third Party relating to any of the intellectual property rights it owns or Controls which would conflict with any of the rights or licenses granted to the other Party hereunder; and

- (iv) such Party and its Affiliates shall perform its activities pursuant to this Agreement, in compliance (and shall ensure compliance by any of its subcontractors) in all material respects with all applicable Laws, including GCP, GLP and GMP as applicable and with respect to the Development, Manufacturing and Commercialization activities hereunder.
- (b) <u>Third Party Agreement Covenants</u>. Agios hereby covenants to Celgene that Agios shall maintain the Existing Third Party Agreements and each Party hereby covenants to the other Party that it shall maintain any Subsequent Third Party Agreements, and shall not amend or terminate such agreements entered into by such Party, and will not breach such agreements, if such amendment, modification, termination or breach would adversely affect the other Party's rights under this Agreement.

Section 12.4 Agios Covenants During the Term. Except to the extent expressly permitted under Section 8.6, during the Term, neither Agios nor its Affiliates will, other than to an Affiliate of Agios who agrees in writing to be bound by the terms and conditions of this Agreement (a) assign, transfer, convey, encumber (including any liens or charges, but excluding any licenses, which are the subject of subsection (b), below) or dispose of, or enter into any agreement with any Third Party to assign, transfer, convey, encumber (including any liens or charges, but excluding any licenses, which are the subject of subsection (b), below) or dispose of, any assets specifically related to this Agreement, including with respect to the Compound(s), any Licensed Product(s) and any then-identified Companion Diagnostic(s) developed therefor, or pre-clinical study or Clinical Trial results or other data specifically related to such Program, or any intellectual property specifically related to any of the foregoing (with respect to each Program, the "Agios Program Assets"), except to the extent such assignment, transfer, conveyance, encumbrance or disposition would not fundamentally frustrate the purpose of this Agreement with respect to such Program, (b) license or grant to any Third Party, or agree to license or grant to any Third Party, any rights to any Agios Program Assets if such license or grant would fundamentally frustrate the purpose of this Agreement with respect to such Program, or (c) disclose any Confidential Information relating to the Agios Program Assets to any Third Party if such disclosure would fundamentally frustrate the purpose of this Agreement with respect to such Program. Agios and/or its Affiliates shall have the right to assign, transfer, convey or dispose of any assets specifically related to such Program to any Affiliate of Agios to the extent permitted under Section 15.4.

Section 12.5 <u>Disclaimer</u>. Except as otherwise expressly set forth in this Agreement, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY THAT ANY PATENTS ARE VALID OR ENFORCEABLE, AND EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT. Without limiting the generality of the foregoing, each Party disclaims any warranties with regards to: (a) the success of any study or test commenced under this Agreement; (b) the safety or usefulness for any purpose of the technology or materials, including any Compound, Licensed Product or Companion Diagnostic; and/or (c) the validity, enforceability, or non-infringement of any intellectual property rights or technology it provides or licenses to the other Party under this Agreement.

Section 12.6 <u>Additional Celgene Representations</u>. Celgene represents and warrants to Agios, as of the Execution Date that Celgene possesses sufficient rights to enable Celgene to grant all rights and licenses it purports to grant to Agios under this Agreement as of the Execution Date.

Article XIII Indemnification; Product Liabilities

Section 13.1 By Celgene.

- (a) <u>Celgene Indemnification Obligation</u>. Celgene agrees, at Celgene's cost and expense, to defend, indemnify and hold harmless Agios and its Affiliates and their respective directors, officers, employees and agents (the "<u>Agios Indemnified Parties</u>") from and against any Damages arising out of any Third Party claim relating to:
- (i) any breach by Celgene of any of its representations, warranties or obligations pursuant to this Agreement; or
 - (ii) the gross negligence, or willful misconduct or violation of Law of Celgene or its Affiliates.
- (b) Indemnification Procedures. In the event of any such claim against the Agios Indemnified Parties by any Third Party, Agios shall promptly, and in any event within [**], notify Celgene in writing of the claim. Celgene shall have the right, exercisable by notice to Agios within [**] after receipt of notice from Agios of the claim, to assume direction and control of the defense, litigation, settlement, appeal or other disposition of the claim (provided that such claim is solely for monetary damages and Celgene agrees to pay all Damages relating to such matter, as evidenced in a written confirmation delivered by Celgene to Agios) with counsel selected by Celgene and reasonably acceptable to Agios; provided that the failure to provide timely notice of a claim by a Third Party shall not limit an Agios Indemnified Party's right for indemnification hereunder except to the extent such failure results in actual prejudice to Celgene. The Agios Indemnified Parties shall cooperate with Celgene and may, at their option and expense, be separately represented in any such action or proceeding. Celgene shall not be liable for any litigation costs or expenses incurred by the Agios Indemnified Parties without Celgene's prior written authorization. In addition, Celgene shall not be responsible for the indemnification or defense of any Agios Indemnified Party to the extent arising from any negligent or intentional acts by any Agios Indemnified Party or the breach by Agios of any representation, obligation or warranty under this Agreement, or any claims compromised or settled without its prior written consent. Each Party shall use reasonable efforts to mitigate Damages indemnified under this Section 13.1.

Section 13.2 By Agios.

- (a) <u>Agios Indemnification Obligation</u>. Agios agrees, at Agios' cost and expense, to defend, indemnify and hold harmless Celgene and its Affiliates and their respective directors, officers, employees and agents (the "<u>Celgene Indemnified Parties</u>") from and against any Damages arising out of any Third Party claim relating to:
 - (i) any breach by Agios of any of its representations, warranties or obligations pursuant to this Agreement;

- (ii) the gross negligence, willful misconduct or violation of Law of Agios or its Affiliates;
- (iii) any of the matters disclosed by Agios in a disclosure schedule pursuant to Section 12.2, where the cause of action underlying such Damages accrued prior to the Execution Date. For the avoidance of doubt, amounts payable under Subsequent Third Party Agreements shall be borne by the Parties as set forth in Section 9.6(b), and shall not be subject to indemnification under this Section 13.2; or
- (iv) any of the matters disclosed by Agios in a disclosure schedule pursuant to Section 12.2, where the cause of action underlying such Damages accrued prior to the Execution Date. For the avoidance of doubt, amounts payable under Third Party licenses entered into under Section 9.6(b) shall be borne by Celgene as set forth in Section 9.6(b), and shall not be subject to indemnification under this Section 13.2.
- (b) Indemnification Procedures. In the event of any such claim against the Celgene Indemnified Parties by any Third Party, Celgene shall promptly, and in any event within [**], notify Agios in writing of the claim. Agios shall have the right, exercisable by notice to Celgene within [**] after receipt of notice from Celgene of the claim, to assume direction and control of the defense, litigation, settlement, appeal or other disposition of the claim (provided that such claim is solely for monetary damages and Agios agrees to pay all Damages relating to such matter, as evidenced in a written confirmation delivered by Celgene to Agios) with counsel selected by Agios and reasonably acceptable to Celgene; provided that the failure to provide timely notice of a claim by a Third Party shall not limit a Celgene Indemnified Party's right for indemnification hereunder except to the extent such failure results in actual prejudice to Agios. The Celgene Indemnified Parties shall cooperate with Agios and may, at their option and expense, be separately represented in any such action or proceeding. Agios shall not be liable for any litigation costs or expenses incurred by the Celgene Indemnified Parties without Agios' prior written authorization. In addition, Agios shall not be responsible for the indemnified Party or the breach by Celgene of any representation, obligation or warranty under this Agreement, or any claims compromised or settled without its prior written consent. Each Party shall use reasonable efforts to mitigate Damages indemnified under this Section 13.2.
- Section 13.3 <u>Product Liability Costs</u>. Except with respect to such portion (if any) of Product Liabilities that are claims entitled to indemnification under Section 13.1 or Section 13.2, the Parties shall be responsible for all Product Liabilities, all Out-of-Pocket Costs and FTE Costs incurred by the controlling Party under Section 13.4 in connection with any litigation or proceeding related to such Third Party Products Liability Action, and all Out-of-Pocket Costs and FTE Costs incurred by the non-controlling Party under Section 13.4 at the request of the controlling Party under Section 13.4 as follows:
- (a) All such costs and expenses incurred before the Agios Opt-Out Date relating to Licensed Products distributed prior to the Agios Opt-Out Date shall be taken into account in determining Profit or Loss as, and to the extent, provided in Exhibit D.

(b) All such costs and expenses incurred after the Agios Opt-Out Date relating to Licensed Products shall be borne solely by Celgene if and only to the extent such Product Liabilities arose from Licensed Products distributed after the Agios Opt-Out Date.

Section 13.4 Conduct of Product Liability Claims.

- (a) Each Party shall promptly notify the other in the event that any Third Party asserts or files any products liability claim or other action relating to alleged defects in the Licensed Product (whether design defects, manufacturing defects or defects in sales or marketing) ("Third Party Products Liability Action") against such Party. In the event of a Third Party Products Liability Action against such a single Party, the unnamed Party shall have the right, in the unnamed Party's sole discretion, to join or otherwise participate in such legal action with legal counsel selected by the unnamed Party and reasonably acceptable to the named Party. The Party named in such Third Party Products Liability Action shall have the right to control the defense of the action, but shall notify and keep the unnamed Party apprised in writing of such action and shall consider and take into account the unnamed Party's reasonable interests and requests and suggestions regarding the defense of such action; provided that, in the event of an Agios Opt-Out Notice, Celgene shall have the right to control the defense of all Third Party Product Liability Actions after the Agios Opt-Out Date. In the event of a Third Party Products Liability Action against both Parties, unless otherwise agreed by the Parties in writing, the Lead Party of the relevant portion of the Territory shall control the response to such Third Party Products Liability Action; provided that, in the event of an Agios Opt-Out Notice, Celgene shall have the right to control the defense of all Third Party Product Liability Actions.
- (b) The non-controlling Party of a Third Party Products Liability Action shall reasonably cooperate with the controlling Party in the preparation and formulation of a defense to such Third Party Products Liability Action, and in taking other steps reasonably necessary to respond to such Third Party Products Liability Action. The controlling Party shall have the right to select its counsel for the defense to such Third Party Products Liability Action, which counsel must be reasonably acceptable to the non-controlling Party. If required under applicable Law in order for the controlling Party to maintain a suit in response to such Third Party Products Liability Action, the non-controlling Party shall join as a party to the suit. The non-controlling Party shall also have the right to participate and be represented in any such suit on a voluntary basis by its own counsel at its own expense. The controlling Party shall not settle or compromise any Third Party Products Liability Action without the consent of the other Party, which consent shall not be unreasonably withheld.

Section 13.5 <u>Limitation of Liability</u>. EXCEPT WITH RESPECT TO A BREACH OF SECTION 8.6 OR ARTICLE XI, OR A PARTY'S LIABILITY PURSUANT TO SECTION 13.1 OR SECTION 13.2, NEITHER PARTY SHALL BE LIABLE FOR SPECIAL, CONSEQUENTIAL, EXEMPLARY, PUNITIVE, MULTIPLE OR OTHER INDIRECT OR REMOTE DAMAGES, OR FOR LOSS OF PROFITS, LOSS OF DATA OR LOSS OF USE DAMAGES ARISING IN ANY WAY OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, WHETHER BASED UPON WARRANTY, CONTRACT, TORT, STRICT LIABILITY OR OTHERWISE, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES OR LOSS.

Section 13.6 <u>Insurance</u>. Beginning on [**] and thereafter during the Term, each Party shall maintain commercial general liability insurance (including product liability insurance) from a recognized, creditworthy insurance company, with coverage limits of at least [**] US Dollars (\$[**]) per claim and annual aggregate. Celgene may elect to self-insure all or parts of the limits described above. Within [**] following written request from the other Party, each Party shall furnish to the other Party a certificate of insurance evidencing such coverage. If such coverage is modified or cancelled, the insured Party shall notify the other Party and promptly provide such other Party with a new certificate of insurance evidencing that such insured Party's coverage meets the requirements of this Section 13.6.

Article XIV Term and Termination

- Section 14.1 <u>Term.</u> The term of this Agreement (the "<u>Term</u>") shall commence on the Effective Date and shall continue, unless earlier terminated pursuant to Section 14.3 on a Licensed Product-by-Licensed Product and country-by-country basis, in full force and effect:
- (a) as long as the Parties continue to Develop or Commercialize Licensed Products in accordance with the terms and conditions of this Agreement; or,
 - (b) in the event of an Agios Opt-Out Date, this Agreement shall expire:
- (i) on a Licensed Product-by-Licensed Product and country-by-country basis, upon the expiration of the applicable Royalty Term with respect to such Licensed Product in such country; and
- (ii) in its entirety upon the expiration of all applicable Royalty Terms under this Agreement with respect to all Licensed Products in all countries worldwide.

For the avoidance of doubt, this Agreement shall not be effective until the Effective Date, and this Agreement may be subject to termination prior to the Effective Date as set forth in Section 3.2 of the Master Agreement, in which case all rights to the Program (as defined in the Master Agreement) that is the subject of this Agreement shall revert to Agios in accordance with Section 2.12 of the Master Agreement.

- Section 14.2 <u>Effect of Expiration</u>. Following any Agios Opt-Out, after the expiration of the Term pursuant to Section 14.1(b) above, the following terms shall apply:
- (a) <u>Licenses after Licensed Product Expiration</u>. After expiration of the Term (but not after early termination) with respect to any Licensed Product in a country in the world pursuant to Section 14(b)(i), Celgene's rights and licenses hereunder under the Agios Intellectual Property, Agios Co-Co Collaboration Intellectual Property and Agios' rights in the Joint Collaboration IP to develop, manufacture, have manufactured, use, offer for sale, sell, import and otherwise commercialize such Licensed Product and related Companion Diagnostics in the Field in such country, for so long as it continues to do so, shall convert to irrevocable, non-terminable rights and licenses, with the right to grant sublicenses; <u>provided that</u>, following such expiration and notwithstanding Section 9.6(a), (i) Celgene shall be solely responsible for all payments owed to any Third Party licensors and (ii) Celgene shall be responsible for complying with the terms of any license agreements with such Third Party licensors, in each case ((i) and (ii)), solely with respect to Celgene's exercise of such rights.

(b) <u>Licenses after Expiration of Agreement</u>. After expiration of the Term (but not after early termination) with respect to this Agreement in its entirety pursuant to Section 14.1(b)(ii), Celgene's rights and licenses hereunder under the Agios Intellectual Property, Agios Co-Co Collaboration Intellectual Property and Agios' rights in the Joint Collaboration IP to develop, manufacture, have manufactured, use, offer for sale, sell, import and otherwise commercialize Licensed Products and Companion Diagnostics in the Field worldwide, for so long as it continues to do so, shall convert to irrevocable, non-terminable rights and licenses, with the right to grant sublicenses; <u>provided that</u>, following such expiration and notwithstanding Section 9.6(a), (i) Celgene shall be solely responsible for all payments owed to any Third Party licensors and (ii) Celgene shall be responsible for complying with the terms of any license agreements with such Third Party licensors, in each case, ((i) and (ii)), solely with respect to Celgene's exercise of such rights.

Section 14.3 Termination.

(a) <u>Termination for Convenience</u>. Celgene shall have the right to terminate this Agreement in its entirety for convenience upon [**] prior written notice to Agios; <u>provided that</u> Celgene shall not have the right to terminate this Agreement until [**] following the Effective Date (it being understood and agreed that Celgene shall be entitled to terminate upon [**] written notice at any time it reasonably determines that such termination is necessary to comply with any Antitrust Law).

(b) Termination for Material Breach.

(i) Termination by Either Party for Breach. Subject to Section 14.3(b)(ii) (with respect to a Material Breach by either Party of its obligations to use Commercially Reasonable Efforts), this Agreement and the rights granted herein may be terminated by either Party for the material breach of this Agreement in a manner that fundamentally frustrates the transactions contemplated by this Agreement taken as a whole by the other Party to this Agreement (each, a "Material Breach"), provided that, if the breaching Party has not cured such Material Breach within [**] after the date of written notice to the breaching Party of such breach (or [**], in the case of Celgene's payment obligations under this Agreement or the specified time period provided in Section 14.3(b)(ii) with respect to a Material Breach by either Party of its obligation to use Commercially Reasonable Efforts, each as applicable) (the "Cure Period"), which notice shall describe such breach in reasonable detail and shall state the non-breaching Party's intention to terminate this Agreement pursuant to this Section 14.3(b)(i). Notwithstanding the preceding sentence, the Cure Period for any allegation made in good faith as to a Material Breach under this Agreement will run from the date that written notice was first provided to the breaching Party by the non-breaching Party. Any such termination of this Agreement under this Section 14.3(b)(i) shall become effective at the end of the Cure Period, unless the breaching Party has cured any such Material Breach prior to the expiration of such Cure Period, or, if such Material Breach is not susceptible to cure within the Cure Period, then, the non-breaching Party's right of termination shall be suspended only if and for so long as the breaching Party has provided to the non-breaching Party a written plan that is

reasonably calculated to effect a cure and such plan is acceptable to the non-breaching Party, and the breaching Party commits to and carries out such plan as provided to the non-breaching Party within [**] after the date that written notice was first provided to the breaching Party by the non-breaching Party. The Parties understand and agree that the totality of this Agreement and the [**].

- (ii) Additional Procedures for Termination by either Party for Failure of the Other Party to Use Commercially Reasonable Efforts. If either Party wishes to exercise its right to terminate this Agreement pursuant to Section 14.3(b)(i) for the other Party's Material Breach of its obligations to use Commercially Reasonable Efforts, it shall provide to such other Party a written notice of its intent to exercise such right, which notice shall be labeled as a "notice of Material Breach for failure to use Commercially Reasonable Efforts," and shall state the reasons and justification for such termination [**]. For any such notice of breach by a Party, the Cure Period shall, subject to Section 14.3(b)(iii), be [**], and shall become effective in accordance with Section 14.3(b) (i).
- (iii) <u>Disagreement as to Material Breach</u>. If the Parties reasonably and in good faith disagree as to whether there has been a Material Breach pursuant to Section 14.3(b) then subject to Section 15.1: (A) the Party that disputes that there has been a Material Breach may contest the allegation by referring such matter, within [**] for resolution to the Executive Officers, who shall meet promptly to discuss the matter, and determine, within [**] following referral of such matter, whether or not a Material Breach has occurred pursuant to Section 14.3(b); (B) the relevant Cure Period with respect thereto will be tolled from the date the breaching Party notifies the non-breaching Party of such dispute and through the resolution of such dispute in accordance with the applicable provisions of this Agreement (provided, that if such dispute relates to payment, the Cure Period will only be tolled with respect to payment of disputed amounts, and not with respect to undisputed amounts), (C) it is understood and agreed that during the pendency of such dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder) and (D) if it is finally and conclusively determined in accordance with Section 15.2 that the breaching Party committed such Material Breach, then the breaching Party shall have the right to cure such Material Breach after such determination within the Cure Period [**].
- (iv) If the Executive Officers are unable to resolve a dispute within such [**] period after it is referred to them, the matter will be resolved as provided in Section 15.1.
- (v) <u>Payments</u>. No milestone payments by Celgene will be due on milestones achieved during the period between the notice of termination under Section 14.3(b) and the effective date of termination; provided, however, if either Party provides notice of a dispute pursuant to Section 14.3(b) or otherwise and such dispute is resolved in a manner in which no termination of this Agreement occurs with respect to such breach or the breaching Party cures the applicable breach during the Cure Period, then upon such resolution or cure Celgene will within [**] pay to Agios the applicable milestone payment for each milestone achieved during the period between the notice of termination under Section 14.3(b) and the resolution of such dispute or cure of such breach, and if it was determined that Celgene wrongly asserted breach by Agios under Section 14.3(b), then Celgene shall also pay interest on such amount as provided in Section 9.11.

- (c) <u>Termination for Insolvency</u>. To the extent permitted by Law, this Agreement may be terminated 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; <u>provided</u>, <u>however</u>, <u>that</u>, 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 ninety (90) days after the filing thereof.
- (d) Termination for Patent Challenge. Either Party shall have the right to terminate this Agreement solely on a Licensed Product-by-Licensed Product basis upon written notice if the other Party or any of its Affiliates challenges the validity, scope or enforceability of or otherwise opposes any Patent (i) included in the Agios Intellectual Property or Agios Co-Co Collaboration Intellectual Property and that is licensed to Celgene under this Agreement in any action or proceeding, or (ii) included in the Celgene Intellectual Property or Celgene Collaboration Intellectual Property that is licensed to Agios under this Agreement in any action or proceeding (subject to the exceptions described in this Section 14.3(d), a "Challenge") (other than as may be necessary or reasonably required to assert a defense, cross-claim or a counter-claim in an action or proceeding asserted by either Party or any of its Affiliates or Licensee Partners against the other Party or any of its Affiliates or to respond to a court request or order or administrative law, request or order) it being understood and agreed that either Party's right to terminate this Agreement under this Section 14.3(d) shall not apply to any actions undertaken by an Affiliate of the other Party (the "Challenging Party") that first becomes such an Affiliate as a result of a Change of Control involving the Challenging Party, where such new Affiliate was undertaking any of the activities described in the foregoing clause prior to such Change of Control; provided that a Party's right to terminate this Agreement under this Section 14.3(d) shall apply to actions undertaken by such new Affiliate if the Challenging Party is the acquiror in such Change of Control and such new Affiliate does not terminate or otherwise cease participating in such action, proceeding, challenge or opposition within [**] after the effective date of such Change of Control. If a Licensee Partner of either Party challenges the validity, scope or enforceability of or otherwise opposes any Patent included in any of the intellectual property described in this Section 14.3(d) under which such Sublicensee is sublicensed in any action or proceeding, then the Party that granted such sublicense shall, upon written notice from the other Party, terminate such sublicense. For the avoidance of doubt, an action by a Party or any of its Affiliates (collectively the "Pursuing Party") in accordance with this Agreement and the Master Agreement to amend claims within a pending patent application of the other Party during the course of the Pursuing Party's Prosecution of such pending patent application or in defense of a Third Party proceeding, or to make a negative determination of patentability of claims of a patent application of the other Party or to abandon a patent application of the other Party during the course of the Pursuing Party's Prosecution of such pending patent application, shall not constitute a challenge under this Section 14.3(d). Neither Party shall, and each Party shall ensure that its Affiliates and Licensee Partners do not, use or disclose any Confidential Information of the other Party or any nonpublic information regarding the Prosecution or enforcement of any Agios Patent, Celgene Collaboration Patent or Agios Co-Co Collaboration Patent (including Joint Collaboration Patents) to which a Party or any of its Affiliates or

sublicensees are or become privy as a consequence of the rights granted to such Party pursuant to Article X, in initiating, requesting, making, filing or maintaining, or in funding or otherwise assisting any other Person with respect to, any Challenge.

Section 14.4 Effects Of Termination.

- (a) <u>Effects of Celgene Termination for Convenience or Agios Termination for Celgene Breach, Insolvency or Patent Challenge</u>. Upon termination of this Agreement by Celgene under Section 14.3(a) or by Agios under Section 14.3(b), 14.3(c) or 14.3(d), the following shall apply:
- (i) all licenses granted by Agios to Celgene under Section 8.1(a) shall terminate in their entirety if pursuant to Section 14.3(a), Section 14.3(b) or Section 14.3(c), and (ii) with respect to the corresponding Compound and Licensed Product if pursuant to Section 14.3(d), and all licenses granted by Celgene to Agios under Section 8.1(b)(i) shall convert to worldwide licenses as if Agios were the Lead Party worldwide and otherwise remain in effect, and, from and after such termination, Agios shall pay Celgene royalties on Annual Net Sales of Licensed Products pursuant to Section 9.5, reducing such royalties by [**] percent ([**]%) and substituting "Agios" for "Celgene" and vice versa with respect to all obligations and definitions, and otherwise *mutatis mutandis*, with the Agios Opt-Out Date, as used therein, deemed to be the effective date of termination; <u>provided that</u> (i) Agios shall be solely responsible for all payments owed to any Third Party licensors (without any right to offset any such amounts against royalties payable to Celgene hereunder) and (ii) Agios shall be responsible for complying with the terms of any license agreements with such Third Party licensors, in each case ((i) and (ii)), solely with respect to Agios' exercise of such rights
- (ii) each Party shall be released from its Development, Manufacture and Commercialization obligations (except as set forth in Section 14.4(a)(vii) and (viii) below with respect to Celgene's transfer of Manufacturing to Agios hereunder);
- (iii) within [**] after such termination, unless there has been an Agios Opt-Out Date, each Party shall provide the other with a report of Development Costs, Net Sales and Commercialization Expenses and other amounts incurred by such Party that are subject to the Parties' cost-sharing obligations through the effective date of termination for the purpose of calculating a final reconciliation of shared costs and payments in accordance with Section 9.2 and Section 9.4, as applicable. Each Party shall submit any supporting information reasonably requested by the other Party related to such Development Costs, Net Sales, Commercialization Expenses and such other amounts included in such Party's reconciliation report within [**] after the other Party's receipt of such request. The Parties, with the assistance of the JCC, shall conduct a final reconciliation of such costs and payments within [**] after receipt of all such supporting information, and an invoice shall be issued to the Party (if any) that owes the other Party a payment to accomplish the cost sharing or payment envisioned under this Agreement pursuant to Section 9.2 and Section 9.4, as applicable. The paying Party shall pay all amounts payable under any such invoice within [**] after its receipt of such invoice; provided, however, that, Celgene shall remain responsible for its applicable share of all Developments Costs and Commercialization Expenses committed prior to the effective date of termination and not cancelable by Agios, which Agios shall reasonably seek to minimize, with respect to the

Licensed Products to the extent such Development Costs and Commercialization Expenses (A) are within an approved Development Budget under an approved Development Plan or Commercialization Budget under an approved Commercialization Budget, respectively, in place prior to termination and (B) are solely incurred by Agios during the period ending [**] after the effective date of termination of this Agreement.

- (iv) within [**] after such termination, Celgene shall provide to Agios a fair and accurate summary report of the status of Development and Commercialization activities conducted by Celgene with respect to the Licensed Products;
- (v) Celgene shall promptly transfer and assign to Agios all of Celgene's and its Affiliates' rights, title and interests in and to the product trademark(s) (but not any Celgene house marks or composite marks including a house mark) owned by Celgene (if Celgene was the Lead US Party, in accordance with Section 6.4(b)) and solely used for Licensed Products;
- (vi) Celgene shall as soon as reasonably practicable transfer and assign to Agios all Regulatory Approvals of the Licensed Products, their corresponding Regulatory Documentation, and a copy of all of the data comprising the Global Safety Database; provided that Celgene may retain such data and a single copy of such Regulatory Approvals and Regulatory Documentation for its records. Notwithstanding the foregoing, if such Regulatory Approvals or Regulatory Documentation are necessary or useful for the Development, Manufacture or Commercialization of any product other than the Licensed Products, in place of transferring or assigning the foregoing, Celgene shall instead grant Agios a Right of Reference or Use with respect to such approvals or documentation with respect to the Licensed Products;
- (vii) Agios shall have the option, exercisable within [**] following the effective date of such termination of this Agreement, to obtain Celgene's inventory of the Licensed Products at a price equal to [**] percent ([**]%) of Celgene's Manufacturing Costs for such inventory of the Licensed Products; provided that, if Celgene, its Affiliates or sublicensees have outstanding orders, at Agios' election, either Agios shall fulfill such orders or, notwithstanding Agios' option to purchase inventory, Celgene may retain sufficient inventory to fulfill such orders. Agios may exercise such option by written notice to Celgene during such [**] period; provided that, in the event Agios exercises such right to purchase such inventory, Celgene shall grant, and hereby does grant, a royalty-free right and license to any trademarks, names and logos of Celgene contained therein for a period of [**] solely to permit the orderly sale of such inventory, subject to Agios meeting reasonable quality control standards imposed by Celgene on the use of such trademarks, names and logos, which shall be consistent with the standards used by Celgene prior to such termination;
- (viii) to the extent that Celgene is responsible for Manufacturing the Licensed Products immediately prior to such termination, at Agios' written request:
- (A) in exchange for a payment equal to [**] percent ([**]%) of Celgene's Manufacturing Costs and upon other commercially reasonable terms as may be mutually agreed between the Parties or their respective Affiliates in a supply agreement, Celgene shall use Commercially Reasonable Efforts to supply Agios and its Affiliates with comparable

quantities of the Licensed Products in the form, formulation and presentation as were being Developed or Commercialized immediately prior to termination until the earlier of [**] after the effective date of the termination and establishment by Agios of an alternative supply for such product(s);

- (B) in the event Celgene was utilizing a Third Party manufacturer to Manufacture the Licensed Products, to the extent permitted by the terms of such contract, Celgene shall promptly assign to Agios the manufacturing agreements with such Third Party with respect to such product(s); and
- (C) Celgene shall transfer, or have transferred, to Agios or its designee, pursuant to a technology transfer plan to be mutually agreed by the Parties, all Manufacturing Technology Controlled by Celgene within Celgene Collaboration Intellectual Property that is both necessary to Manufacture the Licensed Products as Manufactured by or on behalf of Celgene and its Affiliates prior to termination and has been incorporated in regulatory documentation submitted to a Regulatory Authority in support of Development or Commercialization of the Licensed Products (or is in the process of being incorporated), and Celgene shall provide reasonable assistance in connection with the transfer of such Manufacturing Technology to Agios or its designee, all of which shall be transferred or provided at Celgene's Out-of-Pocket Costs;
- (ix) separate transitional activities shall be undertaken with respect to any Companion Diagnostic(s) to ensure that the appropriate Regulatory Approvals, Manufacturing Technology or other Know-How or Patents necessary for the Development, Manufacture or Commercialization of such Companion Diagnostic(s) shall be transferred to Agios to the same extent as Regulatory Approvals, Manufacturing Technology or other Know-How or Patents otherwise associated with such Licensed Products are transferred:
- (x) notwithstanding anything to the contrary in Section 8.6, Agios shall have the right to pursue the Development, Manufacture and Commercialization of the Licensed Products; and
- (xi) the provisions of Article X (other than Section 10.1) shall terminate, and Celgene shall, if applicable, provide reasonable assistance to Agios and cooperation in connection with the transition of Prosecution and enforcement responsibilities to Agios with respect to Celgene Collaboration Patents, Agios Co-Co Collaboration Patents and Joint Collaboration Patents then being Prosecuted or enforced by Celgene, including execution of such documents as may be necessary to effect such transition.
- (b) <u>Effects of Celgene Termination for Agios Breach, Insolvency or Patent Challenge</u>. Upon any termination of this Agreement by Celgene under Section 14.3(b), 14.3(c) or 14.3(d):
- (i) if Celgene has the right to terminate this Agreement pursuant to Section 14.3(b), (c) or (d), Celgene may elect, upon written notice to Agios, to either:
- (A) terminate this Agreement in its entirety, if pursuant to Section 14.3(b) or (c), or with respect to the corresponding Compound and Licensed Product, if

pursuant to Section 14.3(d), in which case (1) all rights and obligations of the Parties under this Agreement or the corresponding Compound and Licensed Product, respectively, shall terminate, except (I) Celgene's payment obligations (accrued as of the effective date of such termination) and the audit rights set forth in Article IX, and (II) Section 14.4(d) shall, in each case (I) and (II), survive such termination, (2) Agios shall return any Confidential Information of Celgene pursuant to Article VIII of the Master Agreement that is not necessary to practice any licenses retained by Agios following such termination under this Agreement, another Development & Commercialization Agreement (as defined in the Master Agreement) or the Master Agreement, (3) all licenses granted by Celgene to Agios under Section 8.1(b)(i) with respect to the Licensed Product(s) that are the subject of the applicable breach by Agios shall convert to worldwide licenses as if Agios were the Lead Party worldwide and otherwise remain in effect, and, from and after such termination, Agios shall pay Celgene royalties on Annual Net Sales of such Licensed Product(s) pursuant to Section 9.5, reducing such royalties by [**] percent ([**]%) and substituting "Agios" for "Celgene" and vice versa with respect to all obligations and definitions, and otherwise mutatis mutandis, with the Agios Opt-Out Date, as used therein, deemed to be the effective date of termination, under Celgene's rights in Celgene Intellectual Property, Celgene Collaboration Intellectual Property, Joint Inventions, Joint Patents and Manufacturing Technology to Develop, Manufacture and Commercialize Compounds and Licensed Products; provided that (I) Agios shall be solely responsible for all payments owed to any Third Party licensors (without any right to offset any such amounts against rovalties payable to Celgene hereunder) and (II) Agios shall be responsible for complying with the terms of any license agreements with such Third Party licensors, in each case ((I) and (II)), solely with respect to Agios' exercise of such rights, and (4) Celgene may seek any damages that Celgene can establish that are not compensated by the royalties set forth in Section 14.4(b)(i)(A)(3); or

(B) maintain this Agreement in full force and effect (foregoing, for the avoidance of doubt, the right to terminate this Agreement for such occurrence of such breach) and, with respect to the Licensed Product(s) that are the subject of the applicable breach by Agios: (1) all future milestones and royalty obligations in respect of such Licensed Products payable by Celgene under this Agreement following such election shall be subject to a reduction of [**] percent ([**]%) and (2) Agios' Profit or Loss Allocation shall be terminated (and the Parties shall treat this Agreement as though an Agios Opt-Out had occurred pursuant to Section 2.3).

