UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

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|---|---|
| | FORM 10-Q |
| (Mark One) I QUARTERLY REPORT PURSUANT TO SEC | CTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF |
| For the qua | rterly period ended June 30, 2015 |
| | OR |
| ☐ TRANSITION REPORT PURSUANT TO SEC 1934 | TION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF |
| Comm | ission file number 001-36014 |
| | MACEUTICALS, INC. Registrant 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) |
| (Registrant's | (617) 649-8600 Gelephone Number, Including Area Code) |
| | d Floor, Cambridge, Massachusetts 02139 s and Former Fiscal Year, if Changed Since Last Report) |
| | I reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of at the registrant was required to file such reports), and (2) has been subject to such filing |
| | electronically and posted on its corporate Web site, if any, every Interactive Data File ation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter by Yes 🖾 No 🗆 |
| | erated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. ad "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one): |
| Large accelerated filer ⊠ | Accelerated filer □ |
| Non-accelerated filer | ompany) Smaller reporting company |
| Indicate by check mark whether the registrant is a shell comp | any (as defined in Rule 12b-2 of the Exchange Act). Yes □ No ⊠ |
| Number of shares of the registrant's Common Stock, \$0.001 | ar value, outstanding on August 5, 2015: 37,443,687 |

AGIOS PHARMACEUTICALS, INC.

FORM 10-Q FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2015

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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, 2015 | December 31, 2014 |
|---|-------------------|----------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 72,533 | \$ 14,031 |
| Marketable securities | 297,261 | 328,034 |
| Collaboration receivable – related party | 10,474 | 6,492 |
| Tenant improvement and other receivables | 5,282 | 2,334 |
| Prepaid expenses and other current assets | 4,602 | 4,814 |
| Refundable income taxes | | 3,841 |
| Total current assets | 390,152 | 359,546 |
| Marketable securities | 64,243 | 125,382 |
| Property and equipment, net | 19,328 | 6,386 |
| Other assets | 660 | 590 |
| Total assets | <u>\$ 474,383</u> | \$ 491,904 |
| Liabilities and stockholders' equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 8,914 | \$ 11,067 |
| Accrued expenses | 11,584 | 14,026 |
| Deferred revenue – related party | 22,608 | 35,686 |
| Deferred rent | 2,092 | 310 |
| Total current liabilities | 45,198 | 61,089 |
| Deferred revenue, net of current portion – related party | 9,389 | 2,725 |
| Deferred rent, net of current portion | 15,631 | 3,724 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Preferred stock, \$0.001 par value; 25,000,000 shares authorized; no shares issued or outstanding | _ | _ |
| Common stock, \$0.001 par value; 125,000,000 shares authorized; 37,401,576 and 37,100,513 shares issued and | | |
| outstanding at June 30, 2015 and December 31, 2014, respectively | 37 | 37 |
| Additional paid-in capital | 607,708 | 591,334 |
| Accumulated other comprehensive income (loss) | 222 | (57) |
| Accumulated deficit | (203,802) | (166,948) |
| Total stockholders' equity | 404,165 | 424,366 |
| Total liabilities and stockholders' equity | \$ 474,383 | \$ 491,904 |

 $See\ accompanying\ notes\ to\ condensed\ consolidated\ financial\ statements.$

AGIOS PHARMACEUTICALS, INC.

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

| | • | Three Months | Ended J | June 30, 2014 | | Six Months E 2015 | Ended June 30, 2014 | |
|---|----|--------------|---------|------------------|----|----------------------|------------------------|-----------|
| Collaboration revenue – related party | \$ | 13,219 | \$ | 8,411 | \$ | 47,421 | \$ | 16,822 |
| Operating expenses: | | | | | | | | |
| Research and development (net of \$4,546 and \$8,912 of cost | | | | | | | | |
| reimbursement from related party for the three and six months ended | | | | | | | | |
| June 30, 2015, respectively) | | 36,423 | | 22,576 | | 68,866 | | 39,982 |
| General and administrative | | 8,929 | | 4,165 | | 15,883 | | 7,454 |
| Total operating expenses | _ | 45,352 | _ | 26,741 | | 84,749 | | 47,436 |
| Loss from operations | | (32,133) | | (18,330) | | (37,328) | | (30,614) |
| Interest income | | 236 | | 34 | | 474 | | 70 |
| Net loss | \$ | (31,897) | \$ | (18,296) | \$ | (36,854) | \$ | (30,544) |
| Net loss per share – basic and diluted | \$ | (0.85) | \$ | (0.54) | \$ | (0.99) | \$ | (0.94) |
| Weighted-average number of common shares used in net loss per share – basic and diluted | 37 | 7,329,220 | 33 | 3,602,472 | 3′ | 7,272,300 | 3 | 2,506,739 |

 $See\ accompanying\ notes\ to\ condensed\ consolidated\ financial\ statements.$

AGIOS PHARMACEUTICALS, INC.

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

| | Three Months Ended June 30, | | | | , Six Months Ended June 3 | | | June 30, |
|---|-----------------------------|----------|----|----------|---------------------------|----------|----|----------|
| | | 2015 | | 2014 | | 2015 | | 2014 |
| Net loss | \$ | (31,897) | \$ | (18,296) | \$ | (36,854) | \$ | (30,544) |
| Other comprehensive income (loss): | | | | | | | | |
| Unrealized gain (loss) on available-for-sale securities | | 31 | | (21) | | 279 | | (2) |
| Comprehensive loss | \$ | (31,866) | \$ | (18,317) | \$ | (36,575) | \$ | (30,546) |

See accompanying notes to condensed consolidated financial statements.

AGIOS PHARMACEUTICALS, INC.

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

| | Six Mont | 30, |
|--|---------------|-------------|
| | 2015 | 2014 |
| Operating activities Net loss | \$ (36,854) | \$ (30,544) |
| Adjustments to reconcile net loss to net cash used in operating activities: | \$ (30,834) | \$ (30,344) |
| Depreciation | 1.150 | 659 |
| Stock-based compensation expense | 13,237 | 3,886 |
| Net amortization of premium on investments | 319 | 305 |
| Changes in operating assets and liabilities: | 319 | 303 |
| Collaboration receivable – related party | (3,982) | 476 |
| Other receivables | (2,948) | _ |
| Prepaid expenses and other assets | 125 | (791) |
| Accounts payable | (1,210) | 1,684 |
| Accrued expenses and other liabilities | (2,558) | (1,130) |
| Deferred rent | 13,689 | (55) |
| Refundable income taxes and income taxes payable | 3,841 | (5,303) |
| Deferred revenue – related party | (6,414) | 2,702 |
| Net cash used in operating activities | (21,605) | (28,111) |
| Investing activities | | |
| Purchases of marketable securities | (106,205) | (126,338) |
| Proceeds from maturities and sales of marketable securities | 198,078 | 95,501 |
| Purchases of property and equipment | (14,679) | (99) |
| Net cash provided by (used in) investing activities | 77,194 | (30,936) |
| Financing activities | | |
| Net proceeds from public offering of common stock, (payment of) commissions and offering costs | (207) | 94,698 |
| Net proceeds from stock option exercises and employee stock purchase plan | 3,120 | 1,036 |
| Net cash provided by financing activities | 2,913 | 95,734 |
| Net increase in cash and cash equivalents | 58,502 | 36,687 |
| Cash and cash equivalents at beginning of the period | 14,031 | 71,560 |
| Cash and cash equivalents at end of the period | \$ 72,533 | \$ 108,247 |
| Supplemental cash flow information | | |
| Cash paid for income taxes | <u>\$</u> | \$ 5,958 |
| Supplemental disclosure of non-cash investing and financing transactions | | |
| Additions to property and equipment in accounts payable and accrued expenses | \$ 1,531 | \$ 12 |
| Vesting of restricted stock | <u>\$ (4)</u> | \$ (6) |
| Public offering costs in accounts payable and accrued expenses | <u>\$</u> | \$ 13 |
| Proceeds from stock option exercises in other current assets | \$ 3 | <u>\$</u> |

See accompanying notes to condensed consolidated financial statements.

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 metabolism and rare genetic disorders of metabolism. 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. The Company's therapeutic areas of focus are cancer and rare genetic disorders of metabolism, 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, 2015, the condensed consolidated interim statements of operations and comprehensive loss for the three and six months ended June 30, 2015 and 2014 and the statements of cash flows for the six months ended June 30, 2015 and 2014, 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, 2015 and its results of operations for the three and six months ended June 30, 2015 and 2014 and cash flows for the six months ended June 30, 2015 and 2014. The financial data and the other financial information disclosed in these notes to the condensed consolidated interim financial statements related to the three and six months periods ended June 30, 2015 and 2014 are also unaudited. The results of operations for the three and six months ended June 30, 2015 are not necessarily indicative of the results to be expected for the year ending December 31, 2015 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, 2014 that was filed with the Securities and Exchange Commission (the "SEC") on February 24, 2015.

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, 2014.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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 July 2015, the FASB deferred the effective date of this accounting update to annual periods beginning after December 15, 2017, along with an option to permit early adoption as of the original effective date. 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") Topic 820, Fair Value Measurements and Disclosures, established 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, 2015 (in thousands):

| | Level 1 | Level 2 | Level 3 | Total |
|-------------------------|-----------|----------|---|-----------|
| Cash equivalents | \$ 64,924 | \$ 480 | \$ — | \$ 65,404 |
| Marketable securities: | | | | |
| Certificates of deposit | _ | 18,962 | _ | 18,962 |
| U.S. Treasuries | 342,542 | | | 342,542 |
| | \$407,466 | \$19,442 | <u>\$ </u> | \$426,908 |

The following table summarizes the cash equivalents and marketable securities measured at fair value on a recurring basis as of December 31, 2014 (in thousands):

| | Level 1 | Level 2 | Level 3 | Total |
|-------------------------|-----------|----------|---|-----------|
| Cash equivalents | \$ 11,410 | \$ 960 | \$ — | \$ 12,370 |
| Marketable securities: | | | | |
| Certificates of deposit | _ | 13,155 | _ | 13,155 |
| U.S. Treasuries | 440,261 | | | 440,261 |
| | \$451,671 | \$14,115 | <u>\$ </u> | \$465,786 |

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, 2015 or December 31, 2014.

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, 2015 and December 31, 2014, due to their short-term nature.

There have been no changes to the valuation methods during the three and six months ended June 30, 2015 or 2014. 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, 2015 or the year ended December 31, 2014. 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, 2015 or the year ended December 31, 2014.

4. Marketable Securities

Marketable securities at June 30, 2015 and December 31, 2014 consisted primarily of investments in United States Treasuries and certificates of deposit. 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 income (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 immaterial realized gains on marketable securities for the three and six months ended June 30, 2014.

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.

Marketable securities at June 30, 2015 consist of the following (in thousands):

| | Amortized Cost | Unrealized Gains | Unrealized Losses | Fair Value |
|-------------------------|-------------------|---------------------|----------------------|---------------|
| Current: | | | | |
| Certificates of deposit | \$ 18,960 | \$ 2 | \$ — | \$ 18,962 |
| U.S. Treasuries | 278,156 | 143 | _ | 278,299 |
| Non-current: | | | | |
| U.S. Treasuries | 64,166 | 79 | (2) | 64,243 |
| | <u>\$ 361,282</u> | \$ 224 | <u>\$ (2)</u> | \$361,504 |

Marketable securities at December 31, 2014 consist of the following (in thousands):

| | Amortiz | ed Cost | alized ains | ealized osses | Fair Value |
|-------------------------|---------|---------|----------------|------------------|---------------|
| Current: | | _ | _ | | |
| Certificates of deposit | \$ | 13,160 | \$ _ | \$ (5) | \$ 13,155 |
| U.S. Treasuries | 3 | 14,866 | 45 | (32) | 314,879 |
| Non-current: | | | | | |
| U.S. Treasuries | 1: | 25,447 | 5 | (70) | 125,382 |
| | \$ 4: | 53,473 | \$ 50 | \$ (107) | \$453,416 |

At June 30, 2015 and December 31, 2014, 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.

At June 30, 2015 and December 31, 2014, the Company held 9 and 92 debt securities that were in an unrealized loss position for less than one year, respectively. The aggregate fair values of debt securities in an unrealized loss position at June 30, 2015 and December 31, 2014 were \$16.7 million and \$236.9 million, respectively. There were no individual securities that were in a significant unrealized loss position as of June 30, 2015 or December 31, 2014. 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, 2015 or December 31, 2014.

5. Celgene Collaboration Agreements

2010 Agreement and July 2014 Amendment

In April 2010, the Company entered into a collaboration agreement focused on cancer metabolism with Celgene, a related party through ownership of the Company's common stock. The agreement was amended in October 2011 and July 2014, as described below (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 was originally scheduled to expire in April 2014, subject to Celgene's option to extend the discovery phase for up to an additional two years with additional funding to the Company. In December 2013, Celgene elected to extend the term of the initial discovery phase from four years to five years, to April 2015, in exchange for the payment of a \$20.0 million extension fee which was received in May 2014. In December 2014, Celgene elected to exercise its final option to extend the term of the initial discovery phase one additional year, to April 2016, in exchange for the payment of a \$20.0 million extension fee which was received in May 2015.

Pursuant to the 2010 Agreement, the Company is responsible for nominating development candidates, of which two required confirmation by the Joint Research Committee ("JRC") during the discovery phase. During the year ended December 31, 2012 the Company nominated its first development candidate and during the year ended December 31, 2013 the Company nominated its second development candidate, both of which have been confirmed by the JRC pursuant to the 2010 Agreement. For each development candidate, Celgene elected to progress such development candidate into preclinical development requiring the Company to conduct studies to meet the requirements for filing an Investigational New Drug application ("IND"), or IND-enabling studies. Subsequently, the Company was required to file an IND for each development candidate and, upon the FDA's acceptance of the INDs, Celgene requested that the Company conduct an initial phase 1 study.

Celgene may elect to convert each discovery program for which the Company has nominated a development candidate into a co-commercialized licensed program, the attributes of which are described below. The Company has the right, exercisable during a specified period following FDA acceptance of the applicable IND, to convert one of every three co-commercialized licensed programs into a split licensed program, for which the Company will retain the United States rights, other attributes of which are further described below. In June 2014, Celgene exercised its option to an exclusive global license for the development and commercialization of the Company's isocitrate dehydrogenase 2 ("IDH2") program, AG-221. The Company elected to retain U.S. rights to its isocitrate dehydrogenase 1 ("IDH1") program, AG-120, in January 2014. Celgene exercised its rights to this program during the three months ended March 31, 2015. In addition, Celgene may license certain discovery programs that the Company does not nominate or the JRC does not confirm as a development candidate and for which Celgene will lead and fund global development and commercialization.

In July 2014, the Company amended the 2010 Agreement to allow 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. The 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 payable for each program selected by Celgene. The potential milestone payments for each such program 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. The Company is also eligible to receive additional milestone payments specific to co-commercialized licensed programs and split licensed programs. In addition, the Company is eligible to receive a substantive milestone payment of \$22.5 million upon achievement of an early clinical development milestone event for certain co-commercialized licensed programs. In connection with the first split licensed program under the collaboration, the Company's IDH1 program, AG-120, the Company is eligible to receive an additional one-time payment of \$25.0 million upon the dosing of the last patient in a Company-sponsored phase 2 clinical trial.

In addition to the milestone payments described above, for each co-commercialized licensed program, the Company will be reimbursed for all eligible development costs of the related phase 1 multiple ascending dose study. The initial costs will be reimbursed as a milestone payment equal to the greater of \$5.0 million or eligible development costs incurred by the Company upon the earlier of the determination of the maximum tolerated dose or Celgene's election to license the program. Subsequent to the

initial milestone payment, development costs will be reimbursed on a quarterly basis. In addition to the milestone payments described above, for each split licensed program, the Company is eligible for reimbursement of the costs of disease-specific expansion cohort(s) that support the initiation of a subsequent pivotal clinical trial. Costs will be reimbursed as a milestone payment equal to the lesser of \$10.0 million or fifty percent of the eligible costs for the disease-specific expansion cohort(s) upon the first patient dosed under the pivotal clinical trial. The maximum amount for the milestone payment will be \$10.0 million for each split program regardless of the number of disease-specific expansion cohorts and pivotal trials undertaken for each split program.

The Company may also receive royalties at tiered, low- to mid-teen percentage rates on net sales and has the option to participate in the development and commercialization of certain products in the United States. The royalty payments will be recognized as revenue in the period in which they are earned. No other milestone or royalty payments under the 2010 Agreement have been earned.

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 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.

Accounting Analysis and Revenue Recognition

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. Upfront consideration of approximately \$121.2 million received was 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 6 years. In addition, Celgene purchased 5,190,551 shares of Series B convertible preferred stock (Series B Preferred Stock) at a price of \$1.70 per share, resulting in net proceeds to the Company of approximately \$8.8 million. The Company determined the price paid by Celgene for the Series B Preferred Stock represented a premium over the fair value of the Company's Series B Preferred Stock as determined by the implied value of the Series B Preferred Stock pursuant to a contemporaneous valuation analysis that allocated the equity value of the Company to the various classes of its then-outstanding securities. The Company accounted for the \$3.1 million premium as additional consideration under the agreement and recognized the premium as revenue on a straight-line basis over the performance period.