(ii) if Celgene has made the election set forth in Section 14.4(b)(i)(B), from and after such election:

(A) if the Agios Opt-Out Date has not occurred before the effective date of termination, then Celgene shall pay Agios milestones and royalties on Annual Net Sales of Licensed Products following such termination (subject to the [**] percent ([**]%) reduction described in Section 14.4(b)(i) above), with the Agios Opt-Out Date, as used therein, deemed to be the effective date of termination, or

(B) if the Agios Opt-Out Date has occurred before the effective date of termination, then Celgene shall continue to pay to Agios milestones and royalties on Net Sales of Licensed Products following such termination (subject to the [**] percent ([**]%) reduction described in Section 14.4(b)(i) above).

- (iii) all licenses granted by Celgene to Agios under Section 8.1(b) with respect to the Licensed Products shall terminate if Celgene has made the election set forth in Section 14.4(b)(i)(B) and all licenses granted by Agios to Celgene under Section 8.1(a) with respect to the Licensed Product(s) that are the subject of the applicable breach by Celgene shall convert to worldwide licenses as if Celgene were the Lead Party worldwide and otherwise remain in effect, and, from and after such termination;
- (iv) Agios shall be released from its Development, Manufacture and Commercialization obligations (except as set forth in clause (vii) below with respect to Agios' transfer of Manufacturing to Celgene hereunder);
- (v) each Party shall provide the other with a report of the Development Costs and Commercialization Expenses incurred by such Party that are subject to the Parties' cost-sharing obligations through the effective date of termination for the purpose of calculating a final reconciliation of shared costs in accordance with Section 9.2 and Section 9.4;
- (vi) if Celgene has made the election set forth in Section 14.4(b)(i)(B) within [**] after such termination, Agios shall provide to Celgene a fair and accurate summary report of the status of Development and Commercialization activities conducted by Agios with respect to the Licensed Products;
- (vii) if Agios is the Lead US Party and Celgene has made the election set forth in Section 14.4(b)(i)(B) above:
- (A) Agios shall promptly transfer and assign to Celgene all of Agios' and its Affiliates' rights, title and interests in and to the Product Trademark(s) (but not any Agios house marks or composite marks including a house mark) owned by Agios and solely used for Licensed Products in the US Territory;
- (B) Agios shall as soon as reasonably practicable transfer and assign to Celgene all Regulatory Approvals of the Licensed Products for the US Territory, their corresponding Regulatory Documentation, and a copy of all of the data comprising the Global Safety Database for the US Territory; provided that Agios may retain such data and a single copy of such Regulatory Approvals and Regulatory Documentation for its records; and provided further that, if such Regulatory Approvals or Regulatory Documentation are necessary or useful for the Development, Manufacture or Commercialization of any product other than the Licensed Products, in place of transferring or assigning the foregoing, Agios shall grant Celgene a Right of Reference or Use with respect to such approvals or documentation with respect to the Licensed Products; and
- (C) Celgene shall have the option, exercisable within [**] following the effective date of such termination of this Agreement, to obtain Agios' inventory of the Licensed Products at a price equal to [**] percent ([**]%) of Agios' Manufacturing Costs for such inventory of the Licensed Products; provided that, if Agios, its Affiliates or sublicensees have outstanding orders, at Celgene's election, either Celgene shall fulfill such orders or, notwithstanding Celgene's option to purchase inventory, Agios may retain sufficient inventory to fulfill such orders. Celgene may exercise such option by written notice to Agios during such

[**] period; provided that, in the event Celgene exercises such right to purchase such inventory, Agios shall grant, and hereby does grant, a royalty-free right and license to any trademarks, names and logos of Agios contained therein for a period of [**] solely to permit the orderly sale of such inventory, subject to Celgene meeting reasonable quality control standards imposed by Agios on the use of such trademarks, names and logos, which shall be consistent with the standards used by Agios prior to such termination. Unless Celgene exercises its option under the first sentence of this Section 14.4(b)(vii)(C) and Agios, its Affiliates or sublicensees at termination of this Agreement possess Licensed Product, have started the manufacture thereof or have accepted orders therefor, Agios, 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 in the US Territory, subject to the obligation of Agios to pay Celgene any and all payments as provided in this Agreement.

(viii) if Celgene has made the election set forth in Section 14.4(b)(i)(B), Celgene shall be solely responsible for any payments owed to any Third Party licensors of Agios Intellectual Property, Agios Co-Co Collaboration Intellectual Property or Celgene Collaboration Intellectual Property (without deduction under Section 9.5(c)) and shall be responsible for complying with the terms of any license agreements with such Third Party licensors, in either case, directly related to Celgene's exercise of such license; and

- (ix) if Celgene has made the election set forth in Section 14.4(b)(i)(B), the rights of Agios in Article X (other than Section 10.1) shall be terminated and Agios shall, if applicable, provide reasonable assistance to Celgene and cooperation in connection with the transition of Prosecution and enforcement responsibilities to Celgene with respect to Celgene Collaboration Patents, Agios Co-Co Collaboration Patents and Joint Collaboration Patents then being Prosecuted or enforced by Agios, including execution of such documents as may be necessary to effect such transition; and
- (x) if Celgene has made the election set forth in Section 14.4(b)(i)(A), separate transitional activities shall be undertaken with respect to any Companion Diagnostic(s) to ensure that the appropriate Regulatory Approvals, Manufacturing Technology or other Know-How or Patents necessary for the Development, Manufacture or Commercialization of such Companion Diagnostic(s) shall be transferred to Agios to the same extent as Regulatory Approvals, Manufacturing Technology or other Know-How or Patents otherwise associated with such Licensed Products are transferred.
- (c) In the case of any termination of this Agreement, if any Clinical Trials (including any Additional Studies) are then being conducted at the time of such termination with respect to any Licensed Product, the Parties hereby agree (i) to reasonably cooperate in the completion of any such Clinical Trials (including any Additional Studies), and (ii) notwithstanding anything to the contrary contained herein, to grant to the Party that retains global Commercialization rights to such Licensed Product following such termination (A) free of charge, copies of and rights of reference to and use of all Licensed Product Data that is Controlled by such Party and generated pursuant to such Clinical Trials (including any Additional Studies) that are relevant to or necessary to address issues relating to: (1) the safety

of such Licensed Product in the Territory, including data that is related to adverse effects experienced with such Licensed Product and/or (2) all activities relating to CMC regarding such Licensed Product and in each of (1) and (2), that are required to be reported or made available to Regulatory Authorities in the Territory, when and as such data become available, and (B) copies of and rights of reference to and use of all Licensed Product Data (other than the Licensed Product Data referred to in subclause (A) above) that is Controlled by such Party and generated pursuant to such Clinical Trials (including any Additional Studies) that are relevant to or necessary to address the Development and Commercialization of such Licensed Product promptly following the generation of such Licensed Product Data if, but only if, as to such Licensed Product Data described in this subclause (B), such Party that retains global Commercialization rights to such Licensed Product following such termination promptly pays for all Development Costs incurred following any such termination of this Agreement with respect to such Clinical Trials (including any Additional Studies).

- (d) <u>Survival</u>. Upon any termination or expiration of this Agreement, unless otherwise specified in this Agreement and except for any rights or obligations that have accrued prior to the effective date of termination or expiration, all rights and obligations of each Party under this Agreement shall terminate in whole or with respect to the Licensed Products, as the case may be; <u>provided, however, that</u> Section 2.1, Section 3.7(b), Section 8.8, Section 9.2(b), Section 9.5(b)(v), Section 9.7, Section 9.8, Section 9.9, Section 9.10, Section 9.11, Section 10.1, Section 12.5, Section 11.6, Section 13.1, Section 13.2, Section 13.3, Section 13.4, Section 13.5, Section 14.4 and Section 15.2, as well as any other provision which by its terms or by the context thereof is intended to survive, shall survive any such termination or expiration of this Agreement.
- (e) <u>Equitable Relief</u>. Termination of this Agreement shall be in addition to, and shall not prejudice, the Parties' remedies at law or in equity, including the Parties' ability to receive legal damages or equitable relief with respect to any breach of this Agreement, regardless of whether or not such breach was the reason for the termination.
- (f) Accrued Liabilities. Except as otherwise specifically provided herein, termination of this Agreement shall not relieve the Parties of any liability or obligation which accrued hereunder prior to the effective date of such termination, nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement nor prejudice either Party's right to obtain performance of any obligation. In addition, termination of this Agreement shall not terminate provisions which provide by their respective terms for obligations or undertakings following the expiration of the term of this Agreement.

Article XV Miscellaneous

Section 15.1 <u>Dispute Resolution</u>. Except for any disagreements that are within the authority of any Committee as provided in Article II (which disagreements shall be resolved in accordance with Section 2.2), the Parties agree that any disputes arising with respect to the interpretation, enforcement, termination or invalidity of this Agreement (each, a "<u>Dispute</u>") shall first be presented to the Parties' respective Executive Officers for resolution. If the Parties are

unable to resolve a given dispute pursuant to this Section 15.1 after in-person discussions between the Executive Officers within [**] after referring such dispute to the Executive Officers, either Party may, at its sole discretion, seek resolution of such matter in accordance with Section 15.2.

Section 15.2 <u>Submission to Court for Resolution</u>. Subject to Section 15.1, the Parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction of the courts located in the Southern District of New York for any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement, and agree not to commence any action, suit or proceeding (other than appeals therefrom) related thereto except in such courts. The Parties further hereby irrevocably and unconditionally waive any objection to the laying of venue of any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement in the courts of New York, and hereby further irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum. Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in Section 15.8 shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any such court.

Section 15.3 <u>Governing Law</u>. This Agreement and all questions regarding its validity or interpretation, or the performance or breach of this Agreement, shall be governed by and construed and enforced in accordance with the laws of the State of New York, without reference to conflicts of laws principles.

Section 15.4 Assignment.

- (a) <u>Generally</u>. This Agreement may not be assigned by any Party, nor may any Party delegate its obligations or otherwise transfer licenses or other rights created by this Agreement, except as expressly permitted hereunder without the prior written consent of the other Party, which consent will not be unreasonably withheld, delayed or conditioned.
- (b) <u>Celgene</u>. Notwithstanding the limitations in Section 15.4(a), Celgene Corp. and Celgene RIVOT may assign this Agreement, or any rights or obligations hereunder in whole or in part, to (i) one or more Affiliates solely as provided in this Section 15.4(b) or (ii) its successor in interest in connection with the merger, consolidation, or sale of all or substantially all of its assets or that portion of its business pertaining to the subject matter of this Agreement; <u>provided, however, that,</u> except in the case where Celgene Corp., or Celgene RIVOT, as applicable, is involved in a merger or consolidation where it is the surviving entity and no assets of Celgene Corp. or Celgene RIVOT, as applicable have been transferred as a result of such merger or consolidation (for example, a reverse triangular merger), (A) Celgene Corp. or Celgene RIVOT, as applicable, provides Agios with at least [**] advance written notice of any such assignment(s), (B) prior to such assignment(s), Celgene Corp. or Celgene RIVOT, as applicable, agrees in a written agreement delivered to Agios (and upon which Agios may rely) to remain fully liable for the performance of its obligations under this Agreement by its assignee(s), and (C) prior to such assignment(s), the assignee(s) agree in a written agreement delivered to Agios (and upon which Agios may rely) to assume performance of all such assigned obligations. If Celgene Corp. or Celgene RIVOT, as applicable, wishes to assign any Celgene Collaboration

Intellectual Property or Joint Collaboration IP which Celgene Corp. or Celgene RIVOT, as applicable, Controls, or Agios Program Assets for each Program, to one or more permitted Affiliate(s), it will be permitted to do so conditioned on such Affiliate(s) becoming a party to this Agreement, in the form of an amendment to this Agreement executed by Celgene, Agios and such Affiliate(s), pursuant to which such Affiliate(s) would agree to assume all obligations hereunder, and grant to Agios all rights hereunder, with respect to the assets so assigned.

- (c) Agios. Notwithstanding the limitations in Section 15.4(a), Agios Pharmaceuticals and [Agios Ex-US] may assign this Agreement, or any rights or obligations hereunder in whole or in part, to (i) one or more Affiliates solely as provided in this Section 15.4(c) or (ii) its successor in connection with the merger, consolidation, or sale of all or substantially all of its assets or that portion of its business pertaining to the subject matter of this Agreement; provided, however, that, except in the case where [**], (A) Agios Pharmaceuticals or [Agios Ex-US], as applicable, provides Celgene with at least [**] advance written notice of any such assignment(s), (B) prior to such assignment(s), Agios Pharmaceuticals or [Agios Ex-US], as applicable, agrees in a written agreement delivered to Celgene (and upon which Celgene may rely) to remain fully liable for the performance of its obligations under this Agreement by its assignee(s), and (C) prior to such assignment(s), the assignee(s) agree in a written agreement delivered to Celgene (and upon which Celgene may rely) to assume performance of all such assigned obligations, (D) in the case of any assignment(s) by Agios Pharmaceuticals or [Agios Ex-US], as applicable, all Co-Co Collaboration Intellectual Property and Joint Collaboration IP which Agios Pharmaceuticals or [Agios Ex-US], as applicable, Controls, and all Program Assets for each Program will be transferred to such assignee(s) effective as of such assignment(s), and (E) all of the matters referred to in clauses (A), (B), (C) and (D), as applicable, will be set forth in documentation [**] prior to any such assignment(s) ([**]) and in all cases will provide [**]. Subject to the terms of this Section 15.4(c), if Agios Pharmaceuticals or [Agios Ex-US], as applicable, wishes to assign any [**], it will be permitted to do so conditioned on [**], pursuant to which such [**]. Nothing in this Agreement (including this Section 15.4(c)) shall be construed to contradict the requirement in Section 9.3.1(e)(iii)(B) of the Master Agreement.
- (d) In the event the Implementation Date for this Agreement has not occurred within [**] following the Effective Date, Celgene shall be entitled to [**], if required by any Antitrust Law; <u>provided that</u> the right to [**] set forth in this Section 15.4(d) shall not apply if a breach by Celgene of its obligations under Section 8.6(a) is a material cause of the failure to obtain clearance under Antitrust Laws.
- (e) Nothing in this Section 15.4 shall be construed to relieve any Party (or its assignee, as applicable) of its obligation under Sections 4.1(a), 4.1(c), or 4.1(g)(i) of this Agreement to locate a manufacturing facility or Backup Facility in a particular jurisdiction.

Section 15.5 <u>All Other Assignments Null and Void</u>. The terms of this Agreement will be binding upon and will inure to the benefit of the successors, heirs, administrators and permitted assigns of the Parties. Any purported assignment in violation of Section 15.4 will be null and void *ab initio*.

Section 15.6 <u>Change of Control</u>. Notwithstanding anything to the contrary in this Agreement, with respect to any intellectual property rights controlled by the acquiring party or its Affiliates (if other than one of the Parties to this Agreement) involved in any Change of Control of either Party, such intellectual property rights shall not be included in the technology and intellectual property rights licensed to the other Party hereunder to the extent held by such acquirer or its Affiliate (other than the relevant Party to this Agreement) prior to such transaction, or to the extent such technology is developed outside the scope of activities conducted with respect to the Collaboration, Compounds or Licensed Products, or related Companion Diagnostics. The Agios Intellectual Property and the Celgene Intellectual Property shall exclude any intellectual property owned or controlled by a permitted assignee or successor and not developed in connection with the Collaboration, Compounds or Licensed Products, or related Companion Diagnostics, Developed, Manufactured or Commercialized pursuant to this Agreement or the Master Agreement.

Section 15.7 Force Majeure. If the performance of any part of this Agreement by a Party is prevented, restricted, interfered with or delayed by an occurrence beyond the control of such Party (and which did not occur as a result of such Party's financial condition, negligence or fault), including fire, earthquake, flood, embargo, power shortage or failure, acts of war or terrorism, insurrection, riot, lockout or other labor disturbance, governmental acts or orders or restrictions, acts of God (for the purposes of this Agreement, a "force majeure event"), such Party shall, upon giving written notice to the other Party, be excused from such performance to the extent of such prevention, restriction, interference or delay; provided that the affected Party shall use its Commercially Reasonable Efforts to avoid or remove such causes of non-performance and shall continue performance with the utmost dispatch whenever such causes are removed.

Section 15.8 Notices. Unless otherwise agreed by the Parties or specified in this Agreement, all notices required or permitted to be given under this Agreement shall be in writing and shall be sufficient if: (a) personally delivered; (b) sent by registered or certified mail (return receipt requested and postage prepaid); (c) sent by express courier service providing evidence of receipt and postage prepaid where applicable; or (d) sent by facsimile transmission (receipt verified and a copy promptly sent by another permissible method of providing notice described in clauses (a), (b) or (c) above), to address for a Party set forth below, or such other address for a Party as may be specified in writing by like notice:

To Agios Pharmaceuticals:

Agios Pharmaceuticals, Inc. 88 Sidney Street Cambridge, MA 02139

Attention: Chief Executive Officer

Telephone: 617-649-8600

Facsimile: [**]

With a copy to: Agios Pharmaceuticals, Inc. 88 Sidney Street Cambridge, MA 02139

To Celgene Corp. or Celgene RIVOT:

Celgene Corporation 86 Morris Avenue Summit, NJ 07901

Attention: Senior Vice President Business

Development

Telephone: (908) 673-9000

Facsimile: [**]

With a copy to: Celgene Corporation 86 Morris Avenue Summit, NJ 07901 Attention: Legal Department Telephone: (617) 649-8600 Facsimile: [**]

and

WilmerHale 60 State Street Boston, MA 02109

Attention: Steven D. Singer Telephone: (617) 526-6410

Facsimile: (617) 526-5000

Attention: Legal Department Telephone: (908) 673-9000

Facsimile: [**]

and

Celgene RIVOT Ltd. Aon House 30 Woodbourne Avenue Pembroke HM 08 Bermuda

Phone: 441-296-4803

and

Dechert LLP 1900 K St. NW Washington, DC 20006 Attention: David E. Schulman Telephone: (202) 261-3440

Facsimile: [**]

To	[A	gios	Ex-	US]	ŀ

With a copy to:

and

WilmerHale 60 State Street Boston, MA 02109

Attention: Steven D. Singer Telephone: (617) 526-6410 Facsimile: (617) 526-5000

Any such notices shall be effective upon receipt by the Party to whom it is addressed.

Section 15.9 Waiver. Except as otherwise expressly provided in this Agreement, any term of this Agreement may be waived only by a written instrument executed by a duly authorized representative of the Party waiving compliance. The delay or failure of either Party at any time to require performance of any provision of this Agreement shall in no manner affect such Party's rights at a later time to thereafter enforce such provision. No waiver by either Party of any condition or term in any one or more instances shall be construed as a further or continuing waiver of such condition or term or of another condition or term.

Section 15.10 <u>Severability</u>. If any provision of this Agreement should be held invalid, illegal or unenforceable in any jurisdiction, the Parties shall negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties and all other provisions of this Agreement shall remain in full force and effect in such jurisdiction and shall be liberally construed in order to carry out the intentions of the Parties hereto as nearly as may be possible. If the Parties cannot agree upon a substitute provision, the invalid, illegal or unenforceable provision of this Agreement shall not affect the validity of this Agreement as a whole, unless the invalid, illegal or unenforceable provision is 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 provision.

Section 15.11 <u>Entire Agreement</u>. This Agreement (including the Exhibits attached hereto), together with the Master Agreement, constitutes the entire agreement between the Parties relating to its subject matter, and supersedes all prior and contemporaneous agreements, representations or understandings, either written or oral, between the Parties with respect to such subject matter. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as set forth herein and therein.

Section 15.12 <u>Modification</u>. No modification, amendment or addition to this Agreement, or any provision hereof, shall be effective unless reduced to writing and signed by a duly authorized representative of each Party. No provision of this Agreement shall be varied, contradicted or explained by any oral agreement, course of dealing or performance or any other matter not set forth in an agreement in writing and signed by a duly authorized representative of each Party.

Section 15.13 <u>Independent Contractors; No Intended Third Party Beneficiaries</u>. This Agreement is not intended nor shall be deemed or construed to create any relationship of employer and employee, agent and principal, partnership, or joint venture between the Parties. Each Party is an independent contractor. Neither Party shall assume, either directly or indirectly, any liability of or for the other Party. Neither Party shall have any express or implied right or authority to assume or create any obligations on behalf of, or in the name of, the other Party, nor to bind the other Party to any contract, agreement or undertaking with any Third Party. There are no express or implied third party beneficiaries hereunder, (a) except for the indemnitees identified in Section 13.1 and Section 13.2 and (b) except for any licensor under any Existing Third Party Agreement, to the extent described in Exhibit C. Notwithstanding the provisions of this Section 15.13, the provisions of Section 15.17 shall control for US federal income tax purposes, as applicable.

Section 15.14 <u>Interpretation; Construction</u>. The captions to the several Articles and Sections of this Agreement are included only for convenience of reference and shall not in any way affect the construction of, or be taken into consideration in interpreting, this Agreement. In this Agreement, unless the context requires otherwise, (a) the word "including" shall be deemed to be followed by the phrase "without limitation" or like expression, whether or not followed by

the same; (b) references to the singular shall include the plural and vice versa; (c) references to masculine, feminine and neuter pronouns and expressions shall be interchangeable; (d) the words "herein" or "hereunder" relate to this Agreement; (e) "or" is disjunctive but not necessarily exclusive; (f) the word "will" shall be construed to have the same meaning and effect as the word "shall"; and (g) all references to "dollars" or "\$" herein shall mean US Dollars. Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provisions.

Section 15.15 Performance by Affiliates.

- (a) To the extent that this Agreement imposes obligations on Affiliates of a Party, such Party agrees to cause its Affiliates to perform such obligations.
- (b) The Parties hereby acknowledge and agree that (a) Celgene Corp. and Agios Pharmaceuticals are the parties to this Agreement with respect to all rights and obligations (including payment obligations) under this Agreement in the United States; and (b) Celgene RIVOT and [Agios Ex-US] are the parties to this Agreement with respect to all rights and obligations under this Agreement outside of the United States.

Section 15.16 <u>Counterparts</u>. This Agreement may be executed in two (2) counterparts, each of which shall be deemed an original, and both of which together shall constitute one and the same instrument. Any such counterpart, to the extent delivered by means of a fax machine or by .pdf, .tif, .gif, .jpeg or similar attachment to electronic mail (any such delivery, an "<u>Electronic Delivery</u>") shall be treated in all manner and respects as an original executed counterpart and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person. No Party hereto shall raise the use of Electronic Delivery to deliver a signature or the fact that any signature or agreement or instrument was transmitted or communicated through the use of Electronic Delivery as a claim or defense with respect to the formation of a contract, and each Party forever waives any such claim or defense, except to the extent that such claim or defense relates to lack of authenticity.

Section 15.17 <u>Certain US Federal Income Tax Treatment</u>. Pursuant to Section 15.13, this Agreement is not intended nor shall be deemed or construed to create any relationship of employer and employee, agent and principal, legal partnership, or joint venture between the Parties; provided, however, that the Parties hereby acknowledge and agree that the Collaboration shall be treated as a partnership with respect to the [US / ROW] Territory for US federal and state income tax purposes only pursuant to Section 7701(a)(2) of the Code and the Treasury Regulations thereunder, and each of [Agios / Agios Ex-US] and [Celgene Corp. / Celgene RIVOT] shall be treated as partners in such partnership for all taxable periods that the Collaboration is effective and before the Agios Opt-Out Date. Agios and Celgene agree that each will take no position inconsistent with partnership tax treatment for US federal and state income tax purposes for such time. Exhibit G of this Agreement sets forth the Parties' intentions regarding allocations and other tax matters related to the tax partnership. Exhibit G shall be interpreted in a manner consistent with this Section 15.17.

Section 15.18 <u>HSR Clearance; Cooperation</u>. For the avoidance of doubt, the Parties shall continue to comply with Section 3.2 of the Master Agreement.

Section 15.19 <u>Equitable Relief</u>. Notwithstanding anything to the contrary herein, the Parties shall be entitled to seek equitable relief, including injunction and specific performance, as a remedy for any breach of this Agreement. Such remedies shall not be deemed to be the exclusive remedies for a breach of this Agreement but shall be in addition to all other remedies available at law or equity.

Section 15.20 <u>Further Assurances</u>. Each Party shall execute, acknowledge and deliver such further instruments, and do all such other acts, as may be necessary or appropriate in order to carry out the expressly stated purposes and the clear intent of this Agreement.

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF, the Parties have executed this Co-Development and Co-Commercialization Agreement as of the Effective Date.

Name:	Mana	
Solely with respect to the rights and obligations und this Co-Development and Co-Commercialization Agreement outside of the United States (subject to Section 15.15): [AGIOS EX-US] By:		
this Co-Development and Co-Commercialization Agreement outside of the United States (subject to Section 15.15): [AGIOS EX-US] By:	I itie:_	
[AGIOS EX-US] By:	this C Agree	o-Development and Co-Commercialization ement outside of the United States (subject to
By:	Section	n 15.15):
Name:	[AGI0	OS EX-US]
Name:	By:	
Title: CELGENE CORPORATION By: Name: Title: Solely with respect to the rights and obligations und this Co-Development and Co-Commercialization Agreement outside of the United States (subject to Section 15.15): CELGENE RIVOT LTD. By:		
By:		
Name:		
Solely with respect to the rights and obligations und this Co-Development and Co-Commercialization Agreement outside of the United States (subject to Section 15.15): CELGENE RIVOT LTD. By:		
Solely with respect to the rights and obligations und this Co-Development and Co-Commercialization Agreement outside of the United States (subject to Section 15.15): CELGENE RIVOT LTD. By:		
this Co-Development and Co-Commercialization Agreement outside of the United States (subject to Section 15.15): CELGENE RIVOT LTD. By:		
Agreement outside of the United States (subject to Section 15.15): CELGENE RIVOT LTD. By:		
Section 15.15): CELGENE RIVOT LTD. By:		
CELGENE RIVOT LTD. By:	_	
Ву:	Section	n 15.15):
	CELC	GENE RIVOT LTD.
	By:	

AGIOS PHARMACEUTICALS, INC.

Exhibit A

Target, Compound(s), Shared Program Type and Upfront Option Payment

1. apply to	Target: [check applicable box and identify applicable Program Target] The definitions under the selected Target shall this Agreement:				
	□ [**]				
	□ [**]				
	□ Other				
2.	Compounds [check applicable box and include Agios identifiers and structure(s)]:				
	☐ inhibitors of Target				
	or				
	□ activators of Target				
	Description of Compound:				
3.	Shared Program Type: [check applicable boxes]				
	☐ Shared 65/35 Program (and, for clarity, Celgene is the Lead Party)				
	or				
	☐ Shared 50/50 Program				
	Lead US Party: ☐ Agios ☐ Celgene				
4.	Upfront Option Payment calculated as either: [check applicable boxes]				
	☐ If the Program under this Agreement is a Designated Development Program or the Deemed DC Program, the sum of Thirty Million US Dollars (\$30,000,000) plus the Reimbursable Back-up Expenses and the Reimbursable Manufacturing Expenses (such Reimbursable Back-up Expenses and Reimbursable Manufacturing Expenses, in the aggregate, not to exceed [**] US Dollars (\$[**]));				
	A - 1				

	<u>OR</u>
	☐ If the Program under this Agreement is a Continuation Program (other than the Deemed DC Program), the sum of Thirty-Five Million US Dollars (\$35,000,000) plus the Reimbursable Back-up Expenses and the Reimbursable Manufacturing Expenses (such Reimbursable Back-up Expenses and Reimbursable Manufacturing Expenses, in the aggregate, not to exceed [**] US Dollars (\$[**])).
[Note: delete brack	seted references to the [**] and [**] Programs throughout, to the extent not applicable]
[Note: exceptions t	to Agios representations and warranties in Section 12.2 to be identified, if applicable]

ANNEX I

REIMBURSABLE MANUFACTURING EXPENSES AND REIMBURSABLE BACK-UP EXPENSES

Exhibit B

<u>Agios Patents, Celgene Patents and Celgene Collaboration Patents</u>
(as of the Execution Date)

Exhibit C

Existing Third Party Agreements

[Parties to identify each applicable Existing Third Party Agreement referenced in the Option Data Package and each provision thereof that must be included in this Agreement, including for Third Party Programs and Third Party Licenses]

Exhibit D

Certain Financial Definitions

"Accounting Standards" means (a) GAAP (United States Generally Accepted Accounting Principles) or (b) IFRS (International Financial Reporting Standards), in either case, consistently applied, and reported in such Person's financial statements.

"Additional Revenue" means the sum of (a) recoveries pursuant to Section 10.3(f)(ii)(A) of this Agreement, (b) insurance proceeds relating to liabilities previously paid by the Parties and reflected in Commercialization Expenses, and (c) any payments or income (other than Net Sales) received by a Party or its Affiliates that are attributable to the Licensed Products and relate to the Territory.

"Advertising and Market Research Expenses" means those expenses incurred related to: (a) conducting and monitoring professional and consumer appraisals of the Licensed Products in the Territory, such as market share services (*e.g.*, IMS data), pricing analysis, special research testing and focus groups; and (b) advertising and promotion of the Licensed Products in the Territory through any means, including (i) television and radio advertisements; (ii) advertisements appearing in journals, newspapers, magazines or other media; (iii) seminars, symposia and conventions; (iv) packaging design; (v) programs for education of health care professionals; (vi) product samples; (vii) visual aids and other selling materials; (viii) hospital formulary committee presentations; (ix) presentations to state and other governmental formulary committees; and (x) all media costs associated with product advertising.

"Annual Net Sales" means, with respect to Licensed Products sold after the Agios Opt-Out Date under this Agreement, the aggregate Net Sales of such Licensed Products by Celgene or its Affiliates or sublicensees in the portion of such Calendar Year following the Agios Opt-Out Date, and in each subsequent Calendar Year during which this Agreement is in effect.

"Commercialization Expenses" mean those expenses incurred by either Party (as detailed below) for the purpose of, and directly and specifically attributable to, the Commercialization of the Licensed Products in the Territory, and shall consist of the following expenses: (a) Distribution Costs; (b) Health Care Reform Fees; (c) Manufacturing Costs for commercial supply in the Territory; (d) Marketing Expenses; (e) Other Commercialization Costs; (f) Patent and Trademark Prosecution and Enforcement Costs incurred in any country of the Territory from and after the First Commercial Sale of a Licensed Product in the country; (g) Product Liabilities; (h) Recall Expenses; (i) Regulatory Maintenance Costs; (j) Selling Expenses; and (k) Third Party Patent Costs incurred in a country from and after the First Commercial Sale of a Licensed Product in the country.

Commercialization Expenses shall not include: (w) expenses related to any Clinical Trial even if incurred after the First Commercial Sale of a Licensed Product in any country of the Territory; (x) costs that are deductible from Net Sales under the definition thereof; (y) any losses, damages, fees, costs and other liabilities incurred by a Party as a result of such Party's negligence, gross negligence, illegal conduct, willful misconduct or breach of such Party's representations and warranties made hereunder and any such losses, damages, fees, costs and

other liabilities will be treated as the sole and exclusive responsibility of the Party whose actions or omissions gave rise to such losses, damages, fees, costs and other liabilities; or (z) fines, penalties, assessments or other financial sanctions levied by any governmental authority on either Party.

All of such costs shall be as determined from the books and records of the applicable Party and its Affiliates maintained in accordance with the Accounting Standards. Notwithstanding anything in this definition to the contrary, only those Commercialization Expenses that are contemplated by, and materially consistent with, the Commercialization Plan and Commercialization Budget for the Licensed Product shall be chargeable as Commercialization Expenses. For purposes of clarity, no general corporate overhead or fixed charges, such as depreciation, shall constitute Commercialization Expenses (except as otherwise provided under the definition of Manufacturing Costs).

"Development Costs" means the costs and expenses that are actually incurred by or on behalf of a Party and specifically identifiable or specifically allocable to the Development of the Licensed Products or Companion Diagnostics throughout the Territory. "Development Costs" shall include:

- (a) the FTE Costs of the relevant Party or its Affiliates with respect to such Development; it being understood and agreed that, in the case of FTE Costs involving Development activities incurred by Celgene and its Affiliates, in lieu of an FTE Cost reimbursement, Celgene shall be reimbursed at an amount equal to [**] percent ([**]%) of the Out-of-Pocket Costs referred to in clause (b) below;
- (b) all Out-of-Pocket Costs incurred by the Parties or their Affiliates, including payments made to Third Parties, with respect to such Development, including Phase IV Study Expenses (except to the extent that such costs have been included in FTE Costs);
 - (c) Regulatory Expenses other than Regulatory Maintenance Costs;
 - (d) the cost of contract research organizations (CROs);
 - (e) Manufacturing Costs for clinical supply, including:
 - (i) costs of packaging of drug products and distribution of drug products used in Clinical Trials;
 - (ii) expenses incurred to purchase or package comparator drugs;
 - (iii) costs and expenses of disposal of clinical samples; and
- (iv) costs and expenses incurred in scaling up Manufacturing activities related to pre-clinical or clinical supply, including formulation development activities;
 - (f) Manufacturing Scale-Up Costs; and

(g) Third Party Patent Costs and Patent and Trademark Prosecution and Enforcement Costs incurred in each country of the Territory prior to the First Commercial Sale of a Licensed Product in the country.

Development Costs shall not include: (x) any losses, damages, fees, costs and other liabilities incurred by a Party as a result of such Party's negligence, gross negligence, illegal conduct, willful misconduct or breach of such Party's representations and warranties made hereunder and any such losses, damages, fees, costs and other liabilities will be treated as the sole and exclusive responsibility of the Party whose actions or omissions gave rise to such losses, damages, fees, costs and other liabilities; or (y) fines, penalties, assessments or other financial sanctions levied by any governmental authority on either Party.

All of such costs shall be as determined from the books and records of the applicable Party and its Affiliates maintained in accordance with the Accounting Standards. Notwithstanding anything in this definition to the contrary, only those Development Costs that are contemplated by, and materially consistent with, the Development Plan and Development Budget for the Licensed Product shall be chargeable as Development Costs. For purposes of clarity, no general corporate overhead or fixed charges, such as depreciation, shall constitute Development Costs (except as otherwise provided under the definition of Manufacturing Costs).

"<u>Distribution Costs</u>" means Out-of-Pocket Costs and FTE Costs identifiable to the distribution of the Licensed Products in the Territory, including customer and wholesaler services, collection of data on sales, order entry, billing, shipping, logistics, warehousing, product insurance, freight not paid by customers, credit collection and similar activities.

"FTE" means the equivalent of the work of one (1) full-time employee of a Party or its Affiliates for one (1) year (consisting of [**] hours per year) in directly conducting Development, Manufacturing and/or Commercialization activities hereunder. Any Party's employee who devotes fewer than [**] hours per year on the applicable activities shall be treated as an FTE on a pro-rata basis, calculated by dividing the actual number of hours worked by such employee on such activities by [**]. Any employee who devotes more than [**] hours per year on the applicable activities shall be treated as one (1) FTE. For the avoidance of doubt, FTE shall not include the work of general corporate or administrative personnel, except for the portion of such personnel's work time actually spent on conducting scientific, technical or commercial activities directly related to the Development, Manufacture or Commercialization of Licensed Products.

"FTE Costs" means, for any period, the FTE Rate multiplied by the number of FTEs in such period.

"FTE Rate" means, during the Term: (a) with respect to Development activities, \$[**] per FTE and (b) with respect to Commercialization activities, \$[**] per FTE. On January 1 of the Calendar Year following the Effective Date and on January 1st of each subsequent Calendar Year, the foregoing rate shall be increased for the Calendar Year then commencing by the percentage increase, if any, [**] as of December 31 of the then most recently completed Calendar Year with respect to the level of the [**] on December 31 of the Calendar Year preceding the Effective Date. As used in this definition, [**].

"Health Care Reform Fees" means Out-of-Pocket Costs representing the annual fee paid to the US Government as defined in the Patient Protection and Affordable Care Act ("PPACA") and similar taxes and governmental fees in the United States, in each case to the extent directly attributable to the Licensed Products. If any similar governmental fee is legislated or rule created in any jurisdiction in the Territory, such fee would be considered Health Care Reform Fees to the extent directly attributable to the Licensed Products.

"Manufacturing Costs" means, with respect to the Licensed Products, the reasonable FTE Costs and Out-of-Pocket Costs of a Party or any of its Affiliates or sublicensees incurred in Manufacturing the Licensed Products, excluding Manufacturing Scale-Up Costs, but including:

- (h) to the extent that the Licensed Products are manufactured by a Party or any of its Affiliates or sublicensees, direct material and direct labor costs, plus manufacturing overhead attributable to the Compound and any Products (including facility start-up costs, all directly incurred manufacturing variances, and a reasonable allocation of related manufacturing administrative and facilities costs (including depreciation) and a reasonable allocation of the costs of failed batches to be further described in the applicable supply agreement, to be provided for the Licensed Products, but excluding costs associated with excess capacity), all determined in accordance with the books and records of the applicable Party or its Affiliates or sublicensees maintained in accordance with the Accounting Standards, consistently applied; and
- (i) to the extent that the Licensed Products are manufactured by a Third Party manufacturer, the Out-of-Pocket Costs paid by a Party or any of its Affiliates or sublicensees to the Third Party for the manufacture, supply, packaging and labeling of the Licensed Products, and any reasonable Out-of-Pocket Costs and direct labor costs actually incurred by such Party or any of its Affiliates or sublicensees in managing or overseeing the Third Party relationship, determined in accordance with the books and records of the applicable Party or its Affiliates or sublicensees maintained in accordance with the Accounting Standards, consistently applied.

"Manufacturing Scale-Up Costs" means the reasonable FTE Costs and Out-of-Pocket Costs of a Party or any of its Affiliates or sublicensees incurred in scaling up Manufacturing activities related to the Licensed Products for clinical and commercial supply, including (a) costs for process development work, analytical method optimization, and process validation, (b) costs for complete technology transfer to a commercial site (including costs for Manufacturing of demonstration batches on a suitable scale), and (c) Regulatory Expenses associated with such Manufacturing activities.

"Marketing Expenses" mean the sum of Marketing Management Expenses, Advertising and Market Research Expenses and Medical Education Expenses.

"Marketing Management Expenses" mean FTE Costs of the Parties arising from the management of marketing activities for the Licensed Products in the Field in the Territory, including management and administration of managed care and national accounts and other activities associated with developing overall sales and marketing strategies; product-related advertising, market research and public relations; relationship maintenance with opinion leaders, professional societies, contract pricing administrators, and market information systems; education programs for health care professionals; governmental affairs activities for

reimbursement, formulary acceptance; and other activities directly related to the marketing or promotion of a Licensed Product in the Territory; <u>provided that</u>, in each case, such costs may be allocated to the Licensed Product on a percent of sales or other basis consistently applied within and across a Party's operating units; <u>provided</u>, <u>further</u>, <u>that</u> such allocation is made no less favorable to the Licensed Product than to the internal allocation to such Party's other products.

"Medical Education Expenses" means all Out-of-Pocket Costs specifically incurred to educate health care professionals licensed to practice in the Territory with respect to a Licensed Product in the Territory through any means not covered in the definition of "Advertising and Marketing Research Expenses", but including articles appearing in journals, newspapers, magazines or other media; seminars, scientific exhibits, and conventions; and symposia, advisory boards and opinion leader development activities; medical science liaison (MSL) and medical affairs activities, and education grant programs.

"Net Sales" means, with respect to any Licensed Product, the gross amounts invoiced by the Parties, their respective Affiliates or Licensee Partners to Third Parties (that are not Licensee Partners) for the sale or other commercial disposition of such Licensed Product anywhere within the Territory (each, a "Selling Party") to Third Party customers for sales of such Licensed Product, less the following deductions actually incurred, allowed, paid, accrued or specifically allocated in its financial statements in accordance with (as applicable to the Selling Party) the Accounting Standards, for:

[**].

If non-monetary consideration is received by a Selling Party for any Licensed Product in the relevant country, Net Sales will be calculated based on the average price charged for such Licensed Product, as applicable, during the preceding royalty period, or in the absence of such sales, the fair market value of the Licensed Product, as applicable, as determined by the Parties in good faith. Notwithstanding the foregoing, Net Sales shall not be imputed to transfers of Licensed Products, as applicable, for use in Clinical Trials, non-clinical development activities or other development activities with respect to Licensed Products by or on behalf of the Parties, for bona fide charitable purposes or for compassionate use or for Licensed Product samples, if no monetary consideration is received for such transfers.

If a Licensed Product is sold as part of a Combination Product (as defined below), Net Sales will be the product of (i) Net Sales of the Combination Product calculated as above (i.e., calculated as for a non-Combination Product) and (ii) the fraction (A/(A+B)), where:

"A" is the gross invoice price in such country of the Licensed Product comprising a Compound as the sole therapeutically active ingredient; and

"B" is the gross invoice price in such country of the other therapeutically active ingredients contained in the Combination Product.

If "A" or "B" cannot be determined by reference to non-Combination Product sales as described above, then Net Sales will be calculated as above, but the gross invoice price in the above equation shall be determined by mutual agreement reached in good faith by the Parties prior to the end of the accounting period in question based on an equitable method of determining the same that takes into account, in the applicable country, variation in dosage units and the relative fair market value of each therapeutically active ingredient in the Combination Product.

As used in this definition of "Net Sales," "Combination Product" means a Licensed Product that contains one or more additional active ingredients (whether co-formulated or co-packaged) that are neither Compounds nor generic or other non-proprietary compositions of matter. Pharmaceutical dosage form vehicles, adjuvants and excipients shall be deemed not to be "active ingredients."

There shall be no double counting in determining the foregoing deductions from gross amounts invoiced to calculate Net Sales. Subject to the foregoing, the calculations set forth in this definition of Net Sales shall be determined in accordance with Accounting Standards so as to arrive at Net Sales under Accounting Standards as reported by the Selling Party in such Person's financial statements.

"Other Commercialization Costs" means any Out-of-Pocket Costs and FTE Costs approved by the JCC and included in the Commercialization Budget and Commercialization Plan that is not otherwise included in any other Commercialization Expense category. It is understood that Other Commercialization Costs shall not include costs associated with Development activities.

"Out-of-Pocket Costs" means, with respect to certain activities hereunder, direct expenses paid or payable by either Party or its Affiliates to Third Parties (other than employees of such Party or its Affiliates) that are specifically identifiable and incurred to conduct such activities for the Collaboration hereunder and have been recorded in accordance with the Accounting Standards.

"Patent and Trademark Prosecution and Enforcement Costs" means (a) costs incurred pursuant to Section 10.2(c), Section 10.3(e) and Section 10.4, and (b) costs incurred in connection with the selection, protection, utilization and defense of Product Trademarks relating to the Licensed Products.

"Phase IV Study Expenses" means all Out-of-Pocket Costs incurred for the Territory related to a Phase IV Study for any Licensed Product in the Territory, including expenses arising from: (a) the activities related to the performance of the Phase IV Study; (b) Manufacturing Costs for Licensed Product used in connection with such Phase IV Study; (c) preparation, filing, and maintenance of related Regulatory Documentation; and (d) any Product Liabilities relating to a Licensed Product being used in the course of such Phase IV Study; provided, however, that any losses, damages, fees, costs and other liabilities, including any Product Liabilities, that are the result of a Party's negligence, gross negligence, illegal conduct, willful misconduct or breach of such Party's representations or warranties, are expressly excluded from the definition of Phase IV Study Expenses, and shall be treated as the sole and exclusive responsibility of the Party whose actions or omissions gave rise to such losses, damages, fees, costs and other liabilities.

"<u>Product Liabilities</u>" means all losses, damages, fees, costs and other liabilities incurred by a Party, its Affiliate or its sublicensee and resulting from or relating to the use of a Licensed Product in a human (including clinical trials or Commercialization) in the Territory incurred after

the Effective Date. For the avoidance of doubt, Product Liabilities include reasonable attorneys' and experts' fees and costs relating to any claim or potential claim against a Party, its Affiliate, or its sublicensee and all losses, damages, fees and costs associated therewith. Product Liabilities shall not include liabilities associated with recalls or the voluntary or involuntary withdrawal of the Licensed Product.

"Profit or Loss" means the profits or losses resulting from the Commercialization of the Licensed Products in the Territory and which shall be equal to (a) the sum of (i) Net Sales of Licensed Products in the Territory, plus (ii) Additional Revenue, less (b) Commercialization Expenses for such Licensed Products. As used herein, "Profit" refers to a Calendar Quarter or Calendar Year in which a profit exists, and "Loss" refers to a Calendar Quarter or Calendar Year in which a loss exists.

"Recall Expenses" means Out-of-Pocket Costs and FTE Costs directly associated with notification, retrieval and return of Licensed Products, distribution of such returned Licensed Products, replacement Licensed Products and distribution of the replacement Licensed Products, in each case that are incurred with respect to a recall conducted in accordance with Section 5.4 of this Agreement.

"Regulatory Expenses" means, with respect to the Licensed Products, all Out-of-Pocket Costs incurred by or on behalf of a Party in connection with the preparation and filing of regulatory submissions for the Licensed Products and obtaining of Regulatory Approvals and any applicable governmental price and reimbursement approvals.

"Regulatory Maintenance Costs" means Out-of-Pocket Costs and FTE Costs for maintenance fees relating to Regulatory Approvals for the Licensed Products, and personnel engaged in the filing and maintenance of Regulatory Approvals.

"Selling Expenses" means (a) the FTE Costs incurred by the Parties in performance of details or Out-of-Pocket Costs incurred by the Parties for the performance of details by a qualified contract sales force in the Territory; where such FTE Costs shall be calculated on the basis of a fixed rate per detail, which shall be approved by the JSC prior to the First Commercial Sale, and (b) Out-of-Pocket Costs and FTE Costs directly attributable to selling the Licensed Products, including sales managers, exhibits at shows or conventions including samples, charges for space, sales aids and brochures, sales meetings, specialty sales forces, call reporting and Third Party monitoring/tracking services.

"Third Party Patent Costs" means Out-of-Pocket Costs paid to Third Parties pursuant to Section 9.6 of this Agreement.

All costs in this Exhibit D shall be as determined from the books and records of the applicable Party and its Affiliates maintained in accordance with the Accounting Standards.

Exhibit E

Countries for Filing Agios Patents, Celgene Collaboration Patents and Agios Co-Co Collaboration Patents

[**]

Exhibit F

Press Release

F-1

Exhibit G

PARTNERSHIP TAX MATTERS

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of 5 pages were omitted. [**]

SCHEDULE 6.3

Minimum Agios and Celgene Sales Representative Qualifications

[**].

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[tailor as applicable]

Schedule 12.2(d)

Schedule 12.2(e)

Schedule 12.2(f)

Schedule 12.2(h)

Schedule 12.2(i) Patents

Schedule 12.2(j) Existing Third Party Agreements

[Note: exceptions in Section 12.2 to be identified, if applicable]

APPENDIX B

FORM OF LICENSE AGREEMENT

B-1

APPENDIX B

FORM OF LICENSE AGREEMENT

LICENSE AGREEMENT

by and among

AGIOS PHARMACEUTICALS, INC.

and

CELGENE CORPORATION

and

CELGENE RIVOT LTD.

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Exhibits

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Exhibit B Agios Patents and Celgene Collaboration Patents

Exhibit C Existing Third Party Agreements

Exhibit D Countries for Filing Agios Patents, Celgene Collaboration Patents and Joint Patents

Exhibit E Press Release

Disclosure Schedules

[tailor as applicable]

Schedule 12.2(d)

Schedule 12.2(e)

Schedule 12.2(f)

Schedule 12.2(h)

Schedule 12.2(i) Patents

Schedule 12.2(j) Existing Third Party Agreements

LICENSE AGREEMENT

This License Agreement (this "Agreement") is entered into as of [•] (the "Execution Date"), by and among Agios Pharmaceuticals, Inc., a Delaware corporation ("Agios"), on the one hand, and Celgene Corporation, a Delaware corporation ("Celgene Corp."), with respect to all rights and obligations under this Agreement in the United States, and Celgene RIVOT Ltd., a Bermuda company ("Celgene RIVOT"), with respect to all rights and obligations under this Agreement outside of the United States (Celgene RIVOT and Celgene Corp. together, "Celgene"), on the other hand. Celgene and Agios are each referred to herein by name or as a "Party", or, collectively, as the "Parties".

INTRODUCTION

- 1. Agios and Celgene are parties to the Master Research and Collaboration Agreement, dated as of May 17, 2016 (the "Master Agreement").
- 2. Pursuant to the Master Agreement, Agios has discovered and has been developing the compound(s) in the I&I Field identified on Exhibit A, each of which the Parties believe to be a potent [inhibitor/activator] [select applicable direction of modulation at Execution] of the metabolic target identified on Exhibit A.
- 3. Except as provided herein, the Parties have agreed that the further Development and Commercialization of the Compound should be conducted pursuant to the terms of this Agreement and that all further such activities related to the Compound should cease under the Master Agreement.

NOW, THEREFORE, in consideration of the respective representations, warranties, covenants and agreements contained herein, and for other valuable consideration, the receipt and adequacy of which are hereby acknowledged, Agios and Celgene hereby agree as follows:

Article I. Definitions

Terms used but not defined herein shall have the meaning set forth in the Master Agreement. When used in this Agreement, each of the following terms shall have the meanings set forth in this Article I:

- Section 1.1 "<u>Accounting Standards</u>" means (a) GAAP (United States Generally Accepted Accounting Principles) or (b) IFRS (International Financial Reporting Standards), in either case, consistently applied, and reported in such Person's financial statements.
 - Section 1.2 "Agios Intellectual Property" means Agios Know-How and Agios Patents, collectively.
- Section 1.3 "Agios Know-How" means any Know-How that is (a) Controlled by Agios as of the Execution Date or during the Term, and (b) necessary or useful for the Development, Manufacture or Commercialization of the Compounds or Licensed Products.

- Section 1.4 "Agios Patents" means any Patents that (a) are Controlled by Agios as of the Execution Date or during the Term, and (b) Cover, or are useful for, the Development, Manufacture or Commercialization of the Compounds or Licensed Products (including the composition of matter, manufacture or any use thereof). Agios Patents as of the Execution Date are as set forth on Exhibit B to this Agreement.
- Section 1.5 "<u>Annual Net Sales</u>" means, the aggregate Net Sales of a Licensed Product by Celgene or its Affiliates or Licensee Partners in each Calendar Year during which this Agreement is in effect.
- Section 1.6 "<u>Calendar Quarter</u>" means a calendar quarter ending on the last day of March, June, September or December; provided, however, that the first Calendar Quarter shall begin on the Effective Date and end on the last day of the calendar quarter during which the Effective Date occurs.
- Section 1.7 "<u>Calendar Year</u>" means a period of time commencing on January 1 and ending on the following December 31; provided, however, that the first Calendar Year shall begin on the Effective Date and end on December 31 of the calendar year during which the Effective Date occurs.
- Section 1.8 "<u>Celgene Collaboration Intellectual Property</u>" means Celgene Collaboration Know-How and Celgene Collaboration Patents, collectively.
- Section 1.9 "Celgene Collaboration Know-How" means, collectively, (a) Know-How within Celgene Collaboration Intellectual Property (as defined in the Master Agreement) that is necessary or useful for the Development, Manufacture and/or Commercialization of any Compounds or Licensed Products and (b) if the Program (as defined in the Master Agreement) that is the subject of this Agreement is a Qualified Early Exercise I&I Program (as defined in the Master Agreement), all Know-How developed or generated on or after the Execution Date by or on behalf of Celgene and/or its Affiliates in the conduct of the Development, Manufacture and/or Commercialization of any Compounds or Licensed Products pursuant to this Agreement, in each case ((a) and (b)), Controlled by Celgene.
- Section 1.10 "Celgene Collaboration Patents" means, collectively, (a) Patents within Celgene Collaboration Intellectual Property (as defined in the Master Agreement) that are necessary or useful for the Development, Manufacture and/or Commercialization of any Compounds or Licensed Products and (b) if the Program (as defined in the Master Agreement) that is the subject of this Agreement is Qualified Early Exercise I&I Program (as defined in the Master Agreement), all Patents that Cover Celgene Collaboration Know-How, in each case ((a) and (b)) Controlled by Celgene. Celgene Collaboration Patents as of the Execution Date are as set forth on Exhibit B to this Agreement.
 - Section 1.11 "Celgene Intellectual Property" means Celgene Know-How and Celgene Patents, collectively.
- Section 1.12 "<u>Celgene Know-How</u>" means any Know-How that is (a) Controlled by Celgene as of the Effective Date or during the Term; (b) necessary or useful for the Development, Manufacture or Commercialization of the Compounds or Licensed Products; and (c) contributed by Celgene, in Celgene's sole discretion, for use in the Collaboration, as evidenced by written notice from Celgene to Agios; but excluding Celgene Collaboration Know-How.

- Section 1.13 "<u>Celgene Patents</u>" means any Patents that (a) are Controlled by Celgene as of the Effective Date or during the Term; (b) Cover the Compounds or Licensed Products; and (c) are contributed by Celgene, in Celgene's sole discretion, for use in the Collaboration, as evidenced by written notice from Celgene to Agios; but excluding Celgene Collaboration Patents.
- Section 1.14 "Clinical Trial" means a Phase I Study, a Phase II Study, a Phase III Study, a Phase IV Study or a combination of any of the foregoing studies.
 - Section 1.15 "Code" means the United States Internal Revenue Code of 1986, as amended.
- Section 1.16 "<u>Collaboration</u>" means the activities performed or to be performed by a Party or Parties, as the case may be, relating to the Development, Manufacturing and Commercialization of the Licensed Products under this Agreement or the Master Agreement.
- Section 1.17 "Companion Diagnostic" means a biomarker or diagnostic test that is developed by a Party or jointly by the Parties in the course of the Collaboration as a companion diagnostic for use with a Licensed Product in accordance with the Regulatory Approval(s) therefor to generate a result for the purposes of diagnosing a disease or condition, or to facilitate the application of the Licensed Product that is used in the cure, mitigation, treatment, or prevention of disease, including a biomarker or diagnostic test used to diagnose the likelihood that a specific patient will contract a certain disease or condition or to predict which patients are suitable candidates for a specific form of therapy.
- Section 1.18 "Compound" means (a) any compound that is listed on Exhibit A, [or, if the applicable program is a Qualified Early Exercise I&I Program, any Program Compounds (as defined in the Master Agreement, including any chemotypes described on Schedule 1.1.83 thereto) that are listed on Exhibit A] *[insert if applicable]* and (b) to the extent Active (as defined in the Master Agreement) against the Target, any salt, fluorinated derivative, free acid, free base, clathrate, solvate, hydrate, hemihydrates, anhydride, ester, chelate, conformer, congener, crystal form, crystal habit, polymorph, amorphous solid, isomer, stereoisomer, enantiomer, racemate, prodrug, isotopic or radiolabeled equivalent, metabolite, conjugate, complex or mixture, of such chemical entity of any such compound identified in the foregoing clause (a) or in this clause (b).
- Section 1.19 "<u>Confidential Information</u>" means (a) all confidential or proprietary information relating to the Development, Manufacture or Commercialization of the Compounds or Licensed Products, and (b) all other confidential or proprietary documents, technology, Know-How or other information (whether or not patentable) actually disclosed by one Party to the other pursuant to this Agreement or the Master Agreement relating to the Licensed Products and all proprietary biological materials of a Party.

- Section 1.20 "<u>Data</u>" means any and all research data, results, pharmacology data, medicinal chemistry data, preclinical data, market research, clinical data (including investigator reports (both preliminary and final), statistical analysis, expert opinions and reports, safety and other electronic databases), in any and all forms, including files, reports, raw data, source data (including patient medical records and original patient report forms, but excluding patient-specific data to the extent required by applicable Laws) and the like, in each case directed to, or used in, the Development, Manufacture or Commercialization of the Licensed Products.
- Section 1.21 "<u>Effective Date</u>" means the date on or after the Execution Date that is the Implementation Date (as defined in the Master Agreement) with respect to this Agreement.
- Section 1.22 "Executive Officers" means Celgene's Chief Executive Officer (or the officer or employee of Celgene then serving in a substantially equivalent capacity) or his designee and Agios' Chief Executive Officer (or the officer or employee of Agios then serving in a substantially equivalent capacity) or his designee; provided that any such designee must have decision-making authority on behalf of the applicable Party.
 - Section 1.23 "Existing Third Party Agreement" means any agreement listed on Exhibit C to this Agreement.
 - Section 1.24 "Field" means the treatment, control, mitigation, prevention or cure or diagnosis of any Indications.
- Section 1.25 "<u>First Commercial Sale</u>" means the first commercial sale of a Licensed Product by Celgene, its Affiliates, Licensee Partners, distributors or agents in a country in an arms' length transaction to a Third Party following receipt of applicable Regulatory Approval of such product in such country. Sales for test marketing or clinical trial purposes shall not constitute a First Commercial Sale.
 - Section 1.26 "[**]" means [**].
- Section 1.27 "<u>Generic Competition</u>" means, with respect to a Licensed Product in a given country in a given Calendar Year, that, during such Calendar Year one or more Generic Products shall be commercially available in such country.
- Section 1.28 "Generic Product" means, as to a Licensed Product, any product (including a "generic product" approved by way of an Abbreviated New Drug Application by the FDA (or equivalent regulatory mechanism for another Regulatory Authority), "biogeneric," "follow-on biologic," "follow-on biological product," "follow-on protein product," "similar biological medicinal product," or "biosimilar product") that, in each case, (a) is sold by a Third Party that is not a Licensee Partner of Celgene or any of its Affiliates and that has not otherwise been authorized by Celgene or any of its Affiliates under a Regulatory Approval granted by a Regulatory Authority to such Third Party that is based upon or relies upon the Regulatory Approval granted by such Regulatory Authority for such Licensed Product; and (b) in the United States, is "therapeutically equivalent," "comparable," "biosimilar," or "interchangeable," as evaluated by the FDA, applying the definition of "therapeutically equivalent" set forth in the preface to the thencurrent edition of the FDA publication "Approved Drug Products With Therapeutic Equivalence Evaluations" or any other definitions set forth in the U.S. Code, FDA regulations, or other source of U.S. Law and, outside the United States, meets such equivalent determination by the applicable Regulatory Authorities (including a determination that the

product is "comparable," "interchangeable," "bioequivalent," or "biosimilar" with respect to the Licensed Product), in each case, as is necessary to permit a pharmacist or other individual authorized to dispense pharmaceuticals under Law to substitute one product for another product in the absence of specific instruction from a physician or other authorized prescriber under Law

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Section 1.29 "[**]" means [**].
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Section 1.30 "<u>Licensed Products</u>" means (a) a Compound, and (b) any product that contains a Compound as an active ingredient.

Section 1.31 "<u>Licensee Partner</u>" means any Third Party to whom Celgene or any of its Affiliates or any other Licensee Partner grants a sublicense or license with respect to the Development, Manufacture or Commercialization of Licensed Products in the Field under the rights to Agios Intellectual Property, granted to Celgene or its Affiliate hereunder, in each case excluding (a) Third Party Contractors and (b) wholesale distributors or any other Third Party that purchases Licensed Product in an arm's-length transaction, where such Third Party does not have a sublicense to Develop, Manufacture or Commercialize the Licensed Product except for a limited sublicense to the extent required to enable such Third Party to perform final packaging for such Licensed Product for local distribution.

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Section 1.32 "Major [**]" means [**].
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Section 1.33 "Major Market" means [**].

Section 1.34 "Manufacture" or "Manufacturing" means, as applicable, all activities associated with the production, manufacture, processing, filling, packaging, labeling, shipping, and storage of a drug substance or drug product, or any components thereof, including process and formulation development, process validation, stability testing, manufacturing scale up, preclinical, clinical and commercial manufacture and analytical methods development and validation, product characterization, quality assurance and quality control development, testing and release.

Section 1.35 "Manufacturing Technology" means copies of all Agios Know-How or Celgene Know-How, as applicable, which are necessary or useful for Manufacturing preclinical, clinical or commercial supply, as applicable, of the Licensed Products, including specifications, assays, batch records, quality control data, and transportation and storage requirements.