July 2014 - April 2015

The July 2014 amendment was determined to be a material modification of the 2010 Agreement due to a change in the total potential consideration that was more than insignificant and changes to certain of the deliverables in the arrangement. Upon concluding the arrangement had been materially modified in July 2014, the Company identified the remaining deliverables under the arrangement and determined its 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 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 consideration and the best estimate of selling price of the undelivered items was recorded 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 for each through April 27, 2015, the 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 revenues recognized would be different. Based on the analysis using management's best estimate, 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 studies (each of which is a separate unit of accounting): The Company developed the best estimate of selling price of the on-going phase 1 study development services of \$50.8 million for all five studies using management's best estimate of the cost of obtaining these services 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 studies and expects services for the remaining two on-going phase 1 studies 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 from a third-party provider. The amount allocated to this unit of accounting was recognized as revenue ratably through April 2015, 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 through April 2015, 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 initial 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 would 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 would become 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 reimbursements of amounts incurred under third-party contracts should be reported on a net basis in research and development expense during the three months ended March 31, 2015. 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, accordingly. This change in estimate resulted in the recognition of an additional \$5.1 million of revenue. 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 for the three months ended March 31, 2015. During the period January 1, 2015 through April 27, 2015, the Company performed planning services on behalf of Celgene related to an expanded phase 1 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 reimbursements of amounts incurred under the contracts should be reported on a net basis in research and development expense. 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.

Post-April 2015

The AG-881 Agreements executed April 27, 2015 were determined to be a modification of the 2010 Agreement with Celgene 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 all 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 both 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, or ROW, 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 revenues 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. For the period April 27, 2015 through June 30, 2015, the Company recognized \$8.8 million as collaboration revenue.
- Four separate on-going development services for which the Company determined it is the primary obligor 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 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 performance period for these units of accounting to be delivered through the fourth quarter of 2016. The Company determined it is the primary obligor of the arrangements for these activities and when considering the other factors included within ASC 605-45, Revenue Recognition Principal Agent Considerations, determined reimbursements of amounts incurred for these services should be presented as 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 the primary obligor 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 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 performance period for these units of accounting to be delivered through the second quarter of 2017. The Company determined it is not the primary obligor of the arrangements for these activities and, when considering the other factors included within ASC 605-45, Revenue Recognition Principal Agent Considerations, determined reimbursements of amounts incurred for these services should be presented on a net basis as a reduction of research and development expenses. 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 from a third-party provider. The amount allocated to this unit of accounting will be recognized as revenue ratably over the performance period through April 2016. 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 will be recognized as revenue ratably over the performance period, through the fourth quarter of 2016. 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 estimate for the 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.

For the period January 1, 2015 through the April 27, 2015 modification date, the Company recognized a total of \$36.6 million in collaboration revenue. The Company recognized \$10.8 million in revenue subsequent to the modification date. The Company recognized total collaboration revenue of \$13.2 million and \$47.4 million in connection with the Celgene collaborations during the three and six months ended June 30, 2015, respectively. 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, 2015 and December 31, 2014, the Company has recorded a collaboration receivable of \$10.5 million and \$6.5 million, respectively, related to reimbursable development costs.

The Company concluded that certain of the clinical development and regulatory milestones that may be received under the 2010 Agreement and the AG-881 Agreements, 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. Revenues from substantive milestones, if they are nonrefundable, are 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.

6. Accrued Expenses

Accrued expenses consist of the following (in thousands):

| | June 30, 2015 | Dec | ember 31, 2014 |
|---|------------------|-----|-------------------|
| Accrued compensation | \$ 4,266 | \$ | 5,689 |
| Accrued contracted research and development costs | 5,559 | | 7,340 |
| Accrued professional fees | 1,007 | | 549 |
| Accrued other | <u>752</u> | | 448 |
| Total | \$11,584 | \$ | 14,026 |

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 of common stock 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. As of June 30, 2015, the total number of shares reserved under all equity plans is 5,644,695 and the Company had 931,890 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 ended 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, 2015, the annual increase for the 2013 Plan resulted in an additional 1,484,020 shares authorized for issuance.

The following table summarizes the Company's stock option activity for the six months ended June 30, 2015:

| | Number of Stock Options | Weighted- Average Exercise Price | Weighted- Average Remaining Contractual Term (in years) | Aggregate Intrinsic Value (in thousands) |
|--|----------------------------|---|--|---|
| Outstanding at December 31, 2014 | 3,805,420 | \$ 17.19 | 7.58 | \$ 360,935 |
| Granted | 1,204,628 | 107.27 | | |
| Exercised | (284,720) | 9.43 | | |
| Forfeited/expired | (37,523) | 39.61 | | |
| Outstanding at June 30, 2015 | 4,687,805 | \$ 40.63 | 7.79 | \$ 331,288 |
| Exercisable at June 30, 2015 | 1,931,727 | \$ 8.35 | 6.10 | \$ 198,556 |
| Vested and expected to vest at June 30, 2015 | 4,346,726 | \$ 40.28 | 7.73 | \$ 308,700 |

The weighted-average grant date fair value of options granted was \$64.19, \$27.84, \$67.57 and \$23.64 during the three months ended June 30, 2015 and 2014 and six months ended June 30, 2015 and 2014, respectively. The total intrinsic value of options exercised was \$11.3 million, \$10.7 million, \$29.4 million and \$34.8 million during the three months ended June 30, 2015 and 2014 and six months ended June 30, 2015 and 2014, respectively.

At June 30, 2015, the total unrecognized compensation expense related to unvested stock option awards, including estimated forfeitures, was \$93.8 million, which the Company expects to recognize over a weighted-average period of approximately 3.2 years. The Company also has unrecognized stock-based compensation expense of \$1.1 million related to stock options with performance-based vesting criteria that are not considered probable of achievement as of June 30, 2015.

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.

The fair value of the RSUs granted in the three and six months ended June 30, 2015 was approximately \$1.8 million. No RSUs were granted in the three and six months ended June 30, 2014. The Company recorded stock-based compensation expense related to RSUs of \$0.2 million and \$0.3 million for the three and six months ended June 30, 2015, respectively. No stock-based compensation expense related to RSUs was recorded during the three or six months ended June 30, 2014. These amounts are included in the total stock-based compensation expense disclosed below. As of June 30, 2015, there was approximately \$1.8 million of total unrecognized compensation expense related to RSUs, which is expected to be recognized over a weighted-average period of 1.8 years.

The following table presents unvested RSU activity for the six months ended June 30, 2015:

| | Six Months Ended June 30, 2015 | gr | ited-average ant date iir value |
|-------------------------------------|-----------------------------------|----|---------------------------------------|
| Unvested shares beginning of period | 10,000 | \$ | 50.24 |
| Granted | 15,000 | | 122.22 |
| Vested | | | |
| Unvested shares end of period | 25,000 | \$ | 93.43 |

Restricted Stock and Early Exercise of Stock Options

Unvested restricted stock activity for the six months ended June 30, 2015 is summarized as follows:

| | Six Months Ended June 30, 2015 |
|-------------------------------------|-----------------------------------|
| Unvested shares beginning of period | 8,522 |
| Vested | (5,681) |
| Unvested shares end of period | 2,841 |

Performance-Based Stock Option Grants

During the three and six months ended June 30, 2015 and 2014, 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. 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 and clinical 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, 2015, 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, 2015 and, therefore, no expense has been recognized related to these awards. During the three months ended June 30, 2015 and 2014 and six months ended June 30, 2015 and 2014, the Company recognized stock-based compensation expense of \$0.1 million, \$0.1 million, \$0.3 million and \$0.1 million, respectively related to stock options with performance-based vesting criteria.

Stock-Based Compensation Expense

During the three and six months ended June 30, 2015 and 2014, the Company recorded stock-based compensation expense for employee and non-employee stock options, the employee stock purchase plan, restricted stock units and restricted stock, which was allocated as follows in the condensed consolidated interim statements of operations (in thousands):

| | Three Months Ended June 30, | | | Six Months Ended June 3 | | | une 30, | |
|------------------------------------|-----------------------------|-------|----|-------------------------|----|--------|---------|-------|
| | | 2015 | | 2014 | | 2015 | | 2014 |
| Research and development expense | \$ | 4,569 | \$ | 1,397 | \$ | 7,180 | \$ | 2,461 |
| General and administrative expense | | 3,608 | | 984 | | 6,057 | | 1,425 |
| | \$ | 8,177 | \$ | 2,381 | \$ | 13,237 | \$ | 3,886 |

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 options:

| | Three Months End | ded June 30, | Six Months Ended June 30, | | |
|--------------------------|------------------|--------------|---------------------------|--------|--|
| | 2015 | 2014 | 2015 | 2014 | |
| Risk-free interest rate | 1.71% | 1.81% | 1.71% | 1.82% | |
| Expected dividend yield | _ | _ | _ | _ | |
| Expected term (in years) | 5.88 | 5.89 | 6.03 | 6.02 | |
| Expected volatility | 68.93% | 88.00% | 70.02% | 85.34% | |

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 will be 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 did not issue any shares during the three months ended June 30, 2015 and issued 10,664 shares during the six months ended June 30, 2015 under the 2013 ESPP. The 2013 ESPP initially provides participating employees with the opportunity to purchase up to an aggregate of 327,272 shares of the Company's common stock.