Section 1.36 "NDA" means an application submitted to a Regulatory Authority for the marketing approval of a Licensed Product, including (a) a New Drug Application, Product License Application or Biologics License Application (as such capitalized terms are used in C.F.R Title 21) filed with FDA or any successor applications or procedures, (b) a foreign equivalent of a U.S. New Drug Application, Product License Application or Biologics License Application or any successor applications or procedures, including a Marketing Authorization Application in the European Union, and (c) all supplements and amendments that may be filed with respect to the foregoing.

Section 1.37 "Net Sales" means, with respect to any Licensed Product, the gross amounts invoiced by Celgene, its respective Affiliates or Licensee Partners to Third Parties (that are not Licensee Partners) for the sale or other commercial disposition of such Licensed Product anywhere within the Territory (each, a "Selling Party") to Third Party customers for sales of such Licensed Product, less the following deductions actually incurred, allowed, paid, accrued or specifically allocated in its financial statements in accordance with (as applicable to the Selling Party) the Accounting Standards, for:

[**]

If non-monetary consideration is received by a Selling Party for any Licensed Product in the relevant country, Net Sales will be calculated based on the average price charged for such Licensed Product, as applicable, during the preceding royalty period, or in the absence of such sales, the fair market value of the Licensed Product, as applicable, as determined by the Parties in good faith. Notwithstanding the foregoing, Net Sales shall not be imputed to transfers of Licensed Products, as applicable, for use in Clinical Trials, non-clinical development activities or other development activities with respect to Licensed Products by or on behalf of the Parties, for bona fide charitable purposes or for compassionate use or for Licensed Product samples, if no monetary consideration is received for such transfers.

If a Licensed Product is sold as part of a Combination Product (as defined below), Net Sales will be the product of (i) Net Sales of the Combination Product calculated as above (i.e., calculated as for a non-Combination Product) and (ii) the fraction (A/(A+B)), where:

"A" is the gross invoice price in such country of the Licensed Product comprising a Compound as the sole therapeutically active ingredient; and

"B" is the gross invoice price in such country of the other therapeutically active ingredients contained in the Combination Product.

If "A" or "B" cannot be determined by reference to non-Combination Product sales as described above, then Net Sales will be calculated as above, but the gross invoice price in the above equation shall be determined by mutual agreement reached in good faith by the Parties prior to the end of the accounting period in question based on an equitable method of determining the same that takes into account, in the applicable country, variation in dosage units and the relative fair market value of each therapeutically active ingredient in the Combination Product.

As used in this definition of "Net Sales," "Combination Product" means a Licensed Product that contains one or more additional active ingredients (whether co-formulated or co-packaged) that are neither Compounds nor generic or other non-proprietary compositions of matter. Pharmaceutical dosage form vehicles, adjuvants and excipients shall be deemed not to be "active ingredients."

There shall be no double counting in determining the foregoing deductions from gross amounts invoiced to calculate Net Sales. Subject to the foregoing, the calculations set forth in this definition of Net Sales shall be determined in accordance with Accounting Standards so as to arrive at Net Sales under Accounting Standards as reported by the Selling Party in such Person's financial statements.

- Section 1.38 "Out-of-Pocket Costs" means, with respect to certain activities, direct expenses paid or payable by either Party or its Affiliates to Third Parties (other than employees of such Party or its Affiliates) that are specifically identifiable and incurred to conduct such activities and have been recorded in accordance with the Accounting Standards.
- Section 1.39 "<u>Phase IV Study</u>" means a human clinical trial of a product which is (a) conducted to satisfy a requirement of a Regulatory Authority in order to maintain a Regulatory Approval or (b) conducted voluntarily after Regulatory Approval of the product has been obtained from an appropriate Regulatory Authority for enhancing marketing or scientific knowledge of an approved Indication.
- Section 1.40 "<u>Product Liabilities</u>" means all product liability losses, damages, fees, costs and other liabilities incurred by a Party, its Affiliate or its Licensee Partner and resulting from or relating to the use of a Licensed Product in a human (including Clinical Trials or Commercialization) incurred after the Execution Date. For the avoidance of doubt, Product Liabilities include reasonable attorneys' and experts' fees and costs relating to any claim or potential claim against a Party, its Affiliate, or its Licensee Partner and all losses, damages, fees and costs associated therewith. Product Liabilities shall not include liabilities associated with recalls or the voluntary or involuntary withdrawal of the Licensed Product.
- Section 1.41 "Regulatory Documentation" means, with respect to the Licensed Products, all INDs, NDAs and other regulatory applications submitted to any Regulatory Authority, Regulatory Approvals, pre-clinical and clinical data and information, regulatory materials, drug dossiers, master files (including Drug Master Files, as defined in 21 C.F.R. 314.420 and any non-United States equivalents), and any other data, reports, records, regulatory correspondence and other materials relating to Development or Regulatory Approval of the Licensed Products, or required to Manufacture, distribute or sell the Licensed Products, including any information that relates to pharmacology, toxicology, chemistry, Manufacturing and controls data, batch records, safety and efficacy, and any safety database.
- Section 1.42 "Regulatory Exclusivity" means, with respect to a Licensed Product in a country, that the Licensed Product has been granted marketing exclusivity afforded approved drug products, or approved biological products if applicable, pursuant to (a) Sections 505(c), 505(j), and 505A of the FDCA, and the regulations promulgated thereunder, as amended from time to time, or similar laws enacted to apply to biological products, and the regulations promulgated thereunder, as amended from time to time, or their equivalent in a country other than the United States, (b) the orphan drug exclusivity afforded approved drugs designated for rare diseases or conditions under Sections 526 and 527 of the FDCA, and the regulations promulgated thereunder, as amended from time to time, or its equivalent in a country other than the United States, or (c) any future Law.
- Section 1.43 "<u>Reimbursable Back-up Expenses</u>" means, [**]. The amount of the Reimbursable Back-up Expenses, if any, is set forth on Annex I to Exhibit A.
- Section 1.44 "<u>Reimbursable Manufacturing Expenses</u>" means, [**]. The amount of the Reimbursable Manufacturing Expenses, if any, is set forth on Annex I to Exhibit A.

- Section 1.45 "Right of Reference or Use" means a "Right of Reference or Use" as that term is defined in 21 C.F.R. §314.3(b), and any non-United States equivalents.
 - Section 1.46 "Target" means the metabolic target set forth on Exhibit A.
 - Section 1.47 "Territory" means worldwide.
- Section 1.48 "<u>Third Party Agreement</u>" means (a) each [**] and (b) any other Third Party agreement that Celgene may enter into, during the Term in accordance with the terms of this Agreement, to acquire or license Third Party Patents or Know-How that are necessary or useful for the Development, Manufacture or Commercialization of the Compounds or Licensed Products.
- Section 1.49 "<u>Third Party Rights</u>" means, with respect to a Party, any rights of, and any limitations, restrictions or obligations imposed by, Third Parties pursuant to any Third Party Agreements.
- Section 1.50 "<u>Valid Claim</u>" means (a) a claim of any issued, unexpired patent that has not been revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no appeal can be taken, or with respect to which an appeal is not taken within the time allowed for appeal, and that has not been disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise, or (b) a patent application or subject matter of a claim thereof filed by a Person in good faith that has not been cancelled, withdrawn or abandoned, nor been pending for more than [**] from the earliest filing date to which such patent application or claim is entitled.

Section 1.51 Additional Definitions. Each of the following definitions is set forth in the section of this Agreement indicated below:

<u>DEFINITION</u>

SECTION

Section 10.8

35 U.S.C. § 102(c) Patent [**]
Acquirer Program
Affiliate

Agios Indemnified Parties

Agios Program Assets
Agreement
Antitrust Law
Audit Team

Business Day
Celgene
Celgene Corp.
Celgene RIVOT
Celgene Indemnified Parties

Bankruptcy Code

Section 8.6(b)(iii)
Section 8.6(b)(v)(4)
Master Agreement
Preamble
Section 13.1(a)
Section 12.4
Preamble

Master Agreement Section 9.6(a) Section 8.8 Master Agreement Preamble Preamble

Section 13.2(a)

<u>DEFINITION</u> <u>SECTION</u>

Celgene Manufacturing Responsibilities

Challenge

Challenging Party
Combination Product

Commercialization/Commercialize Commercialization Report

Commercially Reasonable Efforts Competitive Infringement Competitive Program

Competitive Program Party Control/Controlled Cooperating Party Cover/Covering/Covered

Cure Period

Develop/Development Development Costs Disclosing Party Dispute Earlier Patent

Electronic Delivery
Execution Date
FDA

FDA force majeure event

IND Indication [**]

Invalidity Claim Joint Inventions Joint Patents Know-How Law

Licensed Branding Licensed Product Data Manufacturing Costs Master Agreement Material Breach Metabolic Target Ongoing Clinical Trial

Party/Parties

Patents
Payee Party
Paying Party
Person
Phase I Study

Section 4.1(a)

Section 14.3)(d) Section 14.3(d) Section 1.37

Master Agreement Section 2.1(c)

Master Agreement Section 10.3(b) Section 8.6(b)(iv) Section 8.6(b)(iv) Master Agreement

Section 11.3(b)(iii) Master Agreement Section 14.3(b)(i)

Master Agreement Master Agreement Section 11.1 Section 15.1 Section 10.8 Section 15.14 Preamble

Master Agreement Master Agreement

Section 15.5
Master Agreement
Master Agreement
Section 9.7(a)
Section 10.4(b)
Section 10.1(c)
Section 10.1(c)
Master Agreement
Master Agreement
Master Agreement
Section 6.2(c)
Section 14.4(c)

Master Agreement Introduction Section 14.3(b)(i) Master Agreement Section 3.1(a) Preamble Master Agreement

Section 9.7(a)
Section 9.7(a)
Master Agreement
Master Agreement

<u>DEFINITION</u> <u>SECTION</u>

Phase II Study Master Agreement Phase III Study Master Agreement **Product Trademarks** Section 6.2(a) Prosecuting Party Section 10.2(d)(i) Prosecution/Prosecute Master Agreement Master Agreement Publication **Pursuing Party** Section 14.3(d) Receiving Party Section 11.1 Redacted Version Section 11.3(b)(i) Regulatory Approval Master Agreement Regulatory Authority Master Agreement

Regulatory Interactions Section 5.1

Requesting Party

Royalty Term

Section 11.3(b)(iii)

Section 9.3(b)

SEC

Section 11.3(b)(i)

Selling Party
Selling Party
Section 1.37
Term
Section 14.1
Therapeutic Modality
Section 8.6(a)
Third Party
Master Agreement

Third Party Contractors

Section 8.2(a)(ii)

Third Party Infringement

Section 10.3(a)

Third Party Infringement Action

Section 10.4(a)

Article II.
Governance

Section 2.1. <u>Meetings and Reports</u>. During the Term:

- (a) <u>Committees</u>. The Committees shall not oversee or review any of the matters under this Agreement.
- (b) <u>Status Reports</u>. Celgene shall provide to Agios a written progress report every [**] during the Term on the status of its material Development activities with respect to the Program under this Agreement. Celgene shall use Commercially Reasonable Efforts to respond to Agios' reasonable requests for further information regarding any status reports provided to Agios by Celgene in accordance with this Section 2.1(b).
- (c) <u>Commercialization Reports</u>. Every [**] during the Term, Celgene shall provide to Agios, a written progress report on the status of its material Commercialization activities with respect to Licensed Products (a "<u>Commercialization Report</u>") during the preceding [**] period. Celgene shall use Commercially Reasonable Efforts to respond to Agios' reasonable requests for further information regarding any status reports provided to Agios by Celgene in accordance with this Section 2.1(c).

- (d) Meetings. The Parties shall meet at least [**] during the Term to discuss Celgene's Development, Commercialization and Prosecution activities.
- Section 2.2. Certain Interactions with and Effects on the Master Agreement. Upon and after the Effective Date, notwithstanding anything to the contrary in the Master Agreement (with each quoted term below having the meaning given in the Master Agreement):
- (a) Except as provided herein, all activities regarding Development, Manufacturing and Commercialization of a Compound, Licensed Product or Companion Diagnostic shall cease under the Master Agreement and all future such activities shall be conducted solely under this Agreement.
- (b) None of the Parties' activities performed in accordance with this Agreement (including those activities specifically permitted upon and after termination) shall be deemed a violation of Section 5.2 of the Master Agreement.
- (c) No decision of any "Committee" or working group under the Master Agreement shall have any binding effect with respect to Development, Manufacturing and Commercialization of a Compound or a Licensed Product under this Agreement.
- (d) All "Confidential Information" disclosed under the Master Agreement that solely relates to a Compound or any Licensed Product shall be deemed to be Confidential Information disclosed under this Agreement and not the Master Agreement. All "Confidential Information" disclosed under the Master Agreement that relates to, but does not solely relate to, any Compound or any Licensed Product shall be deemed "Confidential Information" disclosed under the Master Agreement and also Confidential Information disclosed under this Agreement; provided, however, that any disclosure of such information that is permitted under the Master Agreement shall not be deemed a breach of this Agreement and any disclosure of such information that is permitted under this Agreement shall not be deemed a breach of the Master Agreement.

Article III. Development

- Section 3.1. <u>Development of Licensed Products</u>. As of and after the Effective Date, except as set forth in Sections 3.1(a) and (b) below, Celgene will assume sole responsibility for, and control of, Developing, Manufacturing and Commercializing Compounds, Licensed Products and Companion Diagnostics in the Field in the Territory, and, except as otherwise set forth in this Agreement, will have sole responsibility to pay for all costs and expenses arising from the Development, Manufacture and Commercialization of Compounds, Licensed Products and Companion Diagnostics in the Field in the Territory. Accordingly, the Parties agree as follows:
- (a) <u>Ongoing Clinical Trials</u>. If Agios was conducting a Clinical Trial(s) as part of Pre-Exercise Phase I Development (as defined in the Master Agreement), excluding any expansion cohorts in such Clinical Trial(s) that are not part of Pre-Exercise Phase I Development, anywhere in the world with respect to any Compound and/or Licensed Product under the Collaboration which has not been completed as of the Effective Date ("<u>Ongoing</u>

Clinical Trial"), then, at [**] sole election, [**] will [**] be responsible for the performance of such Ongoing Clinical Trial, at [**] expense, in accordance with the terms of the applicable Clinical Trial protocol, until completion thereof, and notwithstanding Section 5.6, [**] will be responsible for adverse drug experiences reporting with respect to such Ongoing Clinical Trial until its completion; and

- (b) <u>Clinical Supply</u>. If Agios was responsible for supply of Compound and/or Licensed Product for any Ongoing Clinical Trial(s) that have not been completed as of the Effective Date, then Agios will continue to be responsible at its cost for supplying such Compound and/or Licensed Product for such Ongoing Clinical Trial(s) (in the relevant dosage strength, formulation and presentation).
- Section 3.2. <u>Companion Diagnostics</u>. Celgene may, in its sole discretion, Develop, Manufacture or Commercialize a Companion Diagnostic for use with the Licensed Products and may, in its sole discretion, use a Third Party Contractor to perform all Development, Manufacturing and Commercialization for the Companion Diagnostic, which activities may include continued Development of a Companion Diagnostic for which Development was commenced under the Master Agreement. In such event, (i) the definition of "Licensed Product" shall include the Companion Diagnostic for purposes of defining Agios Patents, Celgene Patents, Celgene Collaboration Patents and Joint Patents, and each of the licenses granted to Celgene under Article VIII; <u>provided</u>, <u>however</u>, that in no event shall any payments be owed by Celgene to Agios (including pursuant to Article IX) with respect to a Companion Diagnostic.

Section 3.3. Records; Tech Transfer.

- (a) <u>Maintenance of Records.</u> Celgene shall maintain in all material respects, and shall require its Third Party Contractors to maintain in all material respects, complete and accurate records in segregated books of all Development work conducted under this Agreement and all results, data and developments made in conducting such activities. Such records shall be complete and accurate and shall fully and properly reflect all such work done and results achieved in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes. Celgene shall require the applicable study sites to maintain original source documents from Clinical Trials of the Licensed Products for at least [**] (or such longer period as is commercially reasonable under the circumstances, taking into account maintenance requirements under applicable Law) following completion of the Development activities undertaken by Celgene or its Third Party Contractors; <u>provided that</u> Celgene or Agios shall be entitled to obtain copies of such source documents at the end of such [**] period, but solely to the extent access to such records are necessary for Agios to exercise its rights under this Agreement.
- (b) <u>Inspection</u>. Agios shall have the right (no more than [**]), during normal business hours and upon reasonable notice, to inspect and copy (or request Celgene to copy) all records of Celgene or its Third Party Contractors, as applicable, maintained in connection with the work done and results achieved in the performance of Development activities under this Agreement, but solely to the extent access to such records is necessary for Agios to exercise its rights under this Agreement.

(c) <u>Tech Transfer</u>. As soon as reasonably practical after the Effective Date and thereafter upon Celgene's reasonable request during the Term, Agios shall transfer to Celgene, at no cost to Celgene, copies of all Agios Know-How (including for the avoidance of doubt any Manufacturing Technology Controlled by Agios) and any [**] materials Controlled by Agios that are related to the Program related to the Licensed Product, to the extent not previously transferred to Celgene. In addition, Agios shall provide reasonable assistance, including making its personnel reasonably available for meetings or teleconferences to answer questions and provide technical support to Celgene with respect to regulatory and Manufacturing transition matters and the use of such transferred Know-How in the Development, Manufacture and Commercialization of Licensed Products. The Out-of-Pocket Costs, as indicated with reasonable supporting evidence of such incurred Out-of-Pocket Costs, incurred by Agios in connection with such assistance shall be reimbursed by Celgene within [**] after receipt by Celgene of an invoice for such costs.

Article IV. Manufacture and Supply

Section 4.1. <u>Pre-Clinical, Clinical and Commercial Supply.</u>

- (a) <u>Celgene Responsibilities</u>. Celgene shall be responsible for Manufacturing, or having Manufactured by its designee, all supply of Licensed Products, including drug product manufacturing and processing, filling, packaging, labeling, shipping and storage of Licensed Products for all Clinical Trials (other than Ongoing Clinical Trials conducted by Agios pursuant to Section 3.1) and for Commercialization of Licensed Products (collectively, the "<u>Celgene Manufacturing Responsibilities</u>").
- (b) <u>Manufacturing Costs</u>. Except as otherwise set forth herein, Manufacturing Costs associated with clinical and commercial supply of the Licensed Products shall be borne by Celgene, other than for any Ongoing Clinical Trials conducted by Agios pursuant to Section 3.1.
- Section 4.2. <u>Transfer of Manufacturing Responsibility</u>. In order to assist Celgene to perform the Celgene Manufacturing Responsibilities, Agios shall (a) transfer, or have transferred, to Celgene or its designee all Manufacturing Technology Controlled by Agios and used in Manufacturing Licensed Products at the time of such transfer to the extent relevant to the Celgene Manufacturing Responsibilities and use Commercially Reasonable Efforts to complete such transfer within [**] after the Effective Date, and (b) provide reasonable assistance in connection with the transfer of such Manufacturing responsibility to Celgene or its designee. The Out-of-Pocket Costs incurred by Agios in connection with such transfer shall be reimbursed by Celgene within [**] after receipt by Celgene of an invoice for such costs.
- Section 4.3. <u>Manufacturing Efforts</u>. Celgene shall use Commercially Reasonable Efforts to ensure adequate manufacturing capacity to meet forecast demand for the applicable Licensed Product, including the establishment of an alternative supply source. Celgene shall also use Commercially Reasonable Efforts to ensure adequate pre-clinical, clinical and commercial supply of the applicable Licensed Product to Develop or Commercialize, as applicable, such Licensed Products.

Article V. Regulatory Matters

- Section 5.1. <u>Transfer of Regulatory Documentation</u>. Agios shall transfer, within [**] after the Effective Date (but subject to Section 5.4), to Celgene any and all Regulatory Approvals and Regulatory Documentation (including the IND and any foreign counterparts thereof) for all Compounds, Licensed Products and Companion Diagnostics in the Territory, and thereafter Celgene (or its designee) shall file and hold title to all Regulatory Documentation and Regulatory Approvals and supplements thereto relating to Compounds, Licensed Products and Companion Diagnostics in the Territory.
- Section 5.2. <u>Responsibility for Regulatory Interactions</u>. As of and after the date upon which the transfer described in Section 5.1 is effected, Celgene shall have sole responsibility for all Regulatory Interactions with Regulatory Authorities with respect to each Licensed Product. As used herein, the term "<u>Regulatory Interactions</u>" means (i) monitoring and coordinating all regulatory actions, preparing, submitting and coordinating all communications and filings with, and submissions to, all Regulatory Authorities with respect to the Development, Manufacture and Commercialization of Compounds, Licensed Products and Companion Diagnostics and (ii) interfacing, corresponding and meeting with the Regulatory Authorities with respect to the Compounds, Licensed Products and Companion Diagnostics.
- Section 5.3. Review of Regulatory Documentation. During the Term, Celgene shall keep Agios reasonably informed of all Regulatory Interactions, preparation of all Regulatory Documentation, Regulatory Authority review of Regulatory Documentation, Regulatory Approvals, annual reports, including annual safety reports to the respective health authorities, annual re-assessments, and any subsequent variations and changes to labeling, in each case with respect to the Compounds, Licensed Products and Companion Diagnostics. Celgene shall respond within [**] to all reasonable inquiries by Agios with respect to any information provided pursuant to this Section 5.3 (and sufficiently promptly for Agios to provide meaningful input with respect to responses to Regulatory Authorities).
- Section 5.4. <u>Agios Ownership for Ongoing Clinical Trials</u>. Notwithstanding the foregoing Section 5.1 and Section 5.2, in the event Agios continues to be responsible for the performance of an Ongoing Clinical Trial pursuant to and in accordance with Section 3.1(a), Agios will retain ownership of any Regulatory Documentation and Regulatory Approvals (including the IND and any foreign counterparts thereof) for the corresponding Compound and Licensed Products until completion of such Ongoing Clinical Trial.
- Section 5.5. <u>Right of Reference or Use</u>. In the event of failure to assign such Regulatory Documentation and Regulatory Approvals to Celgene as required by Section 5.1 and Section 5.2, Agios hereby consents and grants to Celgene a Right of Reference or Use (without any further action required on the part of Agios, whose authorization to file this consent with any Regulatory Authority is hereby granted) to any such Regulatory Documentation and Regulatory Approvals (including all data contained or referenced therein) that are necessary for the Development, Manufacture or Commercialization (as set forth in this Agreement) of the Compounds, Licensed Products and Companion Diagnostics.

- Section 5.6. <u>Pharmacovigilance</u>. Celgene will deploy and administer any safety monitoring activity implemented for the Licensed Product in the Territory, and be responsible for all pharmacovigilance activities for the Licensed Product in the Territory. Further, Agios will follow the adverse event reporting requirements and processes set forth in the pharmacovigilance agreement described in this Section 5.6. In addition:
- (a) In accordance with the procedures established by the Parties under Section 5.6, each Party shall cooperate with the other Party and share information concerning the pharmaceutical safety of each Compound and Licensed Product. Each Party shall promptly advise the other Party of any information that comes to its knowledge that may affect the safety, effectiveness or labelling of such Compound or Licensed Product and any actions taken in response to such information. Treatment of safety information, standard operating procedures and training, as well as a statement of respective regulatory obligations shall be agreed in a separate pharmacovigilance agreement between Agios and Celgene (or an Affiliate of Celgene, as designated by Celgene).
- (b) Following the date on which the transfer described in Section 5.1 is effected, Celgene shall be solely responsible for reporting all adverse drug experiences associated with the Compound, Licensed Products and Companion Diagnostics in the Territory, and for establishing, holding and maintaining the global safety database for the Compound, Licensed Products and Companion Diagnostics. Each Party shall provide the other Party with all Licensed Product and Companion Diagnostics complaints, adverse event information and safety data from clinical studies that are in its possession and control and that are necessary or desirable for the other Party to comply with all applicable Laws with respect to Compound, Licensed Products and Companion Diagnostics. Further, the Parties shall commence good faith discussions with respect to entering into a separate pharmacovigilance agreement, as and when requested by Celgene.

Article VI. Commercialization

Section 6.1. Commercialization Responsibilities for Licensed Products.

- (a) <u>Responsibility</u>. Celgene shall have the sole responsibility for, and right to carry out, Commercialization of Licensed Products in the Territory.
- (b) <u>Sales</u>. Celgene will book all sales of the Licensed Products in the Territory and will have the sole responsibility for the processing of orders, invoicing, terms of sale, and distribution of the Licensed Products throughout the Territory associated therewith.

Section 6.2. Trademarks.

(a) <u>Selection of Trademarks</u>. Celgene shall select the trademark(s) to be used in connection with the marketing and sale of the Licensed Products in the Territory (such marks, together will registrations, applications for registration and common law rights therein, collectively, "<u>Product Trademarks</u>").

- (b) Ownership. Celgene shall own all Product Trademarks for any Licensed Product in the Territory.
- (c) Branding. Nothing in this Agreement shall be construed to grant either Party any rights in or to any of the other Party's trademarks, tradenames, logos, or other marks, including use thereof, absent a separate trademark licensing agreement entered into in accordance with this Section 6.2(c). Notwithstanding the foregoing, subject to any restrictions on the form or content of the branding and/or co-branding of the Licensed Products (the "Licensed Branding") imposed by any Regulatory Authority, unless the Parties mutually agree otherwise in writing, the Licensed Branding used with respect to Licensed Products shall feature the logos of Agios and Celgene with approximately equal sizing and similar prominence, with Celgene's name first, on all packaging and materials used for Commercialization of such Licensed Products, to the extent permitted by applicable Law.

Article VII. Diligence

Section 7.1. Compliance with Laws. Celgene shall:

- (i) perform its obligations under this Agreement in a scientifically sound and workmanlike manner; and
- (ii) carry out all work done in the course of the Development, Manufacturing and Commercialization of Licensed Products in compliance with all applicable Laws governing the conduct of such work.

Section 7.2. Diligence Obligations.

- (a) Celgene, directly or through one or more of its Affiliates or Licensee Partners, shall use Commercially Reasonable Efforts to Develop and achieve Regulatory Approval for the Licensed Products in each of the [**], and, following such Regulatory Approval, to Commercialize such Licensed Products in each of the [**].
- (b) A breach of the diligence obligations set forth in this Section 7.2 shall be deemed a material breach and shall be subject to termination under Section 14.3(b). Notwithstanding the foregoing, the Parties acknowledge that it might be commercially reasonable, under certain circumstances, for Celgene in a given [**] to determine not to launch a Licensed Product in such [**], and failure under such circumstances to launch such Licensed Product shall not be a breach of this Agreement.
- Section 7.3. <u>No Representation</u>. Subject to the foregoing obligation to use Commercially Reasonable Efforts, neither Party makes any representation, warranty or guarantee that the Program will be successful, or that any other particular results will be achieved with respect to the Program, or any Compound, Licensed Product or Companion Diagnostic hereunder.

Article VIII. Grant of Rights; Exclusivity

- Section 8.1. <u>License Grants</u>. Subject to the terms and conditions of this Agreement, Agios hereby grants to Celgene an exclusive (even as to Agios and its Affiliates), non-transferable (except as set forth in Section 15.4), worldwide right and license in the Field, with the right to grant sublicenses as set forth in Section 8.2(a) and Section 8.2(a)(ii)(2), under Agios' rights in Agios Intellectual Property, Joint Inventions, Joint Patents and Manufacturing Technology, to Develop, Manufacture and Commercialize Compounds and Licensed Products and Companion Diagnostics; <u>provided that</u>, as to Companion Diagnostics, such license grant shall be limited to Developing, Manufacturing and Commercializing Companion Diagnostics for use as companion diagnostics with Licensed Products under this Agreement.
 - Section 8.2. <u>Sublicense Rights</u>. Subject to Section 8.3, Celgene shall have the following sublicensing rights:
- (a) <u>Sublicenses to Affiliates and Subcontractors</u>. Celgene shall have the right to grant sublicenses within the scope of the licenses and sublicense under Section 8.1:
 - (i) to its Affiliates; and
- (ii) to Third Parties for the purpose of (a) [**] or (b) engaging Third Parties as contract research organizations, contract manufacturers, contract sales forces, consultants, academic researchers and the like ("Third Party Contractors") in connection with Development, Manufacturing or Commercialization activities on behalf of Celgene or its Affiliates under this Agreement, subject to the following:
- Third Party to whom Celgene discloses Confidential Information to enter into an appropriate written agreement obligating such Third Party to be bound by obligations of confidentiality and restrictions on use of such Confidential Information that are no less restrictive than the obligations set forth in Article XI, including requiring such Third Party to agree in writing not to issue any Publications except in compliance with the terms of this Agreement (except that Publications by academic collaborators shall be permitted if (i) the academic collaborator provides an advance copy of the proposed Publication under the time periods as described in Section 11.4(a)), which may be shared with Agios, (ii) agrees to delay such Publication sufficiently long enough to permit the timely preparation and filing of a patent application, and (iii) upon the request of either Party, removes from such Publication any Confidential Information of such Party); and
- (2) unless otherwise agreed by mutual agreement of the Parties, Celgene will obligate such Third Party to agree in writing to assign ownership of, or grant an exclusive, royalty-free, worldwide, perpetual and irrevocable license (with the right to grant sublicenses) to, any inventions arising under its agreement with such Third Party to the extent related to Development, Manufacturing or Commercialization with respect to the Licensed Products in the Field; and Celgene shall structure such assignment or exclusive license so as to enable it to sublicense such Third Party inventions to Agios pursuant to Section 8.1 (including

permitting Agios to grant further sublicenses); <u>provided that</u>, in connection with any academic collaborator performing research work with respect to the Target, Compounds or Licensed Products that is not reasonably expected by Celgene to result in inventions related to composition of matter or methods of use, it shall be sufficient for Celgene to obtain a non-exclusive, worldwide, royalty-free, perpetual license (with the right to grant sublicenses) to, and a right to negotiate for an exclusive license, with the right to grant sublicenses, to, any inventions resulting from such research work, which sublicensing rights must permit sublicensing to Agios pursuant to Section 14.4(a)(ii) (including permitting Agios to grant further sublicenses).

- (b) Other Sublicenses. Except as provided in Section 8.2(a), any other sublicense by Celgene under the licenses and sublicense set forth in Section 8.1 shall require the prior written approval of Agios, which approval shall not be unreasonably withheld, conditioned or delayed.
- Section 8.3. <u>Sublicense Requirements</u>. Any sublicense granted by Celgene pursuant to this Agreement shall be subject to the following:
- (a) each sublicense granted hereunder by Celgene or its Affiliates shall be consistent with the requirements of this Agreement;
- (b) any transfer of rights between Celgene and its Affiliates shall not be deemed a sublicense by Celgene but shall be deemed a direct license by Agios to Celgene's Affiliate; <u>provided</u> that Celgene shall remain responsible for the activities of its Affiliate;
- (c) Celgene's or its Affiliates' Third Party Licensee Partners shall have no right to grant further sublicenses without Agios' prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed;
- (d) Celgene shall be primarily liable for any failure by its Affiliates and Licensee Partners to comply with all relevant restrictions, limitations and obligations in this Agreement; and
- (e) such sublicense must be granted pursuant to a written sublicense agreement and Celgene shall provide Agios with a copy of any sublicense agreement entered into under Section 8.2 above within [**] after the execution of such sublicense agreement; provided that, any such copy may be reasonably redacted to remove any confidential, proprietary or competitive information, but such copy shall not be redacted to the extent that it impairs Agios' ability to ensure compliance with this Agreement. Such sublicense agreement shall be treated as Confidential Information of Celgene and no copies are required with respect to sublicense agreements with Third Party Contractors.
- Section 8.4. <u>Affiliates, Licensee Partners and Third Party Contractors</u>. Celgene may exercise its rights and perform its obligations hereunder itself or through its Affiliates, Licensee Partners and Third Party Contractors. Celgene shall be primarily liable for any failure by its Affiliates, Licensee Partners and Third Party Contractors to comply with all relevant restrictions, limitations and obligations in this Agreement. If Celgene desires to use any Person to conduct any of its Development, Manufacturing, Commercialization or other activities hereunder, Celgene must comply with the obligations of Section 8.2(a)(ii)(1) and Section 8.2(a) (ii)(2) even to the extent no sublicense of rights is granted to such Third Party.