The Company recorded \$0.1 million and \$0.2 million of stock-based compensation expense for the three and six months ended June 30, 2015, respectively, related to the 2013 ESPP. No stock-based compensation expense related to the 2013 ESPP was recorded during the three and six months ended June 30, 2014.

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 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, 2015 and 2014.

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, 2015 and December 31, 2014, 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 Mon | Three and Six Months Ended June 30, | | |
|--------------------------------------|-------------------|-------------------------------------|--|--|
| | 2015 | 2014 | | |
| Stock options | 4,687,805 | 3,983,561 | | |
| Restricted stock units | 25,000 | _ | | |
| Unvested restricted stock | 2,841 | 14,204 | | |
| Employee stock purchase plan options | 3,941 | | | |
| | 4,719,587 | 3,997,765 | | |

10. Subsequent Events

We consider events or transactions that occur after the balance sheet date but prior to the issuance of the financial statements to provide additional evidence for certain estimates or to identify matters that require additional disclosure. Subsequent events have been evaluated as required. There were no material recognized subsequent events recorded in the condensed consolidated financial statements as of and for the three and six months ended June 30, 2015.

Operating Lease

On July 20, 2015, the Company entered into a Second Amendment to the Lease (the "Second Lease Amendment") with Forest City 88 Sidney, LLC (the "Landlord"), which amends certain terms of the Company's existing lease with the Landlord. The Second Lease Amendment expands the rentable square footage of the Company's leased premises from approximately 113,220 square feet to approximately 146,030 square feet. Pursuant to the Second Lease Amendment, the date on which the Company will become responsible for paying rent with respect to such additional square footage is November 1, 2015 (the "Expansion Space Rent Commencement Date"). The monthly base rent will increase from approximately \$549,000 to approximately \$727,000 on the Expansion Space Rent Commencement Date, and will further increase on the first anniversary of the Expansion Space Rent Commencement Date and on each anniversary thereafter up to a maximum monthly base rent of approximately \$844,000. The Second Lease Amendment also provides for, among other things, an increase of the tenant improvement allowance from approximately \$16.6 million to approximately \$20.5 million and an increase of the Company's existing security deposit with the Landlord from approximately \$2.2 million to approximately \$2.9 million.

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, 2015 and for the three and six months ended June 30, 2015 and 2014 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, 2014 filed with the Securities and Exchange Commission, or the SEC, on February 24, 2015. 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 disorders, or RGDs, of metabolism, 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 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 is to discover, develop and commercialize disease-altering therapies in oncology arising out of our cancer metabolism research platform that have achieved development candidate status. On December 8, 2014, Celgene elected to extend the period of its exclusivity for an additional year to April 2016. The extension marks the final year of the discovery phase and Celgene will maintain its exclusive option to certain drug candidates that emerge from our cancer metabolism research platform through April 2016. We received a \$20.0 million payment as a result of the extension in May 2015.

Under the terms of the 2010 Agreement, we lead 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 would lead and fund global development and commercialization of development candidates for which they exercise their option to obtain a co-commercialization license, and we retain development and commercialization rights in the United States for development candidates for which we exercise our option to retain a split license. On all programs under the 2010 Agreement, we are eligible to receive up to \$120.0 million in milestone-based payments as well as royalties on any sales.

AG-221 and AG-120 are two drug candidates that have been nominated to date during the discovery phase of the collaboration under the 2010 Agreement. In June 2014, Celgene exercised its exclusive option to license AG-221 and gained worldwide development and commercialization rights for AG-221. We continue to conduct certain clinical development activities within the AG-221 development program while transitioning responsibilities to Celgene who will lead later development activities. Celgene exercised its exclusive option to license development and commercialization rights to AG-120 outside the United States in January 2015. We retain U.S. development and commercialization rights for AG-120.

During April 2015, we selected our third novel IDH mutant inhibitor, AG-881, for clinical development. On April 27, 2015, we entered into a collaboration and license agreement, the AG-881 US Agreement, with Celgene, and our wholly owned subsidiary, Agios International Sarl, entered into a collaboration and license agreement, the AG-881 ROW Agreement, with

Celgene International II Sarl. Together, the AG-881 US Agreement and AG-881 ROW Agreement, or 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 an initial payment of \$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.

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, private placements of our preferred stock, the 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 losses were \$31.9 million and \$18.3 million for the three months ended June 30, 2015 and 2014, respectively, and \$36.9 million and \$30.5 million for the six months ended June 30, 2015 and 2014, respectively. As of June 30, 2015, we had an accumulated deficit of \$203.8 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; continue to discover and validate novel targets and drug product candidates; expand and protect our intellectual property portfolio; hire additional commercial, development and scientific personnel; and continue to operate as a publicly traded company.

Financial Operations Overview

Revenue

Through June 30, 2015, 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 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 trials 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 FASB ASC 605-45, *Revenue Recognition – Principal Agent Considerations*, the amounts are determinable and collection of the related receivable is reasonably assured.

Milestone Revenues

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.

Revenues 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.

Grant Revenue

Revenue related to research grant agreements is recognized as the underlying services are performed and delivered.

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 FASB ASC 605-45, Revenue Recognition – Principal Agent Considerations 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 (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. We have been evaluating AG-221 in several phase 1 dose-escalation trials evaluating both hematological and solid tumor cancers with IDH2 mutations. To date, all clinical data reported by us highlights that the mechanism of response is consistent with preclinical studies, including substantial reduction of plasma 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 study 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 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 million in milestone payments and a tiered royalty on any net sales of products containing AG-221. 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 study 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. The expansion cohorts are evaluating 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. Also in October 2014, we announced the initiation of a phase 1/2 multicenter study of AG-221 in patients with advanced solid tumors, including gliomas, as well as angioimmunoblastic T-cell lymphoma, or AITL, in each case that carry an IDH2 mutation. This phase 1/2 multicenter, open-label, dose-escalation clinical trial of AG-221, which we are conducting in collaboration with Celgene, is designed to assess the safety, clinical activity, and tolerability of AG-221 among patients who have an IDH2 mutant-positive advanced solid tumor or AITL. The phase 1/2 trial includes a dose expansion phase where three cohorts of patients with glioma, AITL and other solid tumors that are IDH2 mutant-positive are receiving AG-221 to further evaluate safety, tolerability and clinical activity in advanced solid tumors or AITL.

On May 7, 2015, we announced that our ongoing phase 1 study 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 ongoing expansion cohorts, AG-221 will be administered at a dose of 100 mg once daily. The primary objectives of the study are to confirm the safety and clinical activity of AG-221 in a select, highly resistant AML population.

On June 12, 2015, we reported clinical data from the ongoing phase 1 study of AG-221, which included 177 patients (104 in dose escalation and 73 from the first four expansion cohorts) with IDH2 mutant-positive AML. The new data were presented at the 20th Congress of the European Hematology Association (EHA) in Vienna, Austria and showed investigator-assessed objective responses in 63 out of 158 evaluable patients. Of the 63 patients who achieved an objective response, there were 26 complete remissions (CRs), three complete remissions with incomplete platelet recovery (CRps), 14 marrow complete remissions (mCRs), two complete remissions with incomplete hematologic recovery (CRi) and 18 partial responses (PRs). A complete remission is determined by using well-established 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 complete remission with incomplete platelet recovery 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 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 111 patients with relapsed or refractory AML, 46 achieved an objective response, including 20 CRs, one CRp, 16 PRs, eight mCRs and one CRi. Of the 22 patients with AML that had not been treated, seven achieved an objective response, including three CRs, two PRs, one mCR and one CRi. Of the 14 patients with myelodysplastic syndrome, seven achieved an objective response, including two CRs, one CRp and four mCRs. Evidence of durability was observed as long as 15 months in duration. An estimated 88 percent of responses lasted three months or longer, and 76 percent of responses lasted six months or longer. AG-221 was well tolerated, with the majority of adverse events reported as mild to moderate. The majority of serious adverse events reported were disease related, with serious adverse events possibly related to AG-221 reported in 27 patients. As of July 2015 the dose escalation has been completed. 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 the second half of 2015, Celgene, in collaboration with us, intends to initiate a global phase 3 registration-enabling study in relapsed/refractory AML patients that harbor an IDH2 mutation and initiate combination trials to evaluate AG-221 as a potential frontline treatment for patients with AML that harbor an IDH2 mutation.

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 studies 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.

On May 7, 2015, we announced that three expansion cohorts have been added to the ongoing phase 1 study of AG-120 in patients with advanced hematologic malignancies. These three expansion cohorts will evaluate AG-120 in 175 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, and the third cohort will evaluate 25 patients with IDH1 mutant positive advanced hematologic malignancies not eligible for cohorts one or two. AG-120 will be administered at a 500 mg once daily oral dose, in 28-day cycles. The study's primary objectives are to confirm the safety and clinical activity of AG-120.

On June 12, 2015, we reported clinical data from the phase 1 study of AG-120 in patients with advanced hematologic malignancies, which included 57 patients with IDH1 mutant-positive AML. The data were presented at the 20th Congress of the EHA in Vienna, Austria and showed investigator-assessed objective responses in 16 out of 52 evaluable patients. Of the 16 patients who achieved an objective response, there were eight CRs, one CRp, three mCRs, and four PRs. Evidence of durability was observed as long as 11 months in duration. An estimated 79 percent of responses lasted three months or longer, and 50 percent of responses lasted six months or longer. AG-120 was well tolerated, with the majority of adverse events reported as mild to moderate. Thirty-five serious adverse events were reported, the majority being disease related, with four cases of leukocytosis potentially related to AG-120. As of July 2015 the dose escalation has been completed. AG-120 showed 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.

Together with Celgene, we intend to initiate a global registration-enabling phase 3 study in AML patients that harbor an IDH1 mutation in the first half of 2016. We also plan to begin combination trials to evaluate AG-120 as a potential frontline treatment of AML patients that harbor an IDH1 mutation in the second half of 2015.

Celgene exercised its exclusive option to license development and commercialization rights to AG-120 outside the United States during the three months ended March 31, 2015. We had previously elected to exercise our option to retain development and commercialization rights to AG-120 in the United States in January 2014. Upon Celgene's exercise of its exclusive option under the terms of our 2010 Agreement, Celgene leads development and commercialization outside the United States, and we lead development and commercialization in the United States. Celgene is responsible for future development and commercialization costs specific to countries outside the United States, we are responsible for future development and commercialization costs specific to the United States, and we and Celgene will equally fund the future global development costs of AG-120 that are not specific to any particular region or country. Celgene is eligible to receive tiered royalties on any net sales outside the U.S. and up to \$120.0 million in payments on achievement of certain milestones.

AG-881: Lead Pan-IDH Program

AG-881 is an orally available, selective, brain-penetrant, pan-IDH mutant inhibitor, providing 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 the worldwide development program, sharing worldwide development costs and profits with Celgene booking worldwide commercial sales. We will lead commercialization in the U.S. with both companies sharing equally in field-based commercial activities, and Celgene would lead commercialization outside of the U.S. with us providing one third of field-based commercial activities in the major E.U. markets.

In June 2015, we initiated a phase 1 study for AG-881 in patients with advanced solid tumors. The phase 1 multi-center, open-label study is to evaluate the safety, pharmacokinetics, pharmacodynamics and clinical activity of AG-881 in advanced solid tumors, including gliomas. AG-881 will be administered continuously as a single agent dosed orally in a 28-day cycle. The first portion of the study 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 the study 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.

In August 2015, we initiated a second dose-escalating and expansion trial for AG-881 in patients with advanced IDH1 or IDH2 mutant-positive hematologic malignancies whose cancer has progressed on a prior IDH inhibitor therapy.

AG-348: Lead Pyruvate Kinase (PK) Deficiency Program

AG-348 is an orally available small molecule and a potent activator of the PKR enzyme. We have previously reported in nonclinical studies that AG-348 is a potent activator of the wild-type (normal) and mutated PKR enzymes, resulting in restoration of ATP levels and a decrease in 2,3-DPG levels in blood sampled from patients with PK deficiency. The wild-type PKR activity of AG-348 allows 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 April 2014, we initiated a single ascending dose, or SAD, escalation phase 1 clinical trial for AG-348 in healthy volunteers and in June 2014, we initiated a multiple ascending dose, or MAD, escalation phase 1 clinical trial for healthy volunteers. In late 2014, we reported the SAD trial was completed and met its primary endpoint. The MAD trial completed dosing in early 2015 and has also met its primary endpoint. The primary endpoint is defined in the protocol to identify a safe and pharmacodynamically active dose and dosing schedule for AG-348 to be used in subsequent clinical studies in patients with pyruvate kinase deficiency.

On December 8, 2014, during a poster session at ASH 2014, we reported the first clinical data from the phase 1 SAD and MAD clinical trials of AG-348 in healthy volunteers. These results provided early proof-of-mechanism for AG-348 as a novel, first-in-class, oral activator of both wild-type and mutated PKR enzymes. In these phase 1 studies, dosing of AG-348 over 14-days in healthy volunteers resulted in a dose-dependent activation of the PKR pathway as evidenced by a substantial increase in ATP and decrease in 2,3-DPG levels, which are key biomarkers of PKR activity and primary indicators of PK deficiency. These data support the hypothesis that AG-348 treatment may similarly enhance PKR activity in patients with PK deficiency and thus correct the underlying defect of the disease. Results presented were from 64 healthy volunteers who received either AG-348 or placebo, which included 48 people from the completed SAD study and 16 people in the first two cohorts of the MAD study, which recently completed dosing. Complete safety results were reported from the SAD phase 1 study and showed that AG-348 was well tolerated. Although the MAD study remained blinded, no serious adverse events had been reported in the first two analyzed cohorts. AG-348 also showed a favorable pharmacokinetic profile with rapid absorption, low variability and dose-proportional increase in exposure following both single and multiple doses. The observed dose-dependent changes in 2,3-DPG and ATP blood levels seen are consistent with a substantial increase in PKR enzymatic activity.

On June 12, 2015, we reported final clinical data from the phase 1 MAD clinical trial of AG-348 in healthy volunteers and the first data from a natural history study of PK deficiency. The data were presented at the 20th Congress of the EHA in Vienna, Austria. Results presented were from 48 healthy volunteers who received either AG-348 or placebo for fourteen days at 15mg, 60mg, 120mg, 360mg or 700mg twice daily or 120 mg once daily in six sequential cohorts. The study showed that AG-348 was well tolerated, with most adverse events occurring in the highest dose group (700 mg), with all but one being mild to moderate. Thirty-two of 36 healthy

volunteers receiving AG-348 completed the study. Two volunteers receiving AG-348 withdrew due to adverse events, including drug eruption (60 mg) and Grade 3 liver function test abnormalities (700 mg), which resolved after treatment discontinuation. Two additional AG-348 volunteers (both 700 mg) withdrew consent due to nausea or vomiting. Serum hormone changes consistent with reversible aromatase inhibition were observed. AG-348 also showed a favorable pharmacokinetic profile with rapid absorption, low to moderate variability and a dose-proportional increase in exposure following multiple doses.

As predicted by the mechanism of action of AG-348, there was a robust activation of the glycolytic pathway as evidenced by a decrease in 2,3-DPG (2,3-diphosphoglycerate) and increase in ATP (adenosine triphosphate) in blood. The decrease in 2,3-DPG was approximately 50 percent for doses 120 mg and higher with levels returning back to baseline approximately 72 hours after AG-348 was discontinued. There was also an approximately 50 percent increase in ATP in blood with AG-348 at doses 60 mg and higher.

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

We have worldwide development and commercial rights to AG-348 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:

| Three Months En June 30, | | | | x Months Ended June 30, | |
|---|----------|----------|----------|----------------------------|--|
| (in thousands) | 2015 | 2014 | 2015 | 2014 | |
| IDH2 (AG-221) | \$ 2,258 | \$ 6,060 | \$ 5,587 | \$ 9,406 | |
| IDH1 (AG-120) | 12,444 | 4,930 | 22,861 | 8,532 | |
| Pan IDH (AG-881) | 3,441 | 1,626 | 7,314 | 2,803 | |
| PK deficiency (AG-348) | 4,607 | 3,851 | 9,678 | 6,988 | |
| Other research and platform programs | 13,673 | 6,109 | 23,426 | 12,253 | |
| Total research and development expenses | \$36,423 | \$22,576 | \$68,866 | \$39,982 | |

Research and development expenses for AG-221 for the three and six months ended June 30, 2015 are net of \$1.1 million and \$5.5 million, respectively, in reimbursement of certain third-party costs from the 2010 Agreement, which are classified as a reduction of research and development expense. No reimbursements were recognized in our research and development costs during the three and six months ended June 30, 2014.