Section 8.5. Existing Third Party Agreements.

- (a) <u>Acknowledgement</u>. Except as provided in Section 8.5(b) and 9.4, Agios acknowledges that it is responsible for the fulfillment of its obligations under each Existing Third Party Agreement and agrees to fulfill the same, including any provisions necessary to maintain in effect any rights sublicensed to Celgene hereunder and the exclusive or non-exclusive nature of such rights, as applicable, subject to Celgene's compliance with its obligations hereunder.
- (b) Incorporation of Certain Provisions. Celgene agrees and acknowledges that Agios is required to provide to licensors under the Existing Third Party Agreements periodic reports relating to the gross sales and Net Sales of Licensed Products. Celgene shall keep true and accurate records and books of account, and open such books and records for inspection by such licensors, for a duration of [**] from the date of origination of such books or records. Furthermore, Celgene acknowledges that Agios may be required to share certain reports and copies of sublicense agreements provided by Celgene to Agios hereunder with any licensor under an Existing Third Party Agreement, and Celgene consents to the sharing of such reports and such copies of such sublicense agreements to the extent required under such Existing Third Party Agreement to the same extent as disclosures are permitted under Section 11.3(a) hereunder; provided that any such copies of sublicense agreements must be redacted to the extent permitted under such Existing Third Party Agreement. In addition, Celgene acknowledges that the Prosecution, enforcement and other intellectual property management rights under this Agreement with respect to Patents and other intellectual property licensed under Existing Third Party Agreements shall be subject to the terms and conditions of the applicable Existing Third Party Agreements and, in the case of Existing Third Party Agreements in which the licensor is an academic institution, other provisions of such Existing Third Party Agreements that are customarily required to be imposed on sublicensees in academic licenses (in no event to include any exclusivity covenant).
 - (c) Covenants Regarding Existing Third Party Agreements. Agios agrees that during the Term:
- (i) Agios shall not modify or amend any Existing Third Party Agreement in any way that adversely affects Celgene's rights hereunder without Celgene's prior written consent;
- (ii) Agios shall not terminate any Existing Third Party Agreement, in whole or in part, without Celgene's prior written consent;
- (iii) Agios shall not exercise or fail to exercise any of Agios' rights, or fail to perform any of Agios' obligations, under any Existing Third Party Agreement that relate to Celgene's rights hereunder without the prior written consent of Celgene, including rights with respect to including improvements within the licenses granted under such Existing Third Party Agreement; and, at the reasonable request of Celgene, Agios shall exercise such rights and make such requests that relate to Celgene's rights hereunder as are permitted under such Existing Third Party Agreement;

- (iv) Agios shall promptly furnish Celgene with copies of all reports and other communications that Agios furnishes to any licensor under any Existing Third Party Agreement to the extent that such reports relate to this Agreement;
- (v) Agios shall promptly furnish Celgene with copies of all reports and other communications that Agios receives from any licensor under any Existing Third Party Agreement that relate to the subject of this Agreement (including notices relating to improvements under such Existing Third Party Agreement);
- (vi) Agios shall furnish Celgene with copies of all notices received by Agios relating to any alleged breach or default by Agios under any Existing Third Party Agreement within [**] after Agios' receipt thereof; in addition, if Agios should at any time breach an Existing Third Party Agreement or become unable to timely perform its obligations thereunder, Agios shall immediately notify Celgene;
- (vii) If Agios cannot or chooses not to cure or otherwise resolve any alleged breach or default under any Existing Third Party Agreement, (A) Agios shall so notify Celgene within [**] of such decision, which shall not be less than [**] prior to the expiration of the cure period under such Existing Third Party Agreement; provided that Agios shall use Commercially Reasonable Efforts to cure any such breach or default; and (B) Celgene, in its sole discretion, shall be permitted (but shall not be obligated), on behalf of Agios, to cure any breach or default under such Existing Third Party Agreement in accordance with the terms and conditions of such Existing Third Party Agreement or otherwise resolve such breach directly with the applicable licensor(s) under such Existing Third Party Agreement; and (C) if Celgene pays any such licensor any amounts owed by Agios under such Existing Third Party Agreement, then, provided that such amounts have not arisen as a result of Celgene's failure to comply with the terms and conditions of such Existing Third Party Agreement applicable to Celgene as a sublicensee and, subject to Section 9.4, Celgene may deduct Agios' share of such amounts from payments Celgene is required to make thereafter to Agios hereunder or, at Celgene's election, may otherwise seek reimbursement of such amounts from Agios; and
- (viii) Agios shall not provide any Licensed Products to any licensor under any Existing Third Party Agreement without Celgene's prior written consent.
- (d) <u>Survival of Celgene's Rights Following Termination of Existing Third Party Agreement</u>. The Parties agree that in the event of any termination of any Existing Third Party Agreement with respect to any intellectual property rights licensed to Celgene hereunder, Celgene shall have any rights available under such Existing Third Party Agreement to become a direct licensee of the Third Party licensor(s) under such Existing Third Party Agreement and Agios shall use Commercially Reasonable Efforts to assist Celgene in exercising such rights; <u>provided that Celgene</u> has not breached this Agreement, or breached the applicable Third Party Rights under such Existing Third Party Agreement. In addition, notwithstanding the foregoing, in the event of such termination, Celgene may in any event approach any licensor under any Existing Third Party Agreement for a direct license. In the event of any such direct license

following any termination of an Existing Third Party Agreement without Celgene's consent, Celgene shall be entitled to deduct from any payments owed to Agios hereunder the amounts paid by Celgene to such licensor under such direct license with respect to licenses within the scope of the licenses previously granted to Agios under such Existing Third Party Agreement to the extent permitted under Section 9.4(a); provided that such termination was not the result of Celgene breaching the applicable Existing Third Party Agreement.

- (e) <u>Termination of Existing Third Party Agreements</u>. The Parties agree that termination, without Celgene's prior written consent, of any Existing Third Party Agreement with respect to any Patent or Know-How that is necessary to Develop, Manufacture or Commercialize the Licensed Products shall be deemed a material breach of this Agreement by Agios; <u>provided that</u> (i) if Celgene's breach of this Agreement results in a breach of any Existing Third Party Agreement, Celgene agrees to use Commercially Reasonable Efforts to assist Agios in curing such breach of such Existing Third Party Agreement, and (ii) if Celgene's breach of this Agreement results in a termination of any Existing Third Party Agreement, such termination of such Existing Third Party Agreement shall not be deemed a material breach by Agios of this Agreement.
- Section 8.6. <u>Exclusivity</u>. Subject to the terms and conditions of this Agreement, each of the Parties hereby agrees as follows:
- (a) Exclusivity Obligations. From the Effective Date until the end of the Term, the Parties and, subject to Section 8.6(a), their Affiliates shall not, directly or indirectly, Develop, Manufacture or Commercialize any [**] for application in [**] that [**] the Target through direct binding to the Target with [**], except for (i) Licensed Products (including those activities specifically permitted following termination of this Agreement) and (ii) Programs (as defined in the Master Agreement) directed to the Target (A) that are being conducted pursuant to the Master Agreement, (B) to which Celgene has exercised its Option (as defined in the Master Agreement) under the Master Agreement or (C) the rights to which have reverted to Agios in accordance with Section 2.12 of the Master Agreement.

(b) Exceptions.

- (i) <u>Incidental Discoveries</u>. A Party shall be deemed not to be, directly or indirectly (whether such activities are conducted internally or with or through a Third Party), Developing, Manufacturing or Commercializing in violation of the provisions of Section 8.6(a) as a result of conducting a research program or discovery effort (or manufacturing or commercializing a [**] resulting from such research program or discovery effort) that has as its specified and primary goal, as evidenced by items such as laboratory notebooks or other relevant documents contemporaneously kept, taken as a whole, to discover or Develop compounds that [**] through direct binding to a target other than the Target.
- (ii) <u>Celgene Exception</u>. It is agreed and understood by the Parties that any Celgene research, discovery and commercialization activities existing as of the effective date of the Master Agreement, whether such activities are undertaken by Celgene alone or in conjunction with one or more partners, licensors, licensees, and/or collaborators, are expressly excluded from the provisions of this Section 8.6. In particular and without limitation, Celgene research, discovery, and commercialization activities related to (i) [**]; (ii) [**]; (iii) [**]; (iv) [**]; or (vi) [**], are expressly excluded from the provisions of this Section 8.6.

(iii) Academic Collaborations. Notwithstanding the provisions of Section 8.6(a), and without limiting Section 8.2(a)(ii), each Party shall be permitted to perform any of the activities that would otherwise be prohibited under Section 8.6(a) in relation to the Target, if such activities are (A) the subject of an existing agreement between such Party and an academic institution or academic collaborator entered into prior to the effective date of the Master Agreement, provided that such Party shall not be permitted to amend any such agreement unless such amendment contains provisions consistent with the terms and conditions of such agreement in effect as of the effective date of the Master Agreement with respect to (1) [**], or (B) the subject of a new agreement entered into between such Party and an academic institution or academic collaborator that contains terms and conditions with respect to the [**] consistent with the terms and conditions of [**]; provided that, if any [**] of an amendment described in (A) or an agreement described in (B) would not be [**] the agreements between such Party and an academic institution or academic collaborator entered into prior to the effective date of the Master Agreement, such Party [**].

(iv) Competitive Programs. Section 8.6(a) shall not apply if, during the [**], any Party or its Affiliates (other than in a [**] with respect to such Party) merges or consolidates with, or otherwise acquires, a Third Party that is then engaged in activities that would otherwise constitute a breach of this Section 8.6 by any Party or its Affiliates (a "Competitive Program"); it being understood and agreed that, unless the Parties agree otherwise in writing, such Party that is engaged in a Competitive Program (the "Competitive Program Party") shall, within [**] after the date of such merger, consolidation or acquisition, notify the other Party that it intends to either: (A) terminate, or cause its relevant Affiliate to terminate, the Competitive Program or (B) divest, or cause its relevant Affiliate to divest, whether by license or otherwise, the Competitive Program. If the Competitive Program Party notifies the other Party within such [**] period that it intends to [**], such Competitive Program, the Competitive Program Party or its relevant Affiliate, shall (X) terminate such Competitive Program as quickly as possible, and in any event within [**] (unless applicable Law requires a longer termination period) after the Competitive Program Party delivers such notice to the other Party; and (Y) confirm to the other Party when such termination has been completed, and the Competitive Program Party's continuation of the Competitive Program during such [**] (or, as required by applicable Law, longer) period shall not constitute a breach of the Competitive Program Party's exclusivity obligations under Section 8.6(a). If the Competitive Program Party notifies the other Party within such [**] period that it intends to divest such Competitive Program, the Competitive Program Party or its relevant Affiliate shall use all reasonable efforts to effect such divestiture as quickly as possible, and in any event within [**] after the Competitive Program Party delivers such notice to the other Party, and shall confirm to the other Party when such divestiture has been completed. If the Competitive Program Party or its relevant Affiliate fails to complete such divestiture within such [**] period, but has used reasonable efforts to effect such divestiture within such [**] period, then, unless otherwise required by applicable Law, such [**] period shall be extended for such additional reasonable period thereafter as is necessary to enable such Competitive Program to be in fact divested, not to exceed an additional [**]; provided that, such additional [**] period shall be extended for such period as is necessary to obtain any governmental or regulatory approvals required to complete such divestiture if the Competitive

Program Party or its relevant Affiliate is using good faith efforts to obtain such approvals. The Competitive Program Party's continuation of the Competitive Program during such divestiture period shall not constitute a breach of the Competitive Program Party's exclusivity obligations under Section 8.6(a).

(v) Certain Permitted Activities.

- (1) The [**] shall not constitute a breach of Section 8.6(a). Each Party shall report to the other Party on a [**] basis [**] and that would otherwise breach Section 8.6(a). For clarity, [**] without violation of Section 8.6(a) [**] shall not constitute [**] in violation of such Party's exclusivity obligations under this Section 8.6 as long as [**].
- (2) The [**] shall not constitute a breach of Section 8.6(a); <u>provided that</u> [**] shall be subject to Section 8.6(a) and shall not be permitted under this Section 8.6(b)(v).
- (3) The restrictions set forth in Section 8.6(a) shall not be deemed to prevent either Party or its respective Affiliates from (1) fulfilling its obligations under this Agreement, or (2) engaging any subcontractors in accordance with Section 8.2(a)(ii)Section 8.2(a)(i) of this Agreement.
- (4) If [**] occurs with respect to either Party with a Third Party and the Third Party already is conducting or is planning to conduct activities that would cause a Party or an Affiliate to violate Section 8.6(a) (an "Acquirer Program"), then such Third Party [**]; provided that, (1) [**] in any Acquirer Program, (2) [**] in any Acquirer Program, and (4) [**] to such Acquirer Program, including by [**] the activities under this Agreement, and the activities covered under such Acquirer Program (except that this requirement shall not apply to [**] activities under such Acquirer Program).
- (vi) <u>Clinical Combinations</u>. Notwithstanding anything to the contrary in this Agreement, for purposes of this Section 8.6, either Party shall, at all times, have the right to conduct clinical Development of Licensed Products, alone or with Third Parties, in which the [**]'s regulatory filings for purposes of enabling such Party and such Third Party to include the relevant use of Licensed Products in combination with such other therapeutic product in the approved label for such Licensed Products and/or such other therapeutic product, respectively, provided that [**] may grant to any such Third Party the right to sell, offer for sale and otherwise commercially exploit such Licensed Products.

Section 8.7. Retained Rights.

(a) No Implied Licenses or Rights. Except as expressly provided in Section 8.1, and subject to Section 8.5, all rights in and to the Agios Intellectual Property and any other Patents or Know-How of Agios and its Affiliates, are hereby retained by Agios and its Affiliates. For the avoidance of doubt, all rights in and to the Celgene Intellectual Property and any other Patents or Know-How of Celgene and its Affiliates, are hereby retained by Celgene and its Affiliates.

(b) Other Retained Rights. The Parties acknowledge that the licenses granted hereunder are subject to any rights retained by any licensor under any Existing Third Party Agreement pursuant to any provision of such Existing Third Party Agreement, provided that, upon Celgene's reasonable request, Agios shall cooperate fully in requesting and obtaining any waiver with respect to the requirement, if applicable under such agreements, that the Licensed Products used or sold in the United States be manufactured substantially in the United States.

Section 8.8. Section 365(n) of the Bankruptcy Code. All rights and licenses granted under or pursuant to any section of this Agreement are and will otherwise be deemed to be for purposes of Section 365(n) of the United States Bankruptcy Code (Title 11, U.S. Code), as amended (the "Bankruptcy Code"), licenses of rights to "intellectual property" as defined in Section 101(35A) of the Bankruptcy Code. The Parties will retain and may fully exercise all of their respective rights and elections under the Bankruptcy Code or such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the Bankruptcy Code or any other provisions of applicable law outside the United States that provide similar protection for "intellectual property." The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a Party under the Bankruptcy Code or analogous provisions of applicable Law outside the United States, the Party that is not subject to such proceeding will be entitled to a complete duplicate of (or complete access to, as appropriate) such intellectual property and all embodiments of such intellectual property, which, if not already in the non-subject Party's possession, will be promptly delivered to it upon the non-subject Party's written request thereof. Any agreements supplemental hereto will be deemed to be "agreements supplementary to" this Agreement for purposes of Section 365(n) of the Bankruptcy Code.

Article IX. Financial Provisions

Section 9.1. <u>Upfront Option Payment</u>. Within [**] after the Effective Date, Celgene shall make a one-time, non-refundable payment to Agios equal to the applicable Upfront Option Payment set forth in paragraph 3 on Exhibit A, with respect to the Program (as defined in the Master Agreement) under which the Compounds and Licensed Products were Developed.

Section 9.2. Milestone Payments.

(a) <u>Development and Regulatory Milestones</u>. Celgene shall pay Agios the following amounts after the first achievement by or on behalf of Celgene or its Affiliates or Licensee Partners of the corresponding development and regulatory milestone events set forth below with respect to the first Licensed Product to achieve such milestone events.

Milestones	Amount
[**]	US \$25,000,000
[**]	[**]

Milestones	Amount
[**]	[**]
[**]	[**]

- (i) For purposes of determining the occurrence of milestones under items (2) and (3) in the table above, (A) the [**] shall be deemed a single [**] for purposes of determining whether the [**] and (B) achievement of such milestones with respect to the [**] shall be deemed to have occurred only if [**] have been obtained. For purposes of clarity, no milestone amount shall be payable to Agios under item (3) if [**], but Celgene shall pay Agios the milestone amount set forth in item (3) upon receipt of [**], as applicable, than the [**] for purposes of item (3).
- (ii) The milestone payments under items (2), (3) and (4) shall be paid at [**] percent ([**]%) of the specified amounts upon the [**] of the applicable milestone event by a Licensed Product for a different Indication than the Indication for which such Licensed Product first achieved such milestone event. For the avoidance of doubt, each distinct histology shall qualify as a distinct Indication for purposes of this Section 9.2. For the further avoidance of doubt, if a Licensed Product achieves a milestone for an Indication and subsequently achieves the same milestone for an earlier line setting in the same Indication, no milestone payments shall be due for such earlier line setting (e.g., if a Licensed Product [**], no milestone payments would be due if such Licensed Product later [**]. For the further avoidance of doubt, for purposes of this Section 9.2, if a Licensed Product achieves a milestone for an Indication as part of a monotherapy or combination therapy and subsequently achieves the same milestone in the same Indication as part of a combination therapy or monotherapy, respectively, no milestone payments shall be due for such subsequent milestone.
- (iii) No further milestone payments under this Section 9.2 shall be payable, regardless of the number of Licensed Products to achieve the applicable milestone event and regardless of the number of Indications for which the milestone event may be achieved.
- (iv) Each milestone payment under this Section 9.2 shall be made within [**] after the achievement of the applicable milestone by Celgene or any of its Affiliates or Licensee Partners.
- (b) <u>Sales Milestones</u>. Celgene shall make the following non-refundable, non-creditable, one-time payments to Agios within [**] following the first achievement of worldwide Annual Net Sales, on a Licensed Product-by-Licensed Product basis (in no event to include Companion Diagnostics), that meets or exceeds the minimum worldwide Annual Net Sales threshold per such Licensed Product in the Territory set forth below.

Per Licensed Product Worldwide Annual Net Sales Threshold	Milestone Payment
Equal to US\$[**]	US\$[**]
Equal to US\$[**]	US\$[**]

Section 9.3. Royalty Payments.

(a) <u>Royalty Rate</u>. Celgene shall pay to Agios royalties on worldwide Annual Net Sales of Licensed Products, on a Licensed Product-by-Licensed Product basis (in no event to include Companion Diagnostics), as follows:

Per Licensed Product Worldwide Annual Net Sales	Royalty Rate
On the tranche of worldwide Annual Net Sales occurring until aggregate worldwide Annual Net Sales reaches US\$[**]	[**]%
On the tranche of worldwide Annual Net Sales occurring so long as aggregate worldwide Annual Net Sales is equal to or greater than US\$[**] and less than US\$[**]	[**]%
On the tranche of worldwide Annual Net Sales occurring upon and after aggregate worldwide Annual Net Sales equals US\$[**]	[**]%

Each Royalty Rate set forth in the table above will apply only to that portion of the worldwide Annual Net Sales of a given Licensed Product in the Territory during a given Calendar Year that falls within the indicated tranche.

For example, if worldwide Annual Net Sales of a given Licensed Product in the Territory by Celgene, its Affiliates and Licensee Partners was \$[**], then the royalties payable with respect to such worldwide Annual Net Sales, subject to adjustment as set forth in this Section 9.3(a), would be:

[**].

- (b) <u>Royalty Term</u>. Royalties payable under this Section 9.3 shall be paid by Celgene on a Licensed Product-by-Licensed Product and country-by-country basis from the date of First Commercial Sale of each Licensed Product in a country with respect to which royalty payments are due, until the latest of:
- (i) the last to expire of any Valid Claim of Agios Patents, Celgene Collaboration Patents or Joint Patents Covering such Licensed Product in such country;
 - (ii) [**] following the date of First Commercial Sale in such country; and
 - (iii) the expiration of Regulatory Exclusivity for such Licensed Product in such country;

(each such term with respect to a Licensed Product and a country, a "Royalty Term").

Notwithstanding the foregoing, (A) in the event that the Royalty Term for a Licensed Product in a country continues solely due to Section 9.3(b)(ii) above (*i.e.*, the Licensed Product is not Covered by a Valid Claim of Agios Patents, Celgene Collaboration Patents or Joint Patents in the applicable country, and such Licensed Product is not subject to Regulatory Exclusivity in such country) or (B) in the event that, and for so long as, Generic Competition for a Licensed Product occurs in a country, then, in either such event, the royalty rate in such country will be reduced to [**] percent ([**]%) of the applicable rate in Section 9.3(a) in such country.

- (c) Expiration of Royalty Term. Upon the expiration of the Royalty Term with respect to a Licensed Product in a country, the license granted by Agios to Celgene pursuant to Section 8.1 shall be deemed to be fully paid-up, irrevocable and perpetual with respect to such Licensed Product in such country; provided that, notwithstanding Section 9.4(a), Celgene shall assume and be solely responsible for all amounts payable to Third Party licensors and Celgene shall be responsible for complying with the terms of any license agreements with such Third Party licensors, in each case, with respect to Celgene's exercise of such rights as to such Licensed Product in such country following the expiration of the Royalty Term.
- (d) <u>Deduction for Third Party Payments</u>. In the event that royalties are payable by Celgene to Agios with respect to any Licensed Product under this Section 9.3, Celgene shall have the right to deduct a maximum of [**] percent ([**]%) of any royalties or other amounts actually paid by Celgene to a Third Party with respect to any license obtained pursuant to Section 9.4(b) with respect to a Licensed Product in a country, but only to the extent that the Patents or Know-How licensed under such other license are necessary for the Development, Manufacture or Commercialization of such Licensed Product in such country, from royalty payments otherwise due and payable by Celgene to Agios under this Section 9.3 with respect to such Licensed Product in such country, on a Licensed Product-by-Licensed Product and country-by-country basis.
- (e) <u>Royalty Reports</u>; <u>Payments</u>. Within [**] after the end of each Calendar Quarter, Celgene with respect to each Licensed Product shall provide Agios with a report stating the sales in units and in value of such Licensed Product made by Celgene, its Affiliates, and Licensee Partners, as applicable, on a country-by-country basis, together with the calculation of the royalties due to Agios, including the method used to calculate the royalties, the exchange rates used, and itemized deductions. Payments of all amounts payable under this Section 9.3 shall be made by Celgene to the bank account indicated by Agios concurrently with the delivery of such report.
- (f) <u>Cumulative Effect of Royalty Reductions</u>. In no event shall the royalty reductions described in this Section 9.3, alone or together, reduce the royalties payable by Celgene for a Licensed Product in a country in any given Calendar Quarter to less than [**]percent ([**]%) of the amounts otherwise payable by Celgene for such Calendar Quarter. Celgene may carry over and apply any such royalty reductions, which are incurred or accrued in a Calendar Quarter and are not deducted in such Calendar Quarter due to the limitation set forth above in this Section 9.3(f), to any subsequent Calendar Quarter(s) and shall begin applying such reduction to such royalties as soon as practicable and continue applying such reduction on a Calendar Quarterly basis thereafter until fully deducted, in all cases subject to the limitation set forth above in this Section 9.3(f).

Section 9.4. Third Party Payments.

- (a) Existing Third Party Agreements. All royalties payable under the Existing Third Party Agreements, in the aggregate, that (i) directly relate to a Licensed Product and (ii) in no event exceed [**] percent ([**]%) of Net Sales in the aggregate, shall be shared by the Parties, with each Party paying [**] percent ([**]%) of such royalties. For clarity, all royalties payable under the Existing Third Party Agreements in excess of [**] percent ([**]%) of worldwide Net Sales in the aggregate, and all non-royalty amounts payable under such Existing Third Party Agreements, shall be paid by Agios.
- (b) Additional Agreements. After the Effective Date, if Celgene at any time believes that a license under Third Party Patents or Third Party Know-How, other than an Existing Third Party Agreement, is necessary or useful to Develop, Manufacture or Commercialize the Licensed Products, then Celgene shall have the sole right make such determination, without escalation to the Executive Officers. The costs of each such license to the extent the costs directly relate to the Licensed Products shall be paid by Celgene, subject to deduction from royalties to the extent set forth in Section 9.3(d).
- Section 9.5. <u>Financial Records</u>. Celgene shall keep, and shall require its Affiliates and Licensee Partners to keep, complete and accurate books and records in accordance with the applicable Accounting Standards. Celgene shall keep, and shall require its Affiliates and Licensee Partners to keep, such books and records for at least [**] following the end of the Calendar Year to which they pertain. Such books of accounts shall be kept at the principal place of business of the financial personnel with responsibility for preparing and maintaining such records. With respect to royalties, such records shall be in sufficient detail to support calculations of royalties due to Agios.

Section 9.6. Audits.

- (a) <u>Audit Team</u>. Agios may, upon request and at its expense (except as provided for herein), cause an internationally recognized independent accounting firm selected by it (except one to whom Celgene has a reasonable objection) (the "<u>Audit Team</u>") to audit during ordinary business hours the books and records of Celgene and the correctness of any payment made or required to be made, and any report underlying such payment (or lack thereof), pursuant to the terms of this Agreement. Prior to commencing its work pursuant to this Agreement, the Audit Team shall enter into an appropriate confidentiality agreement with Celgene obligating the Audit Team to be bound by obligations of confidentiality and restrictions on use of such Confidential Information that are no less restrictive than the obligations set forth in Article XI.
- (b) <u>Limitations</u>. In respect of each audit of Celgene's books and records: (i) Celgene may be audited [**], (ii) no records for any given year for Celgene may be audited more than [**]; <u>provided that</u> Celgene's records shall still be made available if such records impact another financial year which is being audited, and (iii) Agios shall only be entitled to audit books and records of Celgene from the [**] prior to the Calendar Year in which the audit request is made.

- (c) <u>Audit Notice</u>. In order to initiate an audit for a particular Calendar Year, Agios must provide written notice to Celgene. Agios shall provide Celgene with notice of one or more proposed dates of the audit not less than [**] prior to the first proposed date. Celgene will reasonably accommodate the scheduling of such audit. Celgene shall provide such Audit Team(s) with full and complete access to the applicable books and records and otherwise reasonably cooperate with such audit.
- (d) <u>Payments</u>. If the audit shows any under-reporting or underpayment, or overcharging by Celgene, that underreporting, underpayment or overcharging shall be reported to Agios and Celgene shall remit such underpayment or reimburse such overcompensation (together with interest at the rate set forth in Section 9.9) to Agios within [**] after receiving the audit report. Further, if the audit for an annual period shows an under-reporting or underpayment or an overcharge by Celgene for that period in excess of [**] percent ([**]%) of the amounts properly determined, Celgene, shall reimburse Agios, for its respective audit fees and reasonable Out-of-Pocket Costs in connection with said audit, which reimbursement shall be made within [**] after receiving appropriate invoices and other support for such audit-related costs.

Section 9.7. Tax Matters.

- (a) Withholding Taxes. Each Party shall be entitled to deduct and withhold from any amounts payable under this Agreement such taxes as are required to be deducted or withheld therefrom under any provision of applicable Law. The Party that is required to make such withholding (the "Paying Party") will: (i) deduct those taxes from such payment, (ii) timely remit the taxes to the proper taxing authority, and (iii) send evidence of the obligation together with proof of tax payment to the recipient Party (the "Payee Party") on a timely basis following that tax payment; provided, however, that before making any such deduction or withholding, the Paying Party shall give the Payee Party notice of the intention to make such deduction or withholding (and such notice, which shall set forth in reasonable detail the authority, basis and method of calculation for the proposed deduction or withholding, shall be given at least a reasonable period of time before such deduction or withholding is required, in order for such Payee Party to obtain reduction of or relief from such deduction or withholding). Each Party agrees to cooperate with the other Parties in claiming refunds or exemptions from such deductions or withholdings under any relevant agreement or treaty or other applicable Law which is in effect to ensure that any amounts required to be withheld pursuant to this Section 9.7(a) are reduced in amount to the fullest extent permitted by applicable Laws. In addition, the Parties shall cooperate in accordance with applicable Laws to minimize [**] in connection with this Agreement, as applicable.
- (b) <u>Tax Documentation</u>. Each Party has provided a properly completed and duly executed IRS Form W-9 or applicable Form W-8 to the other Parties. Each Party and any other recipient of payments under this Agreement shall provide to the other Party, at the time or times reasonably requested by such other Parties or as required by applicable Law, such properly completed and duly executed documentation (for example, IRS Forms W-8 or W-9) as will permit payments made under this Agreement to be made without, or at a reduced rate of, withholding for taxes, and the applicable payment shall be made without (or at a reduced rate of) withholding to the extent permitted by such documentation, as reasonably determined by the Paying Party.

- Section 9.8. <u>Currency Exchange</u>. Unless otherwise expressly stated in this Agreement, all amounts specified in, and all payments made under, this Agreement shall be in United States Dollars. If any currency conversion shall be required in connection with the calculation of amounts payable under this Agreement, such conversion shall be performed in a manner consistent with Celgene's normal practices used to prepare its audited financial statements for internal and external reporting purpose. For clarity, Celgene sets currency transaction rates for the month on the last business day of the month prior. Agios has the right to verify that the exchange rates used by Celgene for a given month are within the trading range of the last business day of the month prior.
- Section 9.9. <u>Late Payments</u>. Celgene shall pay interest to Agios on the aggregate amount of any payments that are not paid on or before the date such payments are due under this Agreement at a rate per annum equal to the lesser of the [**], or the highest rate permitted by applicable Law, calculated on the number of days such payments are paid after the date such payments are due; <u>provided that</u>, with respect to any disputed payments, no interest payment shall be due until such dispute is resolved and the interest which shall be payable thereon shall be based on the finally-resolved amount of such payment, calculated from the original date on which the disputed payment was due through the date on which payment is actually made.
- Section 9.10. <u>Blocked Payments</u>. In the event that, by reason of Applicable Law in any country, it becomes impossible or illegal for Celgene (or any of its Affiliates or Licensee Partners) to transfer, or have transferred on its behalf, payments owed Agios hereunder, Celgene will promptly notify Agios of the conditions preventing such transfer and such payments will be deposited in local currency in the relevant country to the credit of Agios in a recognized banking institution designated by Agios or, if none is designated by Agios within a period of [**], in a recognized banking institution selected by Celgene or any of its Affiliates or its Licensee Partners, as the case may be, and identified in a written notice given to Agios.