Research and development expenses for AG-120 for the three and six months ended June 30, 2015 are net of \$2.6 million in reimbursement of certain costs for AG-120 from the 2010 Agreement, which are classified as a reduction of research and development expense. No reimbursements were recognized in our research and development costs for AG-120 during the three and six months ended June 30, 2014.

Research and development expenses for AG-881 for the three and six months ended June 30, 2015 are net of \$0.8 million in reimbursement of certain costs for AG-881 from the 2010 Agreement, which are classified as a reduction of research and development expense. No reimbursements were recognized in our research and development costs for AG-881 during the three and six months ended June 30, 2014.

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-348, AG-881, 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, income taxes, 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, 2014.

Results of Operations

Comparison of Three Months Ended June 30, 2015 and 2014

The following table summarizes our results of operations for the three months ended June 30, 2015 and 2014, together with the changes in those items in dollars and as a percentage:

| | Three Mor June | | | |
|---|-------------------|------------|---------------|----------|
| (in thousands) | 2015 | 2014 | Dollar Change | % Change |
| Total revenue | \$ 13,219 | \$ 8,411 | \$ 4,808 | 57% |
| Operating expenses: | | | | |
| Research and development (net of \$4,546 of cost reimbursement from related party for | | | | |
| the three months ended June 30, 2015) | 36,423 | 22,576 | 13,847 | 61 |
| General and administrative | 8,929 | 4,165 | 4,764 | 114 |
| Loss from operations | (32,133) | (18,330) | (13,803) | 75 |
| Interest income | 236 | 34 | 202 | 594 |
| Net loss | \$(31,897) | \$(18,296) | \$ (13,601) | 74% |

Revenue. Revenue increased by \$4.8 million to \$13.2 million for the three months ended June 30, 2015 from \$8.4 million for the three months ended June 30, 2014, an increase of 57%. In July 2014, we amended our 2010 Agreement with Celgene which resulted in the application of new accounting guidance to the agreement. Similarly, in April 2015, we entered into the AG-881 Agreements with Celgene which were deemed a modification of the 2010 Agreement. Prior to the amendments, arrangement consideration was

recognized ratably over the estimated period of performance. As a result of each amendment, we received additional consideration and were required to evaluate the agreements under the current revenue recognition accounting guidance resulting in additional revenues 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. For the three months ended June 30, 2014, we recognized \$8.4 million under the previous accounting guidance.

Research and Development Expense. Research and development expense increased by \$13.8 million to \$36.4 million for the three months ended June 30, 2015 from \$22.6 million for the three months ended June 30, 2014, an increase of 61%. The increase in research and development expenses was primarily attributable to an additional \$8.5 million in external services, offset by \$4.5 million in reimbursement of certain costs related to AG-221, AG-120 and AG-881, our lead product candidates targeting IDH2 and IDH1, and an increase of \$9.8 million in internal expenses. During the three months ended June 30, 2015, we recognized certain cost reimbursements related to our on-going development activities under the 2010 Agreement and AG-881 Agreements as a reduction of research and development expenses. No cost reimbursements were recorded as a reduction of research and development expenditures during the three months ended June 30, 2014.

The increase in external services for the three months ended June 30, 2015 was attributable to the following:

- net decreases of approximately \$4.6 million and \$0.5 million for external phase 1 clinical studies and manufacturing activities for our lead product candidates AG-221 and AG-348, respectively, and net increases of approximately \$5.2 million and \$0.8 million for external phase 1 clinical studies and manufacturing activities for our lead product candidates AG-120 and AG-881, respectively; and
- approximately \$3.1 million increase for costs related to other early research and platform programs.

We incurred approximately \$9.8 million of additional internal research and development expenses for the three months ended June 30, 2015, related to the following:

- an increase of \$6.2 million in personnel costs related to an increase in our internal headcount of 68%, which includes an increase of \$3.2 million in stock-based compensation expense; and
- approximately \$3.6 million increase for facilities and other related expenses.

General and Administrative Expense. General and administrative expenses increased by \$4.8 million to \$8.9 million for the three months ended June 30, 2015 from \$4.2 million for the three months ended June 30, 2014, an increase of 114%. The increase in general and administrative expenses was primarily attributable to the following:

- an increase of \$3.7 million in personnel costs related to an increase in our internal headcount of 72%, which includes an increase of \$2.6 million for stock-based compensation expense;
- an increase of \$0.4 million in professional service costs and insurance costs; and
- an increase of \$0.7 million in certain operating expenses, including consulting and facility costs.

Interest Income. Interest income increased by \$202,000 to \$236,000 for the three months ended June 30, 2015 from \$34,000 for the three months ended June 30, 2014. The increase is attributable to interest earned on the net proceeds from our follow-on offering in December 2014 and payments received from Celgene related to our collaboration agreements.

Provision for Income Tax. We did not have a provision for income taxes during the three months ended June 30, 2015 or 2014 due to our net loss.

Comparison of Six Months Ended June 30, 2015 and 2014

The following table summarizes our results of operations for the six months ended June 30, 2015 and 2014, together with the changes in those items in dollars and as a percentage:

| | Six Mont June | | | |
|---|------------------|------------|---------------|----------|
| (in thousands) | 2015 | 2014 | Dollar Change | % Change |
| Total revenue | \$ 47,421 | \$ 16,822 | \$ 30,599 | 182% |
| Operating expenses: | | | | |
| Research and development (net of \$8,912 of cost reimbursement from related party for | | | | |
| the six months ended June 30, 2015) | 68,866 | 39,982 | 28,884 | 72 |
| General and administrative | 15,883 | 7,454 | 8,429 | 113 |
| Loss from operations | (37,328) | (30,614) | (6,714) | 22 |
| Interest income | 474 | 70 | 404 | 577 |
| Net loss | \$(36,854) | \$(30,544) | \$ (6,310) | 21% |

Revenue. Revenue increased by \$30.6 million to \$47.4 million for the six months ended June 30, 2015 from \$16.8 million for the six months ended June 30, 2014, an increase of 182%. In July 2014, we amended our 2010 Agreement with Celgene which resulted in the application of new accounting guidance to the agreement. Similarly, in April 2015, we entered into the AG-881 Agreements with Celgene which were deemed a modification of the 2010 Agreement. Prior to the amendments, arrangement consideration was recognized ratably over the estimated period of performance. As a result of the each amendment, we received additional consideration and were required to evaluate the agreements under the current revenue recognition accounting guidance resulting in additional revenues being recognized. For the six months ended June 30, 2015, we recognized \$47.4 million in revenue under the new accounting guidance, which includes revenue recognized at the July 2014 amendment date related to the excess of total allocable consideration over the best estimate of selling price of undelivered elements, which fundamentally related to previously delivered elements under the agreement and includes the exclusive global license for development and commercialization of AG-221, the reimbursement of on-going development costs related to AG-221 through the amendment date, and \$8.8 million of revenue recognized related to the delivery of U.S and ex.-U.S. license for AG-881 upon entry into the AG-881 Agreements in April 2015. For the six months ended June 30, 2014, we recognized \$16.8 million under the previous accounting guidance.

Research and Development Expense. Research and development expense increased by \$28.9 million to \$68.9 million for the six months ended June 30, 2015 from \$40.0 million for the six months ended June 30, 2014, an increase of 72%. The increase in research and development expenses was primarily attributable to an additional \$22.2 million in external services, offset by \$8.9 million in reimbursement of certain costs related to AG-221, AG-120 and AG-881, our lead product candidates targeting IDH2 and IDH1, and an increase of \$15.6 million in internal expenses. During the six months ended June 30, 2015, we recognized certain cost reimbursements related to our on-going development activities under the 2010 Agreement and AG-881 Agreements as a reduction of research and development expenses. No cost reimbursements were recorded as a reduction of research and development expenditures during the six months ended June 30, 2014.

The increase in external services for the six months ended June 30, 2015 was attributable to the following:

- a net decrease of approximately \$5.2 million for external phase 1 clinical studies and manufacturing activities for our lead product candidate AG-221 and net increases of approximately \$11.0 million, \$2.3 million and \$0.8 million for external phase 1 clinical studies and manufacturing activities for our lead product candidates AG-120, AG-881 and AG-348, respectively; and
- approximately \$4.4 million increase for costs related to other early research and platform programs.

We incurred approximately \$15.6 million of additional internal research and development expenses for the six months ended June 30, 2015, related to the following:

- an increase of \$10.0 million in personnel costs related to an increase in our internal headcount of 68%, which includes an increase of \$4.7 million in stock-based compensation expense; and
- approximately \$5.6 million increase for facilities and other related expenses.

General and Administrative Expense. General and administrative expenses increased by \$8.4 million to \$15.9 million for the six months ended June 30, 2015 from \$7.5 million for the six months ended June 30, 2014, an increase of 113%. The increase in general and administrative expenses was primarily attributable to the following:

- an increase of \$6.7 million in personnel costs related to an increase in our internal headcount of 72% which includes an increase of \$4.6 million for stock-based compensation expense;
- an increase of \$0.5 million in professional service costs and insurance costs; and
- an increase of \$1.2 million in certain operating expenses, including consulting and facility costs.

Interest Income. Interest income increased by \$404,000 to \$474,000 for the six months ended June 30, 2015 from \$70,000 for the six months ended June 30, 2014. The increase is attributable to interest earned on the net proceeds from our follow-on offering in December 2014 and payments received from Celgene related to our collaboration agreements.

Provision for Income Tax. We did not have a provision for income taxes during the six months ended June 30, 2015 or 2014 due to our net loss.

Liquidity and Capital Resources

Sources of Liquidity

In addition to our existing cash, cash equivalents and marketable securities, we are eligible to earn a significant amount of milestone payments under our collaboration agreements with Celgene and we are entitled to cost reimbursement under the 2010

Agreement. 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, 2015 and 2014:

| | Six Montl June | , |
|---|-------------------|------------|
| (in thousands) | 2015 | 2014 |
| Net cash used in operating activities | \$(21,605) | \$(28,111) |
| Net cash provided by (used in) investing activities | 77,194 | (30,936) |
| Net cash provided by financing activities | 2,913 | 95,734 |
| Net increase in cash and cash equivalents | \$ 58,502 | \$ 36,687 |

Net Cash Used in Operating Activities

The use of cash in all periods resulted primarily from funding our net losses adjusted for non-cash charges and changes in components of working capital. Net cash used in operating activities was \$21.6 million during the six months ended June 30, 2015 compared to \$28.1 million during the six months ended June 30, 2014. The cash used in operating activities was primarily attributable to increased operating expenses which relates 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 offset by amounts reimbursed by Celgene. Our net loss was significantly reduced by revenue recognized under the 2010 Agreement. 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 while no amounts were received during the six months ended June 30, 2014. In addition, in January 2014, we paid \$6.0 million as payment in full of our U.S. federal income tax liability related to the year ended December 31, 2011, including \$1.5 million of interest and penalties accrued. We filed a carryback claim to apply the net losses incurred during the year ended December 31, 2013 against the previous taxable income and received \$3.8 million of refundable income taxes during the six months ended June 30, 2015.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was \$77.2 million during the six months ended June 30, 2015 compared to cash used in investing activities of \$30.9 million during the six months ended June 30, 2014. The cash provided by investing activities for the six months ended June 30, 2015 was primarily the result of higher proceeds from maturities and sales of marketable securities in comparison to purchases of marketable securities offset by \$14.7 million in purchases of property and equipment. The cash used in investing activities for the six months ended June 30, 2014 was primarily the result of higher purchases of marketable securities than proceeds from maturities and sales of marketable securities.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was \$2.9 million during the six months ended June 30, 2015 compared to \$95.7 million during the six months ended June 30, 2014. The cash provided by financing activities for the six months ended June 30, 2015 was the result of proceeds received from stock option exercises and proceeds received from our employee stock purchase plan. The cash provided by financing activities for the six months ended June 30, 2014 was primarily the result of the proceeds from the follow-on public offering, net of underwriting discounts, commissions and offering costs.

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. Furthermore, we expect to continue to incur additional costs associated with operating as a public company. 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, 2015, 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 until at least late 2017. 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 revenues, 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 revenues, 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 SEC rules.

Contractual Obligations

During the six months ended June 30, 2015, we entered into agreements in the normal course of business with contract research organizations 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, 2015 we are obligated to pay up to \$48.2 million to these vendors.

Operating Lease

On July 20, 2015, we entered into a Second Amendment to the Lease, or the Second Lease Amendment, with Forest City 88 Sidney, LLC, or the Landlord, which amended certain terms of our existing lease with the Landlord. The Second Lease Amendment expands the rentable square footage of our leased premises from approximately 113,220 square feet to approximately 146,030 square feet. Pursuant to the Second Lease Amendment, the date on which we will become responsible for paying rent with respect to such additional square footage under the Lease is November 1, 2015, or the Expansion Space Rent Commencement Date. The monthly base rent will increase from approximately \$549,000 to approximately \$727,000 on the Expansion Space Rent Commencement Date, and will increase on the first anniversary of the Expansion Space Rent Commencement Date and on each anniversary thereafter up to a maximum monthly base rent of approximately \$844,000. The Second Lease Amendment also provides for, among other things, an increase of the tenant improvement allowance from approximately \$16.6 million to approximately \$20.5 million and an increase of our existing security deposit with the Landlord from approximately \$2.2 million to approximately \$2.9 million.

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, 2014.

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, 2015 and December 31, 2014, we had cash, cash equivalents and marketable securities of \$434.0 million and \$467.4 million, respectively, consisting primarily of investments in U.S. Treasuries and certificates of deposit. 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, 2015 and December 31, 2014, 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, 2015, 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, 2015 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 to be materially different from any future 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 F

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 \$53.5 million, \$39.4 million and \$20.1 million for the years ended December 31, 2014, 2013 and 2012, respectively, and \$36.9 million for the six months ended June 30, 2015. As of June 30, 2015, we had an accumulated deficit of \$203.8 million. 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 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, such as during the three months ended September 30, 2014, which was the result of the recognition of previously deferred collaboration revenue upon the amendment of the 2010 Agreement, we generally 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:

- continue our research and preclinical development of our product candidates;
- · seek to identify additional product candidates;
- initiate and continue clinical trials for our product candidates;
- seek marketing approvals for our product candidates that successfully complete clinical trials;
- ultimately establish a sales, marketing and distribution infrastructure to commercialize any medicines for which we may obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, quality control and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; 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 revenues that are significant or large enough to achieve profitability. We are currently in clinical testing stages for our lead 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 the 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. Furthermore, we will continue to incur increased costs associated with operating as a public company. 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, 2015, together with anticipated interest income, the anticipated expense reimbursements under our collaboration agreements with Celgene will fund our operating and capital expenditure requirements until late 2017. 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 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 revenues, 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 revenues, 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 the 2010 Agreement expires in April 2016, after which point 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.

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 and undertaking preclinical and clinical studies of our product candidates. All of our product candidates are still in preclinical and clinical development. We have not yet demonstrated our ability to successfully complete any clinical trials, including large-scale, 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. 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.

In addition, as a new business, 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.

Risks Related to Our Operations

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.

Any medicines that we develop may not effectively correct metabolic pathways. 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. 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. 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 revenues 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 our lead product candidates 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 lead product candidates, AG-221, AG-120 and AG-881 for the treatment of hematological and solid tumors and AG-348 for the treatment of PK deficiency. We initiated phase 1 studies for our lead product candidates. We have not commenced clinical trials for any of our other product candidates. Our ability to generate product revenues, 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;

- receipt of marketing approvals from applicable regulatory authorities;
- establishing both clinical and commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- · 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.

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.

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. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and earlier clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results.

Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

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 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.

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.

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

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

We 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.

Furthermore, we rely on 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. If our product candidates are associated with undesirable side effects or have characteristics that are unexpected, we may need to abandon their development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are

less prevalent, less severe or more acceptable from a risk-benefit perspective. 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.

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.

Under our 2010 collaboration agreement with Celgene, we have the right, exercisable during a specified period following FDA acceptance of the applicable investigational new drug application, or IND, to convert one of every three co-commercialized licensed programs into a split licensed program, for which we retain the United States rights. Due to the limited exercise period, we may have to choose whether a co-commercialized program will be a split licensed program before we have as much information as we would like on another co-commercialized program, including whether and when such co-commercialized program may receive FDA acceptance of the applicable IND. Our IDH2 program is not a split licensed program. We have chosen AG-120, and our IDH1 program, as our first split licensed program. As a result of such incomplete information or due to incorrect analysis by us, we may select a split licensed program that later proves to have less commercial potential than an alternative or none at all.

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 expect 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.