Article X. Intellectual Property Ownership, Protection and Related Matters

Section 10.1. Ownership of Inventions.

- (a) <u>Pre-Existing Know-How</u>. Any Know-How developed or generated by Celgene or Agios prior to the Effective Date shall remain the sole property of such Party.
- (b) <u>Sole Inventions</u>. All Know-How developed or generated solely by employees, agents and consultants of a Party shall be owned exclusively by such Party.
- (c) <u>Joint Inventions</u>. All Know-How developed or generated jointly by employees, agents and consultants of Celgene, on the one hand, and employees, agents and consultants of Agios, on the other hand, in the conduct of activities under this Agreement ("<u>Joint Inventions</u>" and, any Patents Covering such Joint Inventions, "<u>Joint Patents</u>") shall be owned jointly on the basis of each Party having an undivided interest without a duty to account to the other Party (other than as set forth in this Agreement) and shall be deemed to be Controlled by

each Party. Each Party shall have the right to use such Joint Inventions, or license such Joint Inventions to its Affiliates or any Third Party, or sell or otherwise transfer its interest in such Joint Inventions to its Affiliates or a Third Party, in each case without the consent of the other Party (and, to the extent that applicable Law requires the consent of the other Party, this Section 10.1(c) shall constitute such consent), so long as such use, sale, license or transfer is subject to Section 8.6 and the licenses granted pursuant to this Agreement and is otherwise consistent with this Agreement.

- (d) <u>Inventorship</u>. The determination of inventorship shall be made in accordance with United States patent laws. In the event of a dispute regarding inventorship, if the Parties are unable to resolve the dispute, the Parties shall jointly engage mutually acceptable independent patent counsel not regularly employed by either Party to resolve such dispute. The decision of such independent patent counsel shall be binding on the Parties with respect to the issue of inventorship.
- (e) <u>Further Actions and Assignments</u>. Each Party shall take all further actions and execute all assignments requested by the other Party and reasonably necessary or desirable to vest in the other Party the ownership rights set forth in this Article X.
- Section 10.2. Prosecution of Patents. Subject to the terms and conditions of any Existing Third Party Agreement to the extent such agreement applies to the Agios Patents, the following provisions shall apply with respect to the Agios Patents, Celgene Patents, Celgene Collaboration Patents and Joint Patents:
- (a) Agios Patents, Celgene Collaboration Patents and Joint Patents. Subject to the provisions of Section 10.2(f) and coordination with [**] shall have the initial right and option to Prosecute the Agios Patents, Celgene Collaboration Patents and Joint Patents. In the event that [**] declines to Prosecute such Patents, it shall give [**] reasonable notice to this effect, sufficiently in advance to permit [**] to undertake such Prosecution in such country without a loss of rights, and thereafter [**] may, upon written notice to [**], Prosecute such Patents in the owning Party(ies)'s name(s) subject to coordination with [**].
- (b) [**] <u>Patents</u>. Celgene shall have the sole right and option, in its sole discretion and at its sole expense, to Prosecute the [**].
- (c) <u>Costs and Expenses</u>. Each Prosecuting Party shall bear all of its own costs and expenses in Prosecuting Agios Patents, Celgene Collaboration Patents and Joint Patents.

(d) Strategy; Diligence and Cooperation.

(i) The Party conducting Prosecution (the "<u>Prosecuting Party</u>") with respect to an Agios Patent, Celgene Collaboration Patent or Joint Patent shall be entitled to use patent counsel selected by it and reasonably acceptable to the non-Prosecuting Party (including in-house patent counsel as well as outside patent counsel) for the Prosecution of the Patents Rights subject to Section 10.2(a). Each Party agrees to cooperate with the other with respect to the Prosecution of such Patents pursuant to this Section 10.2, including by (X) executing all such documents and instruments and performing such acts as may be reasonably necessary in order to permit the other Party to undertake any Prosecution of Patents that such other Party is entitled, and has elected, to Prosecute, as provided for in Section 10.2(a) and (Y) giving consideration to the proper scope of Patents. The Prosecuting Party shall:

- (1) use Commercially Reasonable Efforts to regularly provide the non-Prosecuting Party in advance with reasonable information relating to the Prosecuting Party's Prosecution of Patents hereunder, including by providing copies of substantive communications, notices and actions submitted to or received from the relevant patent authorities and copies of drafts of filings and correspondence that the Prosecuting Party proposes to submit to such patent authorities, each of which shall be provided as far in advance as is practicable but with sufficient time for the non-Prosecuting party to provide meaningful input;
- (2) use Commercially Reasonable Efforts to consider in good faith and consult with the non-Prosecuting Party regarding its timely comments with respect to the same;
- (3) 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 reasonably requested by the non-Prosecuting Party; and
- (4) consult with the non-Prosecuting Party before taking any action that would have a material adverse impact on the scope of claims within the Agios Patents, Celgene Collaboration Patents and Joint Patents, as applicable.
- (ii) The Prosecuting Party shall determine the countries in which Agios Patents, Celgene Collaboration Patents and Joint Patents shall be Prosecuted, with the understanding that the countries set forth on Exhibit D of this Agreement shall generally form the basis for the overall Prosecution strategy for such Patents.
- (iii) The Prosecuting Party agrees not to abandon any Agios Patent, Celgene Collaboration Patent or Joint Patent without filing a continuation application in respect thereof unless it provides the non-Prosecuting Party with reasonable notice to this effect, sufficiently in advance to permit the non-Prosecuting Party to undertake such Prosecution of such Agios Patent, Celgene Collaboration Patent or Joint Patent, and thereafter such non-Prosecuting Party may, upon written notice to the Prosecuting Party, Prosecute such Agios Patent, Celgene Collaboration Patent or Joint Patent.
- (e) Third Party Rights. Agios covenants and agrees that it shall not grant any Third Party any right to control the Prosecution of the Agios Patents or to approve or consult with respect to any Patents licensed to Celgene hereunder, in any case, that is more favorable to the Third Party than the rights granted to Celgene hereunder or that otherwise conflicts with Celgene's rights hereunder.
- (f) Existing Third Party Agreements. Each Party acknowledges that, pursuant to an Existing Third Party Agreement, the applicable licensor(s) thereunder may retain the right to Prosecute the Agios Patents covered by such agreements; provided that Agios may have certain rights to assume Prosecution under such agreement. Agios agrees to keep Celgene fully informed of these rights, as well as provide to Celgene all information and copies of documents received from the licensor(s) under any such Existing Third Party Agreement or their patent

counsel relating to the Agios Patents covered by such agreements. To the extent that Agios is permitted to proceed with Prosecution or provide comments or suggestions to patent documents under an Existing Third Party Agreement, then the Agios Patents under such Existing Third Party Agreement shall be treated in the same manner as other Agios Patents under this Section 10.2, and Agios shall exercise all such rights with respect to such Agios Patents pursuant to the instructions of Celgene, if Celgene is given the right to act under this Section 10.2.

- Section 10.3. <u>Third Party Infringement of Agios Patents, Celgene Collaboration Patents and Joint Patents.</u> Subject to the terms and conditions of the Existing Third Party Agreements to the extent such agreements apply to the Agios Patents, the following provisions shall apply with respect to the Agios Intellectual Property, Celgene Collaboration Intellectual Property, Joint Patents and Joint Inventions:
- (a) <u>Notice</u>. Each Party shall immediately provide the other Party with written notice reasonably detailing any (i) known or alleged infringement of any Agios Patents, Celgene Collaboration Patents or Joint Patents, or known or alleged misappropriation of any Agios Know-How, Celgene Collaboration Know-How or Joint Inventions, by a Third Party, (ii) "patent certification" filed in the United States under 21 U.S.C. §355(b)(2) or 21 U.S.C. §355(j)(2) or similar provisions in other jurisdictions, and (iii) any declaratory judgment, opposition or similar action alleging the invalidity, unenforceability or non-infringement of any such intellectual property rights (collectively "Third Party Infringement").
- (b) First Right to Initiate Infringement Actions. [**] shall have the initial right, but not the obligation, to initiate a suit or take other appropriate action that [**] believes is reasonably required to protect the Agios Intellectual Property, Celgene Collaboration Intellectual Property, Joint Inventions and Joint Patents against the infringement in the Territory, including Third Party Infringement, unauthorized use or misappropriation by a Third Party that relates to a Licensed Product ("Competitive Infringement"). [**] shall give [**] advance notice of [**] intent to file any such suit or take any such action and the reasons therefor, and shall provide [**] with an opportunity to make suggestions and comments regarding such suit or action. Thereafter, [**] shall keep [**] promptly informed, and shall from time to time consult with [**] regarding the status of any such suit or action and shall provide [**] with copies of all material documents (e.g., complaints, answers, counterclaims, material motions, orders of the court, memoranda of law and legal briefs, interrogatory responses, depositions, material pre-trial filings, expert reports, affidavits filed in court, transcripts of hearings and trial testimony, trial exhibits and notices of appeal) filed in, or otherwise relating to, such suit or action. Without limiting the generality of the foregoing, the Parties shall discuss in good faith [**] intended response to a Competitive Infringement.
- (c) <u>Step-in Rights</u>. If [**] fails to initiate a suit or take such other appropriate action under Section 10.3(b) above within [**] after becoming aware of the Competitive Infringement, then [**] may, in its discretion, provide [**] with written notice of its intent to initiate a suit or take other appropriate action to combat such Competitive Infringement. If [**] provides such notice and [**] fails to initiate a suit or take such other appropriate action within [**] after receipt of such notice from [**], then [**] shall have the right, but not the obligation, to initiate a suit or take other appropriate action that it believes is reasonably required to protect the applicable Agios Intellectual Property, Celgene Collaboration Intellectual Property, Joint

Inventions and Joint Patents from Competitive Infringement. [**] shall give [**] advance notice of its intent to file any such suit or take any such action and the reasons therefor and shall provide [**] with an opportunity to make suggestions and comments regarding such suit or action. Thereafter, [**] shall keep [**] promptly informed and shall from time to time consult with [**] regarding the status of any such suit or action and shall provide [**] with copies of all material documents (e.g., complaints, answers, counterclaims, material motions, orders of the court, memoranda of law and legal briefs, interrogatory responses, depositions, material pre-trial filings, expert reports, affidavits filed in court, transcripts of hearings and trial testimony, trial exhibits and notices of appeal) filed in, or otherwise relating to, such suit or action.

- (d) <u>Conduct of Action; Costs</u>. The Party initiating suit shall have the sole and exclusive right to select counsel for any suit initiated by it under this Section 10.3, which counsel must be reasonably acceptable to the other Party. If required under applicable Law in order for such Party to initiate or maintain such suit, the other Party shall join as a party to the suit. If requested by the Party initiating suit, the other Party shall provide reasonable assistance to the Party initiating suit in connection therewith at no charge to such Party except that the initiating Party shall reimburse the other Party for Out-of-Pocket Costs, other than outside counsel expenses, incurred in rendering such assistance. The Party initiating suit shall assume and pay all of its own Out-of-Pocket Costs incurred in connection with any litigation or proceedings described in this Section 10.3, including the fees and expenses of the counsel selected by it. The other Party shall have the right to participate and be represented in any such suit by its own counsel at its own expense.
- (e) <u>Recoveries</u>. Any recovery obtained as a result of any proceeding described in this Section 10.3 or from any counterclaim or similar claim asserted in a proceeding described in Section 10.4, by settlement or otherwise, shall be applied in the following order of priority:
- (i) first, the Party initiating the suit or action shall be reimbursed for all previously unreimbursed Out-of-Pocket Costs in connection with such proceeding; and
- (ii) second, any remainder shall be paid [**] percent ([**]%) to the Party initiating the suit or action, and [**] percent ([**]%) to the other Party.
- (f) Existing Third Party Agreements. In the event that (i) a Patent covered by an Existing Third Party Agreement is at issue in an action under this Section 10.3 or Section 10.4, (ii) Agios has a right to enforce the Agios Patents under such Existing Third Party Agreement, and (iii) Celgene desires to enforce such Patent in accordance with the procedures under this Section 10.3 or Section 10.4, as applicable, then Agios shall either obtain the licensor(s)' consent under such Existing Third Party Agreement so that Celgene may file such an action in its own name or shall undertake such an action on Celgene's behalf and at Celgene's expense.

Section 10.4. Claimed Infringement; Claimed Invalidity.

- (a) <u>Infringement of Third Party Rights</u>. Each Party shall promptly notify the other Party in writing of any allegation by a Third Party that the activity of either Party or their Affiliates or Licensee Partners under this Agreement infringes or may infringe the intellectual property rights of such Third Party. If a Third Party asserts or files against a Party or its Affiliates any claim of infringement of the intellectual property rights of such Third Party or other action relating to alleged infringement of such intellectual property rights ("<u>Third Party Infringement Action</u>"), then, unless otherwise agreed by the Parties:
- (i) In the event of a Third Party Infringement Action against a single Party, the unnamed Party shall have the right, in the unnamed Party's sole discretion, to participate in the defense of such legal action with legal counsel selected by the unnamed Party and reasonably acceptable to the named Party. The Party named in such Third Party Infringement Action shall have the right to control the defense of the action, but shall notify and keep the unnamed Party apprised in writing of such action and shall consider and take into account the unnamed Party's reasonable interests and requests and suggestions regarding the defense of such action. In the event of a Third Party Infringement Action against both Parties, [**] shall have the right to control the defense of such Third Party Infringement Action.
- (ii) The non-controlling Party of a Third Party Infringement Action shall reasonably cooperate with the controlling Party in the preparation and formulation of a defense to such Third Party Infringement Action, and in taking other steps reasonably necessary to respond to such Third Party Infringement Action. The controlling Party shall have the right to select its counsel for the defense to such Third Party Infringement Action, which counsel must be reasonably acceptable to the non-controlling Party if both Parties have been named as defendants in the action. The non-controlling Party shall also have the right to participate and be represented in any such suit by its own counsel at its own expense. The controlling Party shall not (and shall cause its Affiliates and Licensee Partners not to) either (A) admit infringement, validity or enforceability of the asserted intellectual property rights, (B) pay any amount of money in settlement thereof, or (C) enter into a license for the asserted intellectual property rights upon terms that would restrict either Party from fully exploiting such rights consistently with the scope of the rights and obligations of both Parties under this Agreement, in each case (A) through (C), without the written consent of the non-controlling Party, which will not to be unreasonably withheld, conditioned or delayed. For the avoidance of doubt, except as provided in the foregoing clause (B), the costs of such defense and settlement shall be borne by the controlling Party.
- (iii) If the Party entitled to control the defense under Section 10.4(a)(i) or Section 10.4(a)(ii) fails to proceed in a timely manner with respect to such defense, the other Party shall have the right to control the defense of such claim upon the same conditions set forth therein.
- (iv) If requested by the Party controlling the defense, the Parties shall enter into a joint defense agreement that further outlines their rights and responsibilities consistent with the terms of this Section or as otherwise mutually agreed.
- (b) <u>Patent Invalidity Claim</u>. If a Third Party at any time asserts a claim that any issued Agios Patent, Celgene Collaboration Patent or Joint Patent is invalid or otherwise unenforceable (an "<u>Invalidity Claim</u>"), whether as a defense in an infringement action brought by Agios or Celgene pursuant to Section 10.3(b) or Section 10.3(c), in a declaratory judgment

action or in a Third Party Infringement claim brought against Agios or Celgene, the Parties shall cooperate with each other in preparing and formulating a response to such Invalidity Claim; <u>provided that</u>, subject to the terms and conditions of any Existing Third Party Agreement to the extent such agreement applies to such Agios Patent, the Party who has (or would have) control over litigation pursuant to Section 10.3(b) or Section 10.3(c) shall have the sole right to control the defense and settlement of any such Invalidity Claim as if it were litigation initiated therein. For the avoidance of doubt, any claim asserted against any Agios Patent before any such Patent is issued is deemed a Prosecution matter that is the subject of Section 10.2.

Section 10.5. <u>Patent Term Extensions</u>. The Parties shall, as necessary and appropriate, use reasonable efforts to agree upon a joint strategy for obtaining, and cooperate with each other in obtaining, patent term extensions for Agios Patents, Celgene Collaboration Patents and Joint Patents that Cover Licensed Products. If the Parties are unable to agree upon which of such Patents should be extended, and the matter remains unresolved after the procedure described in the Master Agreement, then [**] shall have the right to resolve the dispute, subject in each case to the terms and conditions of any Existing Third Party Agreement to the extent such agreement applies to an applicable [**] Patent.

Section 10.6. <u>Patent Marking</u>. Celgene shall comply with the patent marking statutes in each country in which the Licensed Product is Manufactured or Commercialized by or on behalf of Celgene or its Affiliates or Licensee Partners, as applicable, hereunder.

Section 10.7. <u>Celgene Intellectual Property</u>. Celgene shall have the sole right, but not the obligation, to initiate a suit or take other appropriate action that it believes is reasonably required to protect the Celgene Intellectual Property without any obligation to consult with Agios. Notwithstanding anything to the contrary in Section 10.3 or Section 10.4, all recoveries with respect to any such action, by settlement or otherwise, shall be [**] percent ([**]%) by Celgene.

Section 10.8. Application of 35 U.S.C. § 102(c). It is agreed and acknowledged that this Agreement establishes a qualifying collaboration within the scope of 35 U.S.C. § 102(c) and, accordingly, shall be deemed to constitute a "Joint Research Agreement" for all purposes under 35 U.S.C. § 102(c). Neither Party shall invoke the provisions of 35 U.S.C. § 102(c), or file this Agreement, in connection with the prosecution of any patent application claiming, in whole or in part, any 35 U.S.C. § 102(c) invention without the prior written consent of the other Party. In the event that a Party, during the course of prosecuting a patent application claiming a 35 U.S.C. § 102(c) invention (a "35 U.S.C. § 102(c) Patent"), deems it necessary to file a terminal disclaimer to overcome an obviousness type double patenting rejection in view of an earlier filed patent held by the other Party (the "Earlier Patent"), then, if the Parties agree, the Parties shall coordinate the filing of such terminal disclaimer in good faith, and, to the extent required under 35 U.S.C. § 102(c), both Parties shall agree, in such terminal disclaimer, that they shall not separately enforce 35 U.S.C. § 102(c) Patent independently from the Earlier Patent. To this end, to the extent required under 35 U.S.C. § 102(c), following the filing of such terminal disclaimer, the Parties shall, in good faith, coordinate all enforcement actions with respect to 35 U.S.C. § 102(c) Patent.

Article XI. Confidentiality

- Section 11.1. <u>Confidential Information</u>. Each Party agrees that a Party (the "<u>Receiving Party</u>") receiving Confidential Information of any other Party (the "<u>Disclosing Party</u>") shall (a) maintain in confidence such Confidential Information using not less than the efforts such Receiving Party uses to maintain in confidence its own proprietary information of similar kind and value, but in no event less than a reasonable degree of effort, (b) not disclose such Confidential Information to any Third Party without the prior written consent of the Disclosing Party, except for disclosures expressly permitted below, and (c) not use such Confidential Information for any purpose except those permitted by this Agreement (it being understood that this clause (c) shall not create or imply any rights or licenses not expressly granted under this Agreement). All Confidential Information of the Disclosing Party shall not be used by the Receiving Party except in performing its obligations or exercising rights explicitly granted under this Agreement, except to the extent that the Confidential Information:
- (a) was known by the Receiving Party or its Affiliates prior to its date of disclosure to the Receiving Party, as established by written evidence; or
- (b) 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) becomes published or generally known to the public 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 such Confidential Information, as established by written records.
 - Section 11.2. <u>Permitted Disclosure</u>. The Receiving Party may provide the Disclosing Party's Confidential Information:
- (a) to the Receiving Party's respective employees, consultants and advisors, and to the employees, consultants and advisors of such Party's Affiliates, who have a need to know such information and materials for performing obligations or exercising rights expressly granted under this Agreement and have an obligation to treat such information and materials as confidential;
- (b) to patent offices in order to seek or obtain Patents or to Regulatory Authorities in order to seek or obtain approval to conduct Clinical Trials or to gain Regulatory Approval with respect to the Licensed Products as contemplated by this Agreement; provided that such disclosure may be made only following reasonable notice to the Disclosing Party and to the extent reasonably necessary to seek or obtain such Patents or Regulatory Approvals; or
- (c) if such disclosure is required by judicial order or applicable Law or to defend or prosecute litigation or arbitration; <u>provided that</u>, prior to such disclosure, to the extent permitted by Law, the Receiving Party promptly notifies the Disclosing Party of such requirement, cooperates with the Disclosing Party to take whatever action it may deem appropriate to protect the confidentiality of the information and furnishes only that portion of the Disclosing Party's Confidential Information that the Receiving Party is legally required to furnish.

Section 11.3. <u>Publicity; Terms of this Agreement; Non-Use of Names.</u>

(a) Public Announcements. Except as required by judicial order or applicable Law (in which case, Section 11.3(a) must be complied with) or as explicitly permitted by this Article XI, neither Party shall make any public announcement concerning this Agreement without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed. The Party preparing any such public announcement shall provide the other Party with a draft thereof at least [**] prior to the date on which such Party would like to make the public announcement (or, in extraordinary circumstances, such shorter period as required to comply with applicable Law). Notwithstanding the foregoing, the Parties shall issue a press release, in the form attached as Exhibit E to this Agreement within [**] after the Effective Date. Neither Party shall use the name, trademark, trade name or logo of the other Party or its employees in any publicity or news release relating to this Agreement or its subject matter, without the prior express written permission of the other Party. For purposes of clarity, either Party may issue a press release or public announcement or make such other disclosure relating to this Agreement if the contents of such press release, public announcement or disclosure (x) (i) does not consist of financial information and has previously been made public other than through a breach of this Agreement by the issuing Party or its Affiliates, (ii) is contained in such Party's financial statements prepared in accordance with Accounting Standards, or (iii) is contained in the a redacted version of this Agreement, and (y) is material to the event or purpose for which the new press release or public announcement is made.

(b) Notwithstanding the terms of this Section 11.3:

- (i) Either Party shall be permitted to disclose the existence and terms of this Agreement to the extent required, in the reasonable opinion of such Party's legal counsel, to comply with applicable Laws, including the rules and regulations promulgated by the Securities and Exchange Commission or any other governmental authority. Notwithstanding the foregoing, before disclosing this Agreement or any of the terms hereof pursuant to this Section 11.3(a), the Parties will coordinate in advance with each other in connection with the redaction of certain provisions of this Agreement with respect to any filings with the US Securities and Exchange Commission ("SEC"), London Stock Exchange, the UK Listing Authority, NYSE, the NASDAQ Stock Market or any other stock exchange on which securities issued by a Party or a Party's Affiliate are traded (the "Redacted Version"), and each Party will use commercially reasonable efforts to seek confidential treatment for such terms as may be reasonably requested by the other Party; provided that the Parties will use commercially reasonable efforts to file redacted versions with any governing bodies which are consistent with the Redacted Version.
- (ii) Notwithstanding Section 11.1, the Receiving Party may disclose Confidential Information belonging to the Disclosing Party, and Confidential Information deemed to belong to both the Disclosing Party and the Receiving Party, to the extent (and only to the extent) such disclosure is reasonably necessary in the following instances:

- (1) subject to Section 11.3, complying with applicable Laws (including the rules and regulations of the SEC or any national securities exchange) and with judicial process, if in the reasonable opinion of the Receiving Party's counsel, such disclosure is necessary for such compliance;
- (including attorneys and accountants), (2) subject to Section 11.3(b)(ii)(3), investment bankers, and (3) in each case of (1) and (2), their and each of the Parties' respective directors, employees, contractors and agents; provided, that in all cases of (1), (2) and (3), prior to any such disclosure, each disclosee must be bound by written obligations of confidentiality, non-disclosure and non-use no less restrictive than the obligations set forth in this Article XI (provided, however, that in the case of prospective investment bankers, the term of confidentiality may be [**] from the date of disclosure and in the case of legal advisors, no written agreement shall be required), which for the avoidance of doubt, will not permit use of such Confidential Information for any purpose except those permitted by this Agreement; provided, however, that, in each of the above situations, the Receiving Party shall remain responsible for any failure by any Person who receives Confidential Information pursuant to this Section 11.3(b)(ii)(2) to treat such Confidential Information as required under this Article XI; and
- (3) in the case of any disclosure of this Agreement to any actual or potential acquirer, assignee, licensee, licensor, investment banker, institutional investor, lender or other financial partners, such disclosure shall solely be [**]; it being understood and agreed that, in connection with a proposed [**] with respect to such Party, only [**] this Agreement as applicable, to such Third Party; provided that, a Party may also disclose an unredacted version of this Agreement to Third Party attorneys, professional accountants and auditors who are engaged by licensors and lenders and who are under obligations of confidentiality not to disclose the unredacted terms of this agreement to such licensors or lenders for the purpose of confirming such Party's compliance with the terms of its applicable license and loan agreements with such licensors and lenders.
- (iii) [**]. Such disclosures may include achievement of milestones, significant events in the development and regulatory process, commercialization activities and the like. In addition to the initial press release described in Section 11.3, a Party (the "Requesting Party") may elect to make any such public disclosure of such achievement of milestones, significant events in the development and regulatory process and commercialization activities, and in such event it shall first notify the other Party (the "Cooperating Party") of such planned press release or public announcement and provide a draft for review at least [**] in advance of issuing such press release or making such public announcement (or, with respect to press releases and public announcements that are required by applicable Law, or by regulation or rule of any public stock exchange (including NASDAQ), with as much advance notice as possible under the circumstances if it is not possible to provide notice at least [**] in advance); provided, however, that a Party may issue such press release or public announcement without such prior review by the other Party if (A) the contents of such press release or public announcement have previously been made public other than through a breach of this Agreement by the issuing Party and (B) such press release or public announcement does not materially differ from the previously issued press release or other publicly available information. The

Cooperating Party may notify the Requesting Party of any reasonable objections or suggestions that the Cooperating Party may have regarding the proposed press release or public announcement, and the Requesting Party shall reasonably consider any such objections or suggestions that are provided in a timely manner. The principles to be observed in such disclosures shall include accuracy, compliance with applicable Law and regulatory guidance documents, reasonable sensitivity to potential negative reactions of the FDA (and its foreign counterparts) and the need to keep investors informed regarding the Requesting Party's business.

- Section 11.4. <u>Publications</u>. The Parties agree that neither Party nor its Affiliates shall have the right to make Publications pertaining to the Compounds or Licensed Products except as provided herein. If a Party or its Affiliates desire to make a Publication, such Party must comply with the following procedure:
- (a) Review by the Non-Publishing Party. The publishing Party shall provide the non-publishing Party with an advance copy of the proposed Publication, and the non-publishing Party shall then have [**] prior to submission for any Publication ([**] in the case of an abstract or oral presentation) in which to determine whether the Publication may be published and under what conditions, including (i) delaying sufficiently long to permit the timely preparation and filing of a patent application or (ii) specifying changes the non-Publishing reasonably believes are necessary to preserve any Patents or Know-How belonging (whether through ownership or license, including under this Agreement) in whole or in part to the non-publishing Party.
- (b) Removal of Confidential Information. In addition, if the non-publishing Party informs the publishing Party that such Publication, in the non-publishing Party's reasonable judgment, discloses any Confidential Information of the non-publishing Party or could be expected to have a material adverse effect on any Know-How which is Confidential Information of the non-publishing Party, such Confidential Information or Know-How shall be deleted from the Publication.
- (c) <u>Scientific Conferences</u>. Each Party shall have the right to present its Publications approved pursuant to this Section 11.4 at scientific conferences, including at any conferences in any country in the world, subject to any conditions imposed by the non-publishing Party in its approval.
- (d) <u>Academic Publications</u>. Notwithstanding the foregoing, the Parties acknowledge that, to the extent that any Publication relates to Agios Intellectual Property that is subject to an Existing Third Party Agreement, the parties to such Existing Third Party Agreement may have retained the right to publish certain information, and nothing in this Section 11.4 is intended to restrict the exercise of such rights; <u>provided that</u>, to the extent that Agios has the right to review and comment on any such publications, Agios shall, to the extent permissible under such Existing Third Party Agreement, exercise such rights after consultation with Celgene.
- Section 11.5. <u>Term.</u> All obligations under Sections 11.1, 11.2, 11.3 and 11.6 shall survive termination or expiration of this Agreement and shall expire [**] following termination or expiration of this Agreement.

Section 11.6. Return of Confidential Information.

- (a) <u>Obligations to Return or Destroy</u>. Upon the expiration or termination of this Agreement, the Receiving Party shall return to the Disclosing Party all Confidential Information received by the Receiving Party from the Disclosing Party (and all copies and reproductions thereof). In addition, the Receiving Party shall destroy:
- (i) any notes, reports or other documents prepared by the Receiving Party which contain Confidential Information of the Disclosing Party; and
- (ii) any Confidential Information of the Disclosing Party (and all copies and reproductions thereof) which is in electronic form or cannot otherwise be returned to the Disclosing Party.
- (b) <u>Destruction</u>. Alternatively, upon written request of the Disclosing Party, the Receiving Party shall destroy all Confidential Information received by the Receiving Party from the Disclosing Party (and all copies and reproductions thereof) and any notes, reports or other documents prepared by the Receiving Party which contain Confidential Information of the Disclosing Party. Any requested destruction of Confidential Information shall be certified in writing to the Disclosing Party by an authorized officer of the Receiving Party supervising such destruction.
- (c) <u>Limitation</u>. Nothing in this Section 11.6 shall require the alteration, modification, deletion or destruction of archival tapes or other electronic back-up media made in the ordinary course of business; <u>provided that</u> the Receiving Party shall continue to be bound by its obligations of confidentiality and other obligations under this Article XI with respect to any Confidential Information contained in such archival tapes or other electronic back-up media.
 - (d) Exceptions. Notwithstanding the foregoing,
- (i) the Receiving Party's legal counsel may retain one copy of the Disclosing Party's Confidential Information solely for the purpose of determining the Receiving Party's continuing obligations under this Article XI; and
- (ii) the Receiving Party may retain the Disclosing Party's Confidential Information and its own notes, reports and other documents
- (A) to the extent reasonably required (1) to exercise the rights and licenses of the Receiving Party expressly surviving expiration or termination of this Agreement; or (2) to perform the obligations of the Receiving Party expressly surviving expiration or termination of this Agreement; or
 - (B) to the extent it is impracticable to do so without incurring disproportionate cost.

Notwithstanding the return or destruction of the Disclosing Party's Confidential Information, the Receiving Party shall continue to be bound by its obligations of confidentiality and other obligations under this Article XI.

Article XII. Representations and Warranties

- Section 12.1. <u>Mutual Representations</u>. Agios and Celgene each represents, warrants and covenants to the other Party, as of the Execution Date, that:
- (a) <u>Authority</u>. Each Party is duly organized, validly existing and in good standing under the Laws of the jurisdiction of its formation and has full corporate power and authority to enter into this Agreement, and to carry out the provisions hereof or thereof, as applicable.
- (b) <u>Consents</u>. All necessary consents, approvals and authorizations of all government authorities and other Persons required to be obtained by it as of the Execution Date in connection with the execution, delivery and performance of this Agreement, and the performance of its obligations hereunder or thereunder, as applicable, have been obtained, except for authorizations and consents that may be necessary under Antitrust Law.
- (c) No Conflict. Notwithstanding anything to the contrary in this Agreement, the execution and delivery of this Agreement, the performance of such Party's obligations in the conduct of the Collaboration and the licenses and sublicenses to be granted pursuant to this Agreement (i) do not and will not conflict with or violate any requirement of applicable Laws existing as of the Execution Date and (ii) do not and will not conflict with, violate, breach or constitute a default under any agreement or any provision thereof, or any contract, oral or written, to which it is a party or by which it or any of its Affiliates is bound, existing as of the Execution Date.
- (d) <u>Enforceability</u>. This Agreement has been duly executed and delivered on behalf of each Party and is a legal and valid obligation binding upon it and is enforceable in accordance with its terms.
- (e) <u>Employee Obligations</u>. To its knowledge, none of its or its Affiliates' employees who have been, are or will be involved in the Collaboration are, as a result of the nature of such Collaboration to be conducted by the Parties, in violation of any covenant in any contract with a Third Party relating to non-disclosure of proprietary information, noncompetition or non-solicitation.
- Section 12.2. <u>Additional Agios Representations</u>. Agios represents, warrants and covenants to Celgene, as of the Execution Date, as follows: [**]
- (a) Agios has all rights, authorizations and consents necessary to grant all rights and licenses it purports to grant to Celgene under this Agreement, except for authorizations and consents that may be necessary under Antitrust Law.
- (b) Agios has not used, and during the Term will not knowingly use, any Know-How in a Program conducted by Agios that is encumbered by any contractual right of or obligation to a Third Party that conflicts or interferes with any of the rights or licenses granted or to be granted to Celgene hereunder.

- (c) Agios has not granted, and during the Term Agios will not grant, any right or license, to any Third Party relating to any of the intellectual property rights it Controls, that conflicts with or limits the scope of the rights or licenses granted or to be granted to Celgene hereunder.
- (d) There are no claims, litigations, suits, actions, disputes, arbitrations, or legal, administrative or other proceedings or governmental investigations pending or, to Agios' knowledge, threatened against Agios, nor is Agios a party to any judgment or settlement, which would be reasonably expected to adversely affect or restrict the ability of Agios to consummate the transactions contemplated under this Agreement and to perform its obligations under this Agreement, or which would affect the Agios Intellectual Property, or Agios' Control thereof, or any Target or Compound.*
- (e) To Agios' knowledge, the practice of the Agios Intellectual Property as contemplated under this Agreement does not (i) infringe any claims of any Patents of any Third Party, or (ii) misappropriate any Know-How of any Third Party.*
- (f) None of (i) the Agios Patents owned by Agios or both Controlled by and Prosecuted by Agios and (ii) to Agios' knowledge, the Agios Patents Controlled but not Prosecuted by Agios are subject to any pending re-examination, opposition, interference or litigation proceedings.*
- (g) To the knowledge of Agios, the Agios Patents Controlled by Agios or any Affiliate pursuant to any Existing Third Party Agreement were not and are not subject to any restrictions or limitations except as set forth in the Existing Third Party Agreements.
- (h) Agios has and, to Agios' knowledge, the applicable licensor under each Existing Third Party Agreement has, if applicable, complied with any and all obligations under the Bayh-Dole Act to perfect rights to the applicable Patent Rights or Know-How licensed thereunder.* Neither Agios nor any of its Affiliates has granted any liens or security interests on the Agios Intellectual Property and the Agios Intellectual Property is free and clear of any mortgage, pledge, claim, security interest, covenant, easement, encumbrance, lien or charge of any kind, except in each case with respect to licenses, covenants not to sue, immunities from suit, standstills, releases and options which would not, in the aggregate, fundamentally frustrate the purposes of the Collaboration.
- (i) <u>Schedule 12.2(i)</u> contains a complete and accurate list of all Patents owned by Agios and/or its Affiliates as of the Execution Date that are included in the Patents licensed hereunder, indicating any co-owner(s), if applicable. Except as set forth on <u>Schedule 12.2(i)</u>, Agios and its Affiliates do not own any Patent that is necessary or, to Agios' reasonable belief as of the Execution Date, reasonably useful to research, Develop, Manufacture or Commercialize any Compounds or Licensed Products.
- (j) Schedule 12.2(j) sets forth a complete and accurate list of all Existing Third Party Agreements, true and correct copies of which have been provided to Celgene, and such agreements are in full force and effect and have not been modified or amended. Neither Agios nor, to the knowledge of Agios, any licensor under the Existing Third Party Agreements is

in default with respect to a material obligation under, and none of such parties has claimed or has grounds upon which to claim that the other party is in default with respect to a material obligation under, the Existing Third Party Agreements.*

(k) Except under the Existing Third Party Agreements in effect as of the Execution Date, and except as set forth on Schedule 12.2(j), Agios and its Affiliates are not subject to any payment obligations to Third Parties as a result of the execution or performance of this Agreement.

Section 12.3. Covenants.

- (a) Mutual Covenants. Each Party hereby covenants to the other Party that:
- (i) all employees of such Party or its Affiliates or Third Party subcontractors working under this Agreement will be under appropriate confidentiality provisions at least as protective as those contained in this Agreement and, to the extent permitted under applicable Law, the obligation to assign all right, title and interest in and to their inventions and discoveries, whether or not patentable, to such Party as the sole owner thereof;
- (ii) to its knowledge, such Party will not (i) employ or use, nor hire or use any contractor or consultant that employs or uses, any individual or entity, including a clinical investigator, institution or institutional review board, debarred or disqualified by the FDA (or subject to a similar sanction by any Regulatory Authority outside the United States) or (ii) employ any individual who or entity that is the subject of an FDA debarment investigation or proceeding (or similar proceeding by any Regulatory Authority outside the United States), in each of subclauses (i) and (ii) in the conduct of its activities under this Agreement
- (iii) neither such Party nor any of its Affiliates shall, during the Term, grant any right or license to any Third Party relating to any of the intellectual property rights it owns or Controls which would conflict with any of the rights or licenses granted to the other Party hereunder; and
- (iv) such Party and its Affiliates shall perform its activities pursuant to this Agreement, in compliance (and shall ensure compliance by any of its subcontractors) in all material respects with all applicable Laws, including GCP, GLP and GMP as applicable and with respect to the Development, Manufacturing and Commercialization activities hereunder.
- (b) <u>Existing Third Party Agreement Covenants</u>. Agios hereby covenants to Celgene that Agios shall maintain the Existing Third Party Agreements, and shall not amend or terminate such agreements, and will not breach such agreements, if such amendment, modification, termination or breach would adversely affect Celgene's rights under this Agreement.
- Section 12.4. Agios Covenants During the Term. Except to the extent expressly permitted under Section 15.4, during the Term, neither Agios nor its Affiliates will, other than to an Affiliate of Agios who agrees in writing to be bound by the terms and conditions of this Agreement (a) assign, transfer, convey, encumber (including any liens or charges, but excluding any licenses, which are the subject of subsection (b), below) or dispose of, or enter into any

agreement with any Third Party to assign, transfer, convey, encumber (including any liens or charges, but excluding any licenses, which are the subject of subsection (b), below) or dispose of, any assets specifically related to this Agreement, including with respect to the Compound(s), Licensed Product(s) and any then-identified Companion Diagnostic(s) developed therefor, or pre-clinical study or Clinical Trial results or other data specifically related to such Program, or any intellectual property specifically related to any of the foregoing (with respect to each Program, the "Agios Program Assets"), except to the extent such assignment, transfer, conveyance, encumbrance or disposition would not fundamentally frustrate the purpose of this Agreement with respect to such Program, (b) license or grant to any Third Party, or agree to license or grant to any Third Party, any rights to any Agios Program Assets if such license or grant would fundamentally frustrate the purpose of this Agreement with respect to such Program, or (c) disclose any Confidential Information relating to the Agios Program Assets to any Third Party if such disclosure would fundamentally frustrate the purpose of this Agreement with respect to such Program. Agios and/or its Affiliates shall have the right to assign, transfer, convey or dispose of any assets specifically related to such Program to any Affiliate of Agios to the extent permitted under Section 15.4.

Section 12.5. <u>Disclaimer</u>. Except as otherwise expressly set forth in this Agreement, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY THAT ANY PATENTS ARE VALID OR ENFORCEABLE, AND EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT. Without limiting the generality of the foregoing, each Party disclaims any warranties with regards to: (a) the success of any study or test commenced under this Agreement; (b) the safety or usefulness for any purpose of the technology or materials, including the Compound, Licensed Product or Companion Diagnostic; and/or (c) the validity, enforceability, or non-infringement of any intellectual property rights or technology it provides or licenses to the other Party under this Agreement.

Article XIII. Indemnification; Product Liabilities

Section 13.1. By Celgene.

- (a) <u>Celgene Indemnification Obligation</u>. Celgene agrees, at Celgene's cost and expense, to defend, indemnify and hold harmless Agios and its Affiliates and their respective directors, officers, employees and agents (the "<u>Agios Indemnified Parties</u>") from and against any losses, costs, damages, fees or expenses arising out of any Third Party claim relating to:
- (i) any breach by Celgene of any of its representations, warranties or obligations pursuant to this Agreement;
- (ii) the gross negligence, or willful misconduct or violation of Law of Celgene or its Affiliates or Licensee Partners; or

- (iii) the Development, Manufacture and Commercialization of the Licensed Products by Celgene, its Affiliates or its Licensee Partners, including all Product Liabilities claims arising from Licensed Products distributed by Celgene or its Affiliates or Licensee Partners.
- (b) Indemnification Procedures. In the event of any such claim against the Agios Indemnified Parties by any Third Party, Agios shall promptly, and in any event within [**], notify Celgene in writing of the claim. Celgene shall have the right, exercisable by notice to Agios within [**] after receipt of notice from Agios of the claim, to assume direction and control of the defense, litigation, settlement, appeal or other disposition of the claim (provided that such claim is solely for monetary damages and Celgene agrees to pay all Damages relating to such matter, as evidenced in a written confirmation delivered by Celgene to Agios) with counsel selected by Celgene and reasonably acceptable to Agios; provided that the failure to provide timely notice of a claim by a Third Party shall not limit an Agios Indemnified Party's right for indemnification hereunder except to the extent such failure results in actual prejudice to Celgene. The Agios Indemnified Parties shall cooperate with Celgene and may, at their option and expense, be separately represented in any such action or proceeding. Celgene shall not be liable for any litigation costs or expenses incurred by the Agios Indemnified Parties without Celgene's prior written authorization. In addition, Celgene shall not be responsible for the indemnification or defense of any Agios Indemnified Party to the extent arising from any negligent or intentional acts by any Agios Indemnified Party or the breach by Agios of any representation, obligation or warranty under this Agreement, or any claims compromised or settled without its prior written consent. Each Party shall use reasonable efforts to mitigate Damages indemnified under this Section 13.1.

Section 13.2. By Agios.

- (a) <u>Agios Indemnification Obligation</u>. Agios agrees, at Agios' cost and expense, to defend, indemnify and hold harmless Celgene and its Affiliates and their respective directors, officers, employees and agents (the "<u>Celgene Indemnified Parties</u>") from and against any losses, costs, damages, fees or expenses arising out of any Third Party claim relating to:
 - (i) any breach by Agios of any of its representations, warranties or obligations pursuant to this Agreement;
- (ii) the gross negligence, willful misconduct or violation of Law of Agios or its Affiliates, or following termination of this Agreement where Section 14.4 is applicable, its Licensee Partners;
- (iii) Licensed Products distributed by Agios or its Affiliates, including all Product Liabilities claims arising from Licensed Products distributed by Agios or its Affiliates; or
- (iv) any of the matters disclosed by Agios in a disclosure schedule pursuant to Section 12.2, where the cause of action underlying such Damages accrued prior to the Execution Date. For the avoidance of doubt, amounts payable under Third Party licenses entered into under Section 9.4(b) shall be borne by Celgene as set forth in Section 9.4(b), and shall not be subject to indemnification under this Section 13.2.

- (b) Indemnification Procedures. In the event of any such claim against the Celgene Indemnified Parties by any Third Party, Celgene shall promptly, and in any event within [**], notify Agios in writing of the claim. Agios shall have the right, exercisable by notice to Celgene within [**] after receipt of notice from Celgene of the claim, to assume direction and control of the defense, litigation, settlement, appeal or other disposition of the claim (provided that such claim is solely for monetary damages and Agios agrees to pay all Damages relating to such matter, as evidenced in a written confirmation delivered by Agios to Celgene) with counsel selected by Agios and reasonably acceptable to Celgene; provided that the failure to provide timely notice of a claim by a Third Party shall not limit a Celgene Indemnified Party's right for indemnification hereunder except to the extent such failure results in actual prejudice to Agios. The Celgene Indemnified Parties shall cooperate with Agios and may, at their option and expense, be separately represented in any such action or proceeding. Agios shall not be liable for any litigation costs or expenses incurred by the Celgene Indemnified Parties without Agios' prior written authorization. In addition, Agios shall not be responsible for the indemnified Party or the breach by Celgene of any representation, obligation or warranty under this Agreement, or any claims compromised or settled without its prior written consent. Each Party shall use reasonable efforts to mitigate Damages indemnified under this Section 13.2.
- Section 13.3. <u>Product Liability Costs</u>. Except with respect to such portion (if any) of Product Liabilities that are claims entitled to indemnification under Section 13.1 or Section 13.2, all costs incurred in connection with any litigation or proceeding relating to such Third Party Products Liability Action shall be borne solely by Celgene.
- Section 13.4. <u>Limitation of Liability</u>. EXCEPT WITH RESPECT TO A BREACH OF SECTION 8.6 OR ARTICLE XI, OR A PARTY'S LIABILITY PURSUANT TO SECTION 13.1 OR SECTION 13.2, NEITHER PARTY SHALL BE LIABLE FOR SPECIAL, CONSEQUENTIAL, EXEMPLARY, PUNITIVE, MULTIPLE OR OTHER INDIRECT OR REMOTE DAMAGES, OR FOR LOSS OF PROFITS, LOSS OF DATA OR LOSS OF USE DAMAGES ARISING IN ANY WAY OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, WHETHER BASED UPON WARRANTY, CONTRACT, TORT, STRICT LIABILITY OR OTHERWISE, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES OR LOSS.

Section 13.5. <u>Insurance</u>. Beginning on [**] and thereafter during the Term, Celgene shall maintain commercial general liability insurance (including product liability insurance) from a recognized, creditworthy insurance company, with coverage limits of at least [**] US Dollars (\$[**]) per claim and annual aggregate. Celgene may elect to self-insure all or parts of the limits described above. Within [**] following written request from Agios, Celgene, shall furnish to Agios a certificate of insurance evidencing such coverage. If such coverage is modified or cancelled, Celgene shall notify the Agios and promptly provide Agios with a new certificate of insurance evidencing that Celgene's coverage meets the requirements of this Section 13.5.

Article XIV. Term and Termination

- Section 14.1. <u>Term.</u> This Agreement shall commence on the Effective Date and, unless earlier terminated pursuant to Section 14.3, shall remain in effect until it expires (the "<u>Term</u>") as follows:
- (a) on a Licensed Product-by-Licensed Product and country-by-country basis, this Agreement shall expire on the date of the expiration of the Royalty Term with respect to such Licensed Product in such country; and
- (b) in its entirety upon the expiration of all applicable Royalty Terms under this Agreement with respect to all Licensed Products in all countries in the Territory.

For the avoidance of doubt, this Agreement shall not be effective until the Effective Date, and this Agreement may be subject to termination prior to the Effective Date as set forth in Section 3.2 of the Master Agreement, in which case all rights to the Program (as defined in the Master Agreement) that is the subject of this Agreement shall revert to Agios in accordance with Section 2.12 of the Master Agreement.

- Section 14.2. <u>Effect of Expiration</u>. After the expiration of the Term pursuant to Section 14.1 above, the following terms shall apply:
- (a) <u>Licenses after Licensed Product Expiration</u>. After expiration of the Term (but not after early termination) with respect to any Licensed Product in a country in the Territory pursuant to Section 14.1(a), Celgene's rights and licenses hereunder under Agios' rights in Agios Intellectual Property, Joint Inventions, Joint Patents and Manufacturing Technology to develop, manufacture, have manufactured, use, offer for sale, sell, import and otherwise commercialize such Licensed Product and related Companion Diagnostics in the Field in such country, for so long as it continues to do so, shall convert to irrevocable, non-terminable rights and licenses, with the right to grant sublicenses; provided that, following such expiration and notwithstanding Section 9.4(a), (i) Celgene shall be solely responsible for all payments owed to any Third Party licensors and (ii) Celgene shall be responsible for complying with the terms of any license agreements with such Third Party licensors, in each case ((i) and (ii)), solely with respect to Celgene's exercise of such rights.
- (b) <u>Licenses after Expiration of Agreement</u>. After expiration of the Term (but not after early termination) with respect to this Agreement in its entirety pursuant to Section 14.1(b), Celgene's rights and licenses hereunder under Agios' rights in Agios Intellectual Property, Joint Inventions, Joint Patents and Manufacturing Technology to develop, manufacture, have manufactured, use, offer for sale, sell, import and otherwise commercialize Licensed Products and Companion Diagnostics in the Field worldwide, for so long as it continues to do so, shall convert to irrevocable, non-terminable rights and licenses, with the right to grant sublicenses; <u>provided that</u>, following such expiration and notwithstanding Section 9.4(a), (i) Celgene shall be solely responsible for all payments owed to any Third Party licensors and (ii) Celgene shall be responsible for complying with the terms of any license agreements with such Third Party licensors, in each case ((i) and (ii)), solely with respect to Celgene's exercise of such rights.

Section 14.3. <u>Termination</u>.

(a) <u>Termination for Convenience</u>. Celgene shall have the right to terminate this Agreement in its entirety for convenience upon [**] prior written notice to Agios; <u>provided that</u> Celgene shall not have the right to terminate this Agreement until [**] following the Effective Date (it being understood and agreed that Celgene shall be entitled to terminate upon [**] written notice at any time it reasonably determines that such termination is necessary to comply with any Antitrust Law).

(b) Termination for Material Breach.

(i) Termination by Either Party for Breach. Subject to Section 14.3(b)(ii) (with respect to a Material Breach by either Party of its obligations to use Commercially Reasonable Efforts), this Agreement and the rights granted herein may be terminated by either Party for the material breach of this Agreement in a manner that fundamentally frustrates the transactions contemplated by this Agreement taken as a whole by the other Party to this Agreement (each, a "Material Breach"), provided that, if the breaching Party has not cured such Material Breach within [**] after the date of written notice to the breaching Party of such breach (or [**], in the case of Celgene's payment obligations under this Agreement or the specified time period provided in Section 14.3(b)(ii) with respect to a Material Breach by either Party of its obligation to use Commercially Reasonable Efforts, each as applicable) (the "Cure Period"), which notice shall describe such breach in reasonable detail and shall state the non-breaching Party's intention to terminate this Agreement pursuant to this Section 14.3(b)(i). Notwithstanding the preceding sentence, the Cure Period for any allegation made in good faith as to a Material Breach under this Agreement will run from the date that written notice was first provided to the breaching Party by the non-breaching Party. Any such termination of this Agreement under this Section 14.3(b)(i) shall become effective at the end of the Cure Period, unless the breaching Party has cured any such Material Breach prior to the expiration of such Cure Period, or, if such Material Breach is not susceptible to cure within the Cure Period, then, the non-breaching Party's right of termination shall be suspended only if and for so long as the breaching Party has provided to the non-breaching Party a written plan that is reasonably calculated to effect a cure and such plan is acceptable to the non-breaching Party, and the breaching Party commits to and carries out such plan as provided to the non-breaching Party within [**] days after the date that written notice was first provided to the breaching Party by the non-breaching Party. The Parties understand and agree that the totality of this Agreement and the [**].

(ii) Additional Procedures for Termination by either Party for Failure of the Other Party to Use Commercially Reasonable Efforts. If either Party wishes to exercise its right to terminate this Agreement pursuant to Section 14.3(b)(i) for the other Party's Material Breach of its obligations to use Commercially Reasonable Efforts, it shall provide to such other Party a written notice of its intent to exercise such right, which notice shall be labeled as a "notice of Material Breach for failure to use Commercially Reasonable Efforts," and shall state the reasons and justification for such termination [**]. For any such notice of breach by a Party, the Cure Period shall, subject to Section 14.3(b)(iii), be [**], and shall become effective in accordance with Section 14.3(b) (i).

- (iii) Disagreement as to Material Breach. If the Parties reasonably and in good faith disagree as to whether there has been a Material Breach pursuant to Section 14.3(b) then: (A) the Party that disputes that there has been a Material Breach may contest the allegation by referring such matter, within [**] for resolution to the Executive Officers, who shall meet promptly to discuss the matter, and determine, within [**] following referral of such matter, whether or not a Material Breach has occurred pursuant to Section 14.3(b); (B) the relevant Cure Period with respect thereto will be tolled from the date the breaching Party notifies the non-breaching Party of such dispute and through the resolution of such dispute in accordance with the applicable provisions of this Agreement (provided, that if such dispute relates to payment, the Cure Period will only apply with respect to payment of disputed amounts, and not with respect to undisputed amounts), (C) it is understood and agreed that during the pendency of such dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder) and (D) if it is finally and conclusively determined in accordance with Section 15.2 that the breaching Party committed such Material Breach, then the breaching Party shall have the right to cure such Material Breach after such determination within the Cure Period (provided, that if such dispute relates to a failure to use Commercially Reasonable Efforts, such post-determination Cure Period shall be strictly limited to [**] and any cure within such [**] period must fully cure such breach prior to the end of such [**] period).
- (iv) If the Executive Officers are unable to resolve a dispute within such [**] period after it is referred to them, the matter will be resolved as provided in Section 15.2.
- (v) <u>Payments</u>. No milestone payments by Celgene will be due on milestones achieved during the period between the notice of termination under Section 14.3(b) and the effective date of termination; <u>provided</u>, <u>however</u>, <u>that</u> (A) if either Party provides notice of a dispute pursuant to Section 14.3(b)(iii) or otherwise and such dispute is resolved in a manner in which no termination of this Agreement occurs with respect to such breach or (B) the breaching Party cures the applicable breach during the Cure Period, then upon such resolution or cure Celgene will within [**] pay to Agios the applicable milestone payment for each milestone achieved during the period between the notice of termination under Section 14.3(b) and the resolution of such dispute or cure of such breach, and if it was determined that Celgene wrongly asserted breach by Agios under Section 14.3(b)(iii), then Celgene shall also pay interest on such amount as provided in Section 9.9.
- (c) <u>Termination for Insolvency</u>. To the extent permitted by Law, this Agreement may be terminated 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; <u>provided</u>, <u>however</u>, <u>that</u>, in the event of any involuntary bankruptcy or receivership proceeding such right to terminate shall only become effective if either Party consents to the involuntary bankruptcy or receivership or such proceeding is not dismissed within ninety (90) days after the filing thereof.

(d) <u>Termination for Patent Challenge</u>. Either Party shall have the right to terminate this Agreement solely on a Licensed Product-by-Licensed Product basis upon written notice if the other Party or any of its Affiliates challenges the validity, scope or enforceability of or otherwise opposes any Patent (i) included in the Agios Intellectual Property and that is licensed to Celgene under this Agreement in any action or proceeding, or (ii) included in the Celgene Patents or Celgene Collaboration Patents that is licensed to Agios under this Agreement in any action or proceeding (subject to the exceptions described in this Section 14.3(d), a "Challenge") (other than as may be necessary or reasonably required to assert a defense, cross-claim or a counter-claim in an action or proceeding asserted by such Party or any of its Affiliates or Licensee Partners against the other Party or any of its Affiliates or Licensee Partners or to respond to a court request or order or administrative law, request or order), it being understood and agreed that either Party's right to terminate this Agreement under this Section 14.3(d) shall not apply to any actions undertaken by an Affiliate of the other Party (the "Challenging Party") that first becomes such an Affiliate as a result of a Change of Control involving the Challenging Party, where such new Affiliate was undertaking any of the activities described in the foregoing clause prior to such Change of Control; provided that, a Party's right to terminate this Agreement under this Section 14.3(d) shall apply to actions undertaken by such new Affiliate if the Challenging Party is the acquiror in such Change of Control and such new Affiliate does not terminate or otherwise cease participating in such action, proceeding, challenge or opposition within [**] after the effective date of such Change of Control. If a Licensee Partner of Celgene challenges the validity, scope or enforceability of or otherwise opposes any Patent included in any of the intellectual property described in this Section 14.3(d) under which such Licensee Partner is sublicensed in any action or proceeding, then Celgene shall, upon written notice from Licensor, terminate such sublicense. For the avoidance of doubt, an action by a Party or any Affiliate (collectively the "Pursuing Party") in accordance with this Agreement and the Master Agreement to amend claims within a pending patent application of the other Party during the course of the Pursuing Party's Prosecution of such pending patent application or in defense of a Third Party proceeding, or to make a negative determination of patentability of claims of a patent application of the other Party or to abandon a patent application of the other Party during the course of the Pursuing Party's Prosecution of such pending patent application, shall not constitute a challenge under this Section 14.3(d). Neither Party shall, and each Party shall ensure that its Affiliates and Licensee Partners do not, use or disclose any Confidential Information of the other Party or any nonpublic information regarding the Prosecution or enforcement of any Agios Patents, Celgene Collaboration Patents or Joint Patents to which a Party or any of its Affiliates or Licensee Partners are or become privy as a consequence of the rights granted to Celgene pursuant to Article X, in initiating, requesting, making, filing or maintaining, or in funding or otherwise assisting any other Person with respect to, any Challenge.

Section 14.4. Effects of Termination.

(a) <u>Effects of Celgene Termination for Convenience or Agios Termination for Celgene Breach, Insolvency or Patent Challenge</u>. Upon termination of this Agreement by Celgene under Section 14.3(a) or by Agios under Section 14.3(b), 14.3(c) or 14.3(d), the following shall apply:

- (i) all licenses granted by Agios to Celgene under Section 8.1 shall terminate (A) in their entirety if pursuant to Section 14.3(a), (b) or (c), and (B) with respect to the corresponding Compound and Licensed Product if pursuant to Section 14.3(d);
- (ii) Celgene shall grant to Agios an exclusive, non-transferable (except as set forth in Section 15.4), worldwide right and license in the Field, with the right to grant sublicenses in a manner consistent with Section 8.2(a) and Section 8.2(a)(ii)(2), and, from and after such termination, Agios shall pay Celgene royalties on Annual Net Sales of Licensed Products pursuant to Section 9.3, reducing such royalties by [**] percent ([**]%) and substituting "Agios" for "Celgene" and vice versa with respect to all obligations and definitions, and otherwise *mutatis mutandis*, under Celgene's rights in Celgene Intellectual Property, Celgene Collaboration Intellectual Property, Joint Inventions, Joint Patents and Manufacturing Technology to Develop, Manufacture and Commercialize Compounds and Licensed Products; <u>provided that</u>, (i) Agios shall be solely responsible for all payments owed to any Third Party licensors (without any right to offset any such amounts against royalties payable to Celgene hereunder) and (ii) Agios shall be responsible for complying with the terms of any license agreements with such Third Party licensors, in each case ((i) and (ii)), solely with respect to Agios' exercise of such rights;
- (iii) Celgene shall be released from its Development, Manufacture and Commercialization obligations (except as set forth in Section 14.4(a)(vii) and Section 14.4(a)(viii) below with respect to Celgene's transfer of Manufacturing to Agios hereunder);
- (iv) within [**] after such termination, Celgene shall provide to Agios a fair and accurate summary report of the status of Development and Commercialization activities conducted by Celgene with respect to the Licensed Products;
- (v) Celgene shall promptly transfer and assign to Agios all of Celgene's and its Affiliates' rights, title and interests in and to the Product Trademark(s) (but not any Celgene house marks or composite marks including a house mark) owned by Celgene and solely used for Licensed Products in the Territory;
- (vi) Celgene shall as soon as reasonably practicable transfer and assign to Agios all Regulatory Approvals of the Licensed Products in the Territory, their corresponding Regulatory Documentation, and a copy of all of the data comprising the global safety database for the Licensed Products and any related Companion Diagnostics; provided that Celgene may retain such data and a single copy of such Regulatory Approvals and Regulatory Documentation for its records; and provided further that, if such Regulatory Approvals or Regulatory Documentation are necessary or useful for the Development, Manufacture or Commercialization of any product other than the Licensed Products, in place of transferring or assigning the foregoing, Celgene shall grant Agios a Right of Reference or Use with respect to such approvals or documentation with respect to the Licensed Products in the Territory;
- (vii) Agios shall have the option, exercisable within [**] following the effective date of such termination of this Agreement, to obtain Celgene's inventory of the Licensed Products at a price equal to [**] percent ([**]%) of Celgene's Manufacturing Costs for such inventory of the Licensed Products; provided that, if Celgene, its Affiliates or Licensee

Partners have outstanding orders, at Agios' election, either Agios shall fulfill such orders or, notwithstanding Agios' option to purchase inventory, Celgene may retain sufficient inventory to fulfill such orders. Agios may exercise such option by written notice to Celgene during such [**] period; provided that, in the event Agios exercises such right to purchase such inventory, Celgene shall grant, and hereby does grant, a royalty-free right and license to any trademarks, names and logos of Celgene contained therein for a period of [**] solely to permit the orderly sale of such inventory, subject to Agios meeting reasonable quality control standards imposed by Celgene on the use of such trademarks, names and logos, which shall be consistent with the standards used by Celgene prior to such termination;

(viii) at Agios' written request:

- (1) in exchange for a payment equal to [**] percent ([**]%) of Celgene's Manufacturing Costs and upon other commercially reasonable terms as may be mutually agreed between the Parties or their respective Affiliates in a supply agreement, Celgene shall use Commercially Reasonable Efforts to supply Agios and its Affiliates with comparable quantities of the Licensed Products in the form, formulation and presentation as were being Developed or Commercialized immediately prior to termination until the earlier of [**] after the effective date of the termination and establishment by Agios of an alternative supply for such product(s);
- (2) in the event Celgene was utilizing a Third Party manufacturer to Manufacture the Licensed Products, to the extent permitted by the terms of such contract, Celgene shall promptly assign to Agios the manufacturing agreements with such Third Party with respect to such product(s); and
- (3) Celgene shall transfer, or have transferred, to Agios or its designee, pursuant to a technology transfer plan to be mutually agreed by the Parties, all Manufacturing Technology Controlled by Celgene that is both necessary to Manufacture the Licensed Products as Manufactured by or on behalf of Celgene and its Affiliates prior to termination and has been incorporated in regulatory documentation submitted to a Regulatory Authority in support of Development or Commercialization of the Licensed Products (or is in the process of being incorporated), and Celgene shall provide reasonable assistance in connection with the transfer of such Manufacturing Technology to Agios or its designee, all of which shall be transferred or provided at Celgene's Out-of-Pocket Costs:
- (ix) separate transitional activities shall be undertaken with respect to any Companion Diagnostic(s) to ensure that the appropriate Regulatory Approvals, Manufacturing Technology or other Know-How or Patents necessary for the Development, Manufacture or Commercialization of such Companion Diagnostic(s) shall be transferred to Agios to the same extent as Regulatory Approvals, Manufacturing Technology or other Know-How or Patents otherwise associated with such Licensed Products are transferred;
- (x) notwithstanding anything to the contrary in Section 8.6, Agios shall have the right to pursue the Development, Manufacture and Commercialization of the Licensed Products; and

- (xi) the provisions of Article X (other than Section 10.1) terminate, and Celgene shall, if applicable, provide reasonable assistance to Agios and cooperation in connection with the transition of Prosecution and enforcement responsibilities to Agios with respect to Agios Patents, Celgene Collaboration Patents and Joint Patents then being Prosecuted or enforced by Celgene, including execution of such documents as may be necessary to effect such transition.
- (xii) <u>Sell-Down</u>. Unless Agios exercises its option under Section 14.4(a)(vii), if Celgene, its Affiliates or Licensee Partners at termination of this Agreement possess Licensed Product, have started the manufacture thereof or have accepted orders therefor, Celgene, its Affiliates or Licensee Partners 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 Agios any and all payments as provided in this Agreement.
- (b) <u>Effects of Celgene Termination for Agios Breach, Insolvency or Patent Challenge</u>. Upon any termination of this Agreement by Celgene under Section 14.3(b), 14.3(c) or 14.3(d):
- (i) If Celgene has the right to terminate this Agreement pursuant to Section 14.3(b), Section 14.3(c) or Section 14.3(d), Celgene may elect upon written notice to Agios, to either:
- (1) terminate this Agreement in its entirety, if pursuant to Section 14.3(b) or Section 14.3(c), or with respect to the corresponding Compound and Licensed Product, if pursuant to Section 14.3(d), in which case (1) all rights and obligations of the Parties under this Agreement or the corresponding Compound and Licensed Product, respectively, shall terminate, except (I) Celgene's payment obligations (accrued as of the effective date of such termination) and the audit rights set forth in Article IX, and (II) Section 14.4(d), shall, in each of cases (I) and (II), survive such termination, (2) Agios shall return any Confidential Information of Celgene pursuant to Article VIII of the Master Agreement that is not necessary to practice any licenses retained by Agios following such termination under this Agreement, another Development & Commercialization Agreement (as defined in the Master Agreement) or the Master Agreement, (3) Celgene shall grant to Agios an exclusive, non-transferable (except as set forth in Section 15.4), worldwide right and license in the Field, with the right to grant sublicenses in a manner consistent with Section 8.2(a) and Section 8.2(a)(ii)(2), and, from and after such termination, Agios shall pay Celgene royalties on Annual Net Sales of Licensed Products pursuant to Section 9.3, reducing such royalties by [**] percent ([**]%) and substituting "Agios" for "Celgene" and vice versa with respect to all obligations and definitions, and otherwise mutatis mutandis, under Celgene's rights in Celgene Intellectual Property, Celgene Collaboration Intellectual Property, Joint Inventions, Joint Patents and Manufacturing Technology to Develop, Manufacture and Commercialize Compounds and Licensed Products; provided that, (I) Agios shall be solely responsible for all payments owed to any Third Party licensors (without any right to offset any such amounts against royalties payable to Celgene hereunder) and (II) Agios shall be responsible for complying with the terms of any license agreements with such Third Party licensors, in each case ((I) and (II)), solely with respect to Agios' exercise of such rights, and (4) Celgene may seek any damages that Celgene can establish that are not compensated by the royalties set forth in Section 14.4(b)(i)(A)(3); or

- (2) maintain this Agreement in full force and effect (foregoing, for the avoidance of doubt, the right to terminate this Agreement for such occurrence of such breach) and, with respect to the Licensed Product(s) that are the subject of the applicable breach by Agios, all future milestones and royalty obligations in respect of such Licensed Products payable by Celgene under this Agreement following such election shall be subject to a reduction of [**] percent ([**]%).
 - (ii) each Party shall be released from its Development, Manufacture and Commercialization obligations;
- (iii) if Celgene has made the election set forth in Section 14.4(b)(i)(2), the license granted by Agios to Celgene in Section 8.1 shall convert to an irrevocable, non-terminable license, with the right to grant sublicenses; <u>provided that</u>, notwithstanding Section 9.4(a), (i) Celgene shall be solely responsible for all payments owed to any Third Party licensors (without any right to offset any such amounts against royalties payable to Agios hereunder) and (ii) Celgene shall be responsible for complying with the terms of any license agreements with such Third Party licensors, in each case ((i) and (ii)), solely with respect to Celgene's exercise of such rights.; and
- (iv) if Celgene has made the election set forth in Section 14.4(b)(i)(i)(2), the rights of Agios in Article X (other than Section 10.1) shall be terminated and Agios shall, if applicable, provide reasonable assistance to Celgene and cooperation in connection with the transition of Prosecution and enforcement responsibilities to Celgene with respect to Agios Patents, including execution of such documents as may be necessary to effect such transition.
- (c) In the case of any termination of this Agreement, if any Clinical Trials are then being conducted at the time of such termination with respect to any Licensed Product, the Parties hereby agree (i) to reasonably cooperate in the completion of any such Clinical Trials, and (ii) notwithstanding anything to the contrary contained herein, to grant to the Party that retains global Commercialization rights to such Licensed Product following such termination (A) free of charge, copies of and rights of reference to and use of all Licensed Product Data that is Controlled by such Party and generated pursuant to such Clinical Trials that are relevant to or necessary to address issues relating to: (1) the safety of such Licensed Product in the Territory, including data that is related to adverse effects experienced with such Licensed Product and/or (2) all activities relating to CMC regarding such Licensed Product and in each of (1) and (2), that are required to be reported or made available to Regulatory Authorities in the Territory, when and as such data become available, and (B) copies of and rights of reference to and use of all Licensed Product Data (other than the Licensed Product Data referred to in subclause (A) above) that is Controlled by such Party and generated pursuant to such Clinical Trials that are relevant to or necessary to address the Development and Commercialization of such Licensed Product promptly following the generation of such Licensed Product Data if, but only if, as to such Licensed Product Data described in this subclause (B), such Party that retains global Commercialization rights to such Licensed Product following such termination promptly pays

for all Development Costs incurred following any such termination of this Agreement with respect to such Clinical Trials. For purposes of this Section 14.4(c), "<u>Licensed Product Data</u>" means all relevant data included in the Know-How Controlled by either Party or its Affiliates in relation to Licensed Products for use in the Field either: (x) as of the Effective Date; or (y) generated from the applicable Clinical Trials.

- (d) <u>Survival</u>. Upon any termination or expiration of this Agreement, unless otherwise specified in this Agreement and except for any rights or obligations that have accrued prior to the effective date of termination or expiration, all rights and obligations of each Party under this Agreement shall terminate in whole or with respect to the Licensed Products, as the case may be; <u>provided, however, that Section 9.3(c)</u>, Section 9.5, Section 9.6, Section 9.7, Section 9.8, Section 9.9, Section 9.10, Section 10.1, Section 11.5, Section 11.6, Section 13.1, Section 13.2, Section 13.3, Section 13.4, Section 14.4, and Section 15.2, as well as any other provision which by its terms or by the context thereof is intended to survive, shall survive any such termination or expiration of this Agreement.
- (e) Accrued Liabilities. Except as otherwise specifically provided herein, termination of this Agreement shall not relieve the Parties of any liability or obligation which accrued hereunder prior to the effective date of such termination, nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement nor prejudice either Party's right to obtain performance of any obligation. In addition, termination of this Agreement shall not terminate provisions which provide by their respective terms for obligations or undertakings following the expiration of the term of this Agreement.
- (f) <u>Relationship to Other Agreements</u>. Termination or expiration of this Agreement shall not affect in any way the terms or provisions of the Master Agreement or any other then-existing executed Development & Commercialization Agreement.

Article XV. Miscellaneous

- Section 15.1. <u>Dispute Resolution</u>. The Parties agree that any disputes arising with respect to the interpretation, enforcement, termination or invalidity of this Agreement (each, a "<u>Dispute</u>") shall first be presented to the Parties' respective Executive Officers for resolution. If the Parties are unable to resolve a given dispute pursuant to this Section 15.1 after discussions between the Executive Officers within [**] after referring such dispute to the Executive Officers, either Party may, at its sole discretion, seek resolution of such matter in accordance with Section 15.2.
- Section 15.2. <u>Submission to Court for Resolution</u>. Subject to Section 15.1, the Parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction of the courts located in the Southern District of New York for any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement, and agree not to commence any action, suit or proceeding (other than appeals therefrom) related thereto except in such courts. The Parties further hereby irrevocably and unconditionally waive any objection to the laying of venue of any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this

Agreement in the courts of New York, and hereby further irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum. Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in Section 15.6 shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any such court.

Section 15.3. <u>Governing Law</u>. This Agreement and all questions regarding its validity or interpretation, or the performance or breach of this Agreement, shall be governed by and construed and enforced in accordance with the laws of the State of New York, without reference to conflicts of laws principles.

Section 15.4. Assignment.

- (a) <u>Generally</u>. This Agreement may not be assigned by any Party, nor may any Party delegate its obligations or otherwise transfer licenses or other rights created by this Agreement, except as expressly permitted hereunder without the prior written consent of the other Party, which consent will not be unreasonably withheld, delayed or conditioned.
- (b) <u>Celgene</u>. Notwithstanding the limitations in Section 15.4(a), Celgene Corp. and Celgene RIVOT may assign this Agreement, or any rights or obligations hereunder in whole or in part, to (i) one or more Affiliates solely as provided in this Section 15.4(b) or (ii) its successor in interest in connection with the merger, consolidation, or sale of all or substantially all of its assets or that portion of its business pertaining to the subject matter of this Agreement; provided, however, that, except in the case where Celgene Corp., or Celgene RIVOT, as applicable, is involved in a merger or consolidation where it is the surviving entity and no assets of Celgene Corp. or Celgene RIVOT, as applicable have been transferred as a result of such merger or consolidation (for example, a reverse triangular merger), (A) Celgene Corp. or Celgene RIVOT, as applicable, provides Agios with at least [**] advance written notice of any such assignment(s), (B) prior to such assignment(s), Celgene Corp. or Celgene RIVOT, as applicable, agrees in a written agreement delivered to Agios (and upon which Agios may rely) to remain fully liable for the performance of its obligations under this Agreement by its assignee(s), and (C) prior to such assignment(s), the assignee(s) agree in a written agreement delivered to Agios (and upon which Agios may rely) to assume performance of all such assigned obligations. If Celgene Corp. or Celgene RIVOT, as applicable, wishes to assign any Celgene Intellectual Property, Celgene Collaboration Intellectual Property, Joint Inventions, Joint Patents or Manufacturing Technology which Celgene Corp. or Celgene RIVOT, as applicable, Controls, or Agios Program Assets for each Program, to one or more permitted Affiliate(s), it will be permitted to do so conditioned on such Affiliate(s) becoming a party to this Agreement, in the form of an amendment to this Agreement executed by Celgene, Agios and such Affiliate(s), pursuant to which such Affiliate(s) would agree to assume all obligations hereunder, and grant to Agios all rights hereunder, with respect to the assets so assigned.
- (c) Agios. Notwithstanding the limitations in Section 15.4(a), Agios may assign this Agreement, or any rights or obligations hereunder in whole or in part, to (i) one or more Affiliates solely as provided in this Section 15.4(c) or (ii) its successor in connection with the merger, consolidation, or sale of all or substantially all of its assets or that portion of its

business pertaining to the subject matter of this Agreement; provided, however, that, except in the case where [**], (A) Agios provides Celgene with at least [**] advance written notice of any such assignment(s) no later than [**] after such assignment(s), (B) prior to such assignment(s), Agios agrees in a written agreement delivered to Celgene (and upon which Celgene may rely) to remain fully liable for the performance of its obligations under this Agreement by its assignee(s), and (C) prior to such assignment(s), the assignee(s) agree in a written agreement delivered to Celgene (and upon which Celgene may rely) to assume performance of all such assigned obligations, (D) in the case of any assignment(s) by Agios of any Agios Intellectual Property, Joint Inventions, Joint Patents or Manufacturing Technology which Agios Controls, and all Program Assets for each Program will be transferred to such assignee(s) effective as of such assignment(s), and (E) all of the matters referred to in clauses (A), (B), (C) and (D), as applicable, will be set forth in documentation [**] prior to any such assignment(s) ([**]) and in all cases will provide [**]. Subject to the terms of this Section 15.4(c), if Agios wishes to assign any [**], it will be permitted to do so conditioned on [**], pursuant to which such [**].

- (d) In the event the Implementation Date for this Agreement has not occurred within [**] following the Effective Date, Celgene shall be entitled to [**], if required by any Antitrust Law; provided that, the right to [**] set forth in this Section 15.4(d) shall not apply if a breach by Celgene of its obligations under Section 8.6(a) is a material cause of the failure to obtain clearance under Antitrust Laws.
- (e) All Other Assignments Null and Void. The terms of this Agreement will be binding upon and will inure to the benefit of the successors, heirs, administrators and permitted assigns of the Parties. Any purported assignment in violation of this Section 15.4 will be null and void ab initio.
- (f) Change of Control. Notwithstanding anything to the contrary in this Agreement, with respect to any intellectual property rights controlled by the acquiring party or its Affiliates (if other than one of the Parties to this Agreement) involved in any Change of Control of either Party, such intellectual property rights shall not be included in the technology and intellectual property rights licensed to the other Party hereunder to the extent held by such acquirer or its Affiliate (other than the relevant Party to this Agreement) prior to such transaction, or to the extent such technology is developed outside the scope of activities conducted with respect to the Collaboration, Compounds, Licensed Products, or related Companion Diagnostics. The Agios Intellectual Property and the Celgene Intellectual Property shall exclude any intellectual property owned or controlled by a permitted assignee or successor and not developed in connection with the Collaboration, Compounds, Licensed Products, or related Companion Diagnostics, Developed, Manufactured or Commercialized pursuant to this Agreement or the Master Agreement.
- Section 15.5. Force Majeure. If the performance of any part of this Agreement by a Party is prevented, restricted, interfered with or delayed by an occurrence beyond the control of such Party (and which did not occur as a result of such Party's financial condition, negligence or fault), including fire, earthquake, flood, embargo, power shortage or failure, acts of war or terrorism, insurrection, riot, lockout or other labor disturbance, governmental acts or orders or restrictions, acts of God (for the purposes of this Agreement, a "force majeure event"), such Party shall, upon giving written notice to the other Party, be excused from such performance to

the extent of such prevention, restriction, interference or delay; <u>provided that</u> the affected Party shall use its Commercially Reasonable Efforts to avoid or remove such causes of non-performance and shall continue performance with the utmost dispatch whenever such causes are removed.

Section 15.6. Notices. Unless otherwise agreed by the Parties or specified in this Agreement, all notices required or permitted to be given under this Agreement shall be in writing and shall be sufficient if: (a) personally delivered; (b) sent by registered or certified mail (return receipt requested and postage prepaid); (c) sent by express courier service providing evidence of receipt and postage prepaid where applicable; or (d) sent by facsimile transmission (receipt verified and a copy promptly sent by another permissible method of providing notice described in clauses (a), (b) or (c) above), to address for a Party set forth below, or such other address for a Party as may be specified in writing by like notice:

To Agios:

Agios Pharmaceuticals, Inc. 88 Sidney Street Cambridge, MA 02139 Attention: Chief Executive Officer Telephone: 617-649-8600

Facsimile: [**]

To Celgene Corp. or Celgene RIVOT:

Celgene Corporation 86 Morris Avenue Summit, NJ 07901 Attention: Senior Vice President Business Development Telephone: (908) 673-9000

Egginile [**]

Facsimile: [**]

With a copy to:

Agios Pharmaceuticals, Inc. 88 Sidney Street Cambridge, MA 02139 Attention: Legal Department

Telephone: (617) 649-8600

Facsimile: [**]

and

WilmerHale 60 State Street Boston, MA 02109

Attention: Steven D. Singer Telephone: (617) 526-6410 Facsimile: (617) 526-5000

With a copy to:

Celgene Corporation 86 Morris Avenue Summit, NJ 07901

Attention: Legal Department Telephone: (908) 673-9000

Facsimile: [**]

and

Celgene RIVOT Ltd. Aon House 30 Woodbourne Avenue Pembroke HM 08

Bermuda

Phone: 441-296-4803

and

Dechert LLP 1900 K St. NW Washington, DC 20006

Attention: David E. Schulman Telephone: (202) 261-3440

Facsimile: [**]

Any such notices shall be effective upon receipt by the Party to whom it is addressed.

Section 15.7. Waiver. Except as otherwise expressly provided in this Agreement, any term of this Agreement may be waived only by a written instrument executed by a duly authorized representative of the Party waiving compliance. The delay or failure of either Party at any time to require performance of any provision of this Agreement shall in no manner affect such Party's rights at a later time to thereafter enforce such provision. No waiver by either Party of any condition or term in any one or more instances shall be construed as a further or continuing waiver of such condition or term or of another condition or term.

Section 15.8. Severability. If any provision of this Agreement should be held invalid, illegal or unenforceable in any jurisdiction, the Parties shall negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties and all other provisions of this Agreement shall remain in full force and effect in such jurisdiction and shall be liberally construed in order to carry out the intentions of the Parties hereto as nearly as may be possible. If the Parties cannot agree upon a substitute provision, the invalid, illegal or unenforceable provision of this Agreement shall not affect the validity of this Agreement as a whole, unless the invalid, illegal or unenforceable provision is 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 provision.

Section 15.9. <u>Entire Agreement</u>. This Agreement (including the Exhibits attached hereto), together with the Master Agreement, constitutes the entire agreement between the Parties relating to its subject matter, and supersedes all prior and contemporaneous agreements, representations or understandings, either written or oral, between the Parties with respect to such subject matter. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as set forth herein and therein.

Section 15.10. <u>Modification</u>. No modification, amendment or addition to this Agreement, or any provision hereof, shall be effective unless reduced to writing and signed by a duly authorized representative of each Party. No provision of this Agreement shall be varied, contradicted or explained by any oral agreement, course of dealing or performance or any other matter not set forth in an agreement in writing and signed by a duly authorized representative of each Party.

Section 15.11. <u>Independent Contractors; No Intended Third Party Beneficiaries</u>. This Agreement is not intended nor shall be deemed or construed to create any relationship of employer and employee, agent and principal, partnership, or joint venture between the Parties. Each Party is an independent contractor. Neither Party shall assume, either directly or indirectly, any liability of or for the other Party. Neither Party shall have any express or implied right or authority to assume or create any obligations on behalf of, or in the name of, the other Party, nor to bind the other Party to any contract, agreement or undertaking with any Third Party. There are no express or implied third party beneficiaries hereunder, (a) except for the indemnitees identified in Section 13.1 and Section 13.2, and (b) except for any licensor under any Existing Third Party Agreement.

Section 15.12. <u>Interpretation; Construction</u>. The captions to the several Articles and Sections of this Agreement are included only for convenience of reference and shall not in any way affect the construction of, or be taken into consideration in interpreting, this Agreement. In this Agreement, unless the context requires otherwise, (a) the word "including" shall be deemed to be followed by the phrase "without limitation" or like expression, whether or not followed by the same; (b) references to the singular shall include the plural and vice versa; (c) references to masculine, feminine and neuter pronouns and expressions shall be interchangeable; (d) the words "herein" or "hereunder" relate to this Agreement; (e) "or" is disjunctive but not necessarily exclusive; (f) the word "will" shall be construed to have the same meaning and effect as the word "shall"; and (g) all references to "dollars" or "\$" herein shall mean U.S. Dollars. Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provisions.

Section 15.13. Performance by Affiliates.

- (a) To the extent that this Agreement imposes obligations on Affiliates of a Party, such Party agrees to cause its Affiliates to perform such obligations.
- (b) The Parties hereby acknowledge and agree that (a) Celgene Corp. is the party to this Agreement with respect to all rights and obligations (including payment obligations) under this Agreement in the United States; and (b) Celgene RIVOT is the party to this Agreement with respect to all rights and obligations under this Agreement outside of the United States.
- Section 15.14. Counterparts. This Agreement may be executed in two (2) counterparts, each of which shall be deemed an original, and both of which together shall constitute one and the same instrument. Any such counterpart, to the extent delivered by means of a fax machine or by .pdf, .tif, .gif, .jpeg or similar attachment to electronic mail (any such delivery, an "<u>Electronic Delivery</u>") shall be treated in all manner and respects as an original executed counterpart and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person. No Party hereto shall raise the use of Electronic Delivery to deliver a signature or the fact that any signature or agreement or instrument was transmitted or communicated through the use of Electronic Delivery as a claim or defense with respect to the formation of a contract, and each Party forever waives any such claim or defense, except to the extent that such claim or defense relates to lack of authenticity.
- Section 15.15. <u>HSR Clearance; Cooperation</u>. For the avoidance of doubt, the Parties shall continue to comply with Section 3.2 of the Master Agreement.
- Section 15.16. <u>Equitable Relief.</u> Notwithstanding anything to the contrary herein, the Parties shall be entitled to seek equitable relief, including injunction and specific performance, as a remedy for any breach of this Agreement. Such remedies shall not be deemed to be the exclusive remedies for a breach of this Agreement but shall be in addition to all other remedies available at law or equity.
- Section 15.17. <u>Further Assurances</u>. Each Party shall execute, acknowledge and deliver such further instruments, and do all such other acts, as may be necessary or appropriate in order to carry out the expressly stated purposes and the clear intent of this Agreement.

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Execution Date.

Ву:
Name:
Title:
CELGENE CORPORATION
By:
Name:
Title:
Solely with respect to the rights and obligations under this License Agreement outside of the United States (subject to Section 15.13):
CELGENE RIVOT LTD.
By:
Title:

AGIOS PHARMACEUTICALS, INC.

Exhibit A

Target, Compound(s) and Upfront Option Payment

1.	Target:					
2.	Compounds [check applicable box and include Agios identifiers and structure(s)]:					
	□ inhibitors of Target					
	or					
	□ activators of Target					
	Description of Compound:					
3.	Upfront Option Payment calculated as: [check applicable boxes]					
	☐ If the Program under this Agreement is a Designated Development Program or the Deemed DC Program, the sum of Thirty Million US Dollars (\$30,000,000) plus the Reimbursable Back-up Expenses and the Reimbursable Manufacturing Expenses (such Reimbursable Back-up Expenses and Reimbursable Manufacturing Expenses, in the aggregate, not to exceed [**] US Dollars (\$[**]));					
	<u>OR</u>					
	☐ If the Program under this Agreement is a Continuation Program (other than the Deemed DC Program), the sum of Thirty-Five Million US Dollars (\$35,000,000) plus the Reimbursable Back-up Expenses and the Reimbursable Manufacturing Expenses (such Reimbursable Back-up Expenses and Reimbursable Manufacturing Expenses, in the aggregate, not to exceed [**] US Dollars (\$[**]));					
	<u>OR</u>					
	$\hfill\Box$ If the Program under this Agreement is a Qualified Early Exercise I&I Program, Ten Million US Dollars (\$10,000,000).					

ANNEX I

$\frac{\text{REIMBURSABLE MANUFACTURING EXPENSES AND REIMBURSABLE BACK-UP}}{\text{EXPENSES}}$

Reference is made to the Upfront Option Payment described in paragraph 3 of Exhibit A to this Agreement, which will include the following Reimbursable Manufacturing Expenses and/or Reimbursable Back-Up Expenses as applicable: [check applicable boxes]

_	
□ Reimbu	rsable Back-up Expenses shall only include amounts incurred for:
•	[describe pre-approved back-up Compounds] which back-up Compounds have been agreed to by the Parties on [insert relevant dates] and
•	in the aggregate, equals \$ (which amount is subject to review pursuant to Section 9.6 and, in the event of any good faith dispute between the Parties, such amount shall not be payable until the final resolution pursuant to Section 9.6).
□ Reimbu	rsable Manufacturing Expenses shall only include amounts incurred for:
•	[describe pre-approved Manufacturing Expenses, including any relevant quantities of conforming Compounds that were Manufactured for post-Pre-Exercise Phase I Development activities]; and
•	in the aggregate, equals \$ (which amount is subject to review pursuant to Section 9.6 and, in the event of any good faith dispute between the Parties, such amount shall not be payable until the final resolution pursuant to Section 9.6).
	A-2

Exhibit B

Agios Patents
(as of the Execution Date)

<u>Celgene Collaboration Patents</u> (as of the Execution Date)

Exhibit C

Existing Third Party Agreements

[Parties to identify each applicable Existing Third Party Agreement referenced in the Option Data Package and each provision thereof that must be included in this Agreement, including for Third Party Programs and Third Party Licenses]

Exhibit D

Countries for Filing Agios Patents, Celgene Collaboration Patents and Joint Patents

[**]

Exhibit E

Press Release

E-1

Disclosure Schedules
[tailor as applicable]

Schedule 12.2(d)

Schedule 12.2(e)

Schedule 12.2(f)

Schedule 12.2(h)

Schedule 12.2(i) Patents

Schedule 12.2(j) Existing Third Party Agreements

[Note: exceptions in Section 12.2 to be identified, if applicable]

APPENDIX C

CERTAIN FINANCIAL DEFINITIONS

"Accounting Standards" means (a) GAAP (United States Generally Accepted Accounting Principles); or (b) IFRS (International Financial Reporting Standards), in either case, consistently applied.

"<u>Development Costs</u>" means the costs and expenses that are actually incurred by or on behalf of a Party and specifically identifiable or specifically allocable to Development activities for a given Program. "Development Costs" shall include:

- (a) the FTE costs (determined by multiplying the number of FTE hours of service spent by the FTE Rate) of Agios or its Affiliates with respect to such Development, and in the case of Celgene or its Affiliates, instead of reimbursing Celgene on an FTE basis, Celgene shall be reimbursed for [**]% of Out-of-Pocket costs incurred by Celgene in connection with any Development Activity);
- (b) all Out-of-Pocket Costs incurred by the Parties or their Affiliates, including payments made to Third Parties with respect to such Development (except to the extent that such costs have been included in FTE costs);
 - (c) Regulatory Expenses;
 - (d) the cost of contract research organizations (CROs); and
 - (e) Manufacturing Costs for clinical supply, including:
 - (i) costs of packaging of drug products and distribution of drug products used in clinical trials;
 - (ii) expenses incurred to purchase or package comparator drugs;
 - (iii) costs and expenses of disposal of clinical samples; and
- (iv) costs and expenses incurred in scaling up Manufacturing activities related to pre-clinical or clinical supply, including formulation development activities;

all of such costs, as determined from the books and records of the applicable Party and its Affiliates maintained in accordance with the Accounting Standards. Notwithstanding anything in this definition to the contrary, only those Development Costs that are contemplated by, and materially consistent with, the Development Plan and Development Budget for the applicable Program shall be chargeable as Development Costs.

"Manufacturing Costs" means, with respect to Program Compounds included in a given Program, the reasonable FTE costs and Out-of-Pocket Costs of a Party or any of its Affiliates or sublicensees incurred in Manufacturing such Program Compounds, and including:

- (a) to the extent that any such Program Compound is Manufactured by a Party or any of its Affiliates or sublicensees, direct material and direct labor costs, plus manufacturing overhead attributable to such Program Compound (including facility start-up costs, all directly incurred manufacturing variances, and a reasonable allocation of related manufacturing administrative and facilities costs (including depreciation) and a reasonable allocation of the costs of failed batches to be further described in the applicable supply agreement, to be provided for such Program Compound, but excluding costs associated with excess capacity), all determined in accordance with the books and records of the applicable Party or its Affiliates or sublicensees maintained in accordance with the Accounting Standards, consistently applied; and
- (b) to the extent that any such Program Compound is Manufactured by a Third Party manufacturer, the Out-of-Pocket Costs paid by a Party or any of its Affiliates or sublicensees to the Third Party for the manufacture, supply, packaging and labeling of such Program Compound, and any reasonable Out-of-Pocket Costs and direct labor costs actually incurred by such Party or any of its Affiliates or sublicensees in managing or overseeing the Third Party relationship, determined in accordance with the books and records of the applicable Party or its Affiliates or sublicensees maintained in accordance with the Accounting Standards, consistently applied.

"Out-of-Pocket Costs" means, with respect to certain activities hereunder, direct expenses paid or payable by either Party or its Affiliates to Third Parties (other than employees of such Party or its Affiliates) that are specifically identifiable and incurred to conduct such activities for a Program hereunder and have been recorded in accordance with the Accounting Standards.

"Regulatory Expenses" means, with respect to a Program Compound, all Out-of-Pocket Costs incurred by or on behalf of a Party in connection with the preparation and filing of regulatory submissions for such Program Compound and obtaining of Regulatory Approvals and any applicable governmental price and reimbursement approvals.

SCHEDULE 1.1.29

DATA PACKAGE INFORMATION

Development Candidate Nomination Data Package: All available, relevant data (including [**]) with respect to the applicable Program as laid out in the Development Candidate Criteria, including [**].

End-of-Research Term Program Data Package: All available, relevant data (including [**]) with respect to the applicable Program as laid out in the Development Candidate Criteria, including [**].

Option Data Package: All relevant data (including [**]) with respect to the applicable Program (including any applicable [**]), including (1) [**], (2) [**], and (3) [**].

<u>SCHEDULE 1.1.35</u>

DEVELOPMENT CANDIDATE CRITERIA

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of 2 pages were omitted. [**]

1.1.35-1

SCHEDULE 1.1.82

PUBLICATION GUIDELINES

Unless the JSC by mutual agreement agrees otherwise, the Parties agree as follows:

[**]

1.1.82 - 1

SCHEDULE 1.1.83

QUALIFIED EARLY EXERCISE I&I PROGRAM CRITERIA

[**]

SCHEDULE 9.2.9

AGIOS PATENTS

[**]

AGIOS DOCKET	CC	APPLICATION NO.	FILING DATE	PUBLICATION NO.	PATENT NO.
[**]	[**]	[**]	[**]		
[**]	[**]	[**]	[**]		

CERTIFICATION

I, David P. Schenkein, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of Agios Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(f)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2016

/s/ David P. Schenkein

David P. Schenkein President and Chief Executive Officer (principal executive officer)

CERTIFICATION

I, Glenn Goddard, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of Agios Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(f)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2016

/s/ Glenn Goddard

Glenn Goddard Senior Vice President, Finance (principal financial and accounting officer)

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

In connection with the Quarterly Report on Form 10-Q of Agios Pharmaceuticals, Inc. (the "Company") for the fiscal quarter ended June 30, 2016, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, David P. Schenkein, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that, to his knowledge on the date hereof:

- (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 8, 2016

/s/ David P. Schenkein

David P. Schenkein President and Chief Executive Officer (principal executive officer)

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

In connection with the Quarterly Report on Form 10-Q of Agios Pharmaceuticals, Inc. (the "Company") for the fiscal quarter ended June 30, 2016, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Glenn Goddard, Senior Vice President, Finance of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that, to his knowledge on the date hereof:

- (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 8, 2016

/s/ Glenn Goddard

Glenn Goddard Senior Vice President, Finance (principal financial and accounting officer)