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 revenues 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, in the future, 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 do not have a sales or marketing infrastructure and 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. In the future, we may choose to build a focused 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 revenues or the profitability of these product revenues 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 and high risk myelodysplasia. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches, 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 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 market 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 Holdings Inc. and its subsidiary Genentech, Inc., GlaxoSmithKline plc, Merck & Co., Novartis International AG, Pfizer, Inc., and Genzyme, a Sanofi company. There are also biotechnology companies of various size 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, Shire Biochem Inc. and Raze 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 regulations that govern marketing approvals, pricing and reimbursement for new medicines vary widely from country to country. In the United States, recently enacted legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a medicine 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 our collaborators might obtain marketing approval for a medicine in a particular country, but then be subject to price regulations that delay our commercial launch of the medicine, possibly for lengthy time periods, and negatively impact the revenues we or our collaborators are able to generate from the sale of the medicine in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

Our and our collaborators' ability to commercialize any medicines successfully also will depend in part on the extent to which reimbursement for these medicines and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any medicine that we or our collaborators commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we or our collaborators may not be able to successfully commercialize any product candidate for which we or they obtain marketing approval.

There may be significant delays in obtaining reimbursement for newly approved medicines, and coverage may be more limited than the purposes for which the medicine is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for reimbursement does not imply that any medicine will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new medicines, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the medicine and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost medicines and may be incorporated into existing payments for other services. Net prices for medicines may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of medicines from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our or our collaborators' inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved medicines that we or they develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize medicines 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; 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 our collaboration with Celgene focused on cancer metabolism. The collaboration involves a complex allocation of rights, provides for milestone payments to us based on the achievement of specified clinical development, regulatory and commercial milestones, provides for additional payments upon Celgene's election to extend the term of the discovery phase, provides us with royalty-based revenue if certain product candidates are successfully commercialized and provides for cost reimbursements of certain development activities. In April 2015, we entered into a joint worldwide development and profit share collaboration for AG-881 with Celgene and our wholly owned subsidiary, Agios International Sarl, entered into a collaboration and license agreement with Celgene International II Sarl. 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 revenues 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 our collaborations with Celgene, 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, 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. For example, under the
 2010 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.
- A collaborator 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 under the 2010 Agreement with respect to certain licensed programs 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 any program under the 2010 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 60 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 collaborator 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 2010 Agreement, we may not directly or indirectly develop, manufacture or commercialize, except pursuant to the agreement, any medicine or product candidate for any cancer indication: with specified activity against certain metabolic targets except in connection with certain third party collaborations; or with specified activity against any collaboration target, or any target for which Celgene is conducting an independent program that we elected not to buy in to. 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.

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 expect to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials. 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 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 revenues could be delayed.

We also expect 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-348 and AG-881 for our ongoing 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 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 currently have patent protection for one of our lead product candidates in the United States, and do not own or license any issued patents for our other lead product candidates in major markets such as the United States and Europe.

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 which protect our technology or medicines or which 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 infringing 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 collaborator may not be able to obtain any required license on commercially reasonable terms or at all. Even if we or our collaborator 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

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, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We 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 regulatory 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.

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 revenues 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 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 could 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 compared to conventional FDA procedures. The FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program.

Failure to obtain marketing approval in international jurisdictions would prevent our 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, it is required that the 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 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, 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. The FDA closely regulates the post-approval marketing and promotion of medicines to ensure that they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes 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.

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

- restrictions on such medicines, 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 clinical trials;
- warning or untitled letters;
- withdrawal of the medicines from the market;
- · refusal to approve pending applications or supplements to approved applications that we submit;
- · recall of medicines;
- · 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; and
- injunctions or the imposition of civil or criminal penalties.

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

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers 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 our medicines for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal healthcare 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 either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;
- the federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements under the Affordable Care Act requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims
 involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws
 require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance
 guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to
 physicians and other health care providers or marketing expenditures.

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, exclusion 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 providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Recently enacted and future legislation may increase the difficulty and cost for us or our collaborators to obtain marketing approval of and commercialize our 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 prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our or our collaborators ability to profitably sell any product candidates for which we or they obtain marketing approval.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or Medicare Modernization Act, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

More recently, in March 2010, U.S. President Barack Obama signed into law the Affordable Care Act, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Effective October 1, 2010, the Affordable Care Act revises the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the new law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with health care practitioners. We will not know the full effects of the Affordable Care Act until applicable federal and state agencies issue regulations or guidance under the new law. Although it is too early to determine the effect of the Affordable Care Act, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. 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 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.

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 may be volatile and fluctuate substantially, 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. Since our initial public offering in July 2013 the price of our common stock on the NASDAQ Global Select Market has ranged from \$15.77 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:

- the success of competitive products or technologies;
- results of clinical trials of our product candidates or those 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 discover, develop, acquire or in-license additional product candidates or medicines;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- · general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

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

Persons who were our stockholders prior to our initial public offering continue to hold a substantial number of shares of our common stock. If such persons 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 could have a material adverse effect on the trading price of our common stock.

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 carryforwards 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 carryforwards that we expect to expire unutilized. If additional limitations were to apply, utilization of a portion of our net operating loss and tax credit carryforwards could be further limited in future periods and a portion of the carryforwards 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 as of January 1, 2015 when we ceased to be an "emerging growth company," we do and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The NASDAQ Global Select Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and will make some activities more time-consuming and costly especially as we are no longer an "emerging growth company", as defined in the Jumpstart Our Business Startups Act of 2012, and are no longer able to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are "emerging growth companies" and were applicable to us prior to January 1, 2015.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, as of January 1, 2015 we are required to furnish with our periodic Exchange Act reports a report by our management on our internal control over financial reporting. As of January 1, 2015, because we are no longer an emerging growth company, we 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 within the prescribed period, we have been 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.

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† | Collaboration and License Agreement by and between Agios Pharmaceuticals, Inc. and Celgene Corporation Re: AGI-23088 for the US Territory, dated as of April 27, 2015 | | | | | X |
| 10.2† | Collaboration and License Agreement by and between Agios International Sarl and Celgene International II Sarl Re: AGI-23088 for the ROW Territory, dated as of April 27, 2015 | | | | | X |
| 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.

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

COLLABORATION

AND LICENSE AGREEMENT

by and between

AGIOS PHARMACEUTICALS, INC.

and

CELGENE CORPORATION

Re:

AGI-23088

for the

US Territory

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Exhibits

AGI-23088 Exhibit A Exhibit B Agios Patent Rights and Agios Collaboration Patent Rights Exhibit C [Exhibit no longer used.] Exhibit D **Existing Third Party Agreement** Exhibit E Certain Financial Definitions $Exhibit \, F$ Countries for Filing Agios Patent Rights and Collaboration Patent Rights Press Release Exhibit G Exhibit H JSC, JDC and JPC Appointments Partnership Tax Matters Exhibit I

COLLABORATION AND LICENSE AGREEMENT (AGI-23088 for the US Territory)

This Collaboration and License Agreement (this "Agreement") is entered into as of April 27, 2015 (the "Effective Date"), by and between Agios Pharmaceuticals, Inc., a corporation organized and existing under the laws of the State of Delaware and having its principal office at 38 Sidney St., 2nd Floor, Cambridge, MA 02139-4169 ("Agios"), and Celgene Corporation, a corporation organized and existing under the laws of the State of Delaware and having its principal office at 86 Morris Avenue, Summit, NJ 07901 ("Celgene").

INTRODUCTION

- 1. Agios and Celgene are parties to the Discovery and Development Collaboration and License Agreement, dated as of April 14, 2010, as amended (the "2010 Agreement").
- 2. Pursuant to the 2010 Agreement, Agios has discovered and is developing a compound referred to as AGI-23088 and as AG-881, which the Parties believe to be a potent inhibitor of IDH1 and IDH2 mutants and wild type, with the potential for penetration of the blood brain barrier.
- 3. The Parties have agreed that the further Development and Commercialization of AGI-23088, which has potential overlaps with other programs currently being undertaken pursuant to the 2010 Agreement, should be conducted pursuant to the terms of this Agreement between the Parties for the US Territory and another agreement between Celgene International II Sarl ("CIS II") and Agios International Sarl ("AIS") for the ROW Territory ("AGI-23088 ROW Agreement") and that all further such activities related to AGI-23088 should cease under the 2010 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

When used in this Agreement, each of the following terms shall have the meanings set forth in this Article I:

Section 1.1 "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, "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.

- Section 1.2 "AGI-23088" means the compound described on Exhibit A to this Agreement. Such compound may also be referred to from time to time as AG-881.
- Section 1.3 "Agios Collaboration Intellectual Property," "Agios Collaboration Know-How" and "Agios Collaboration Patent Rights" means, respectively, the Collaboration Intellectual Property Controlled by Agios or AIS, the Collaboration Know-How Controlled by Agios or AIS, and the Collaboration Patent Rights Controlled by Agios or AIS.
 - Section 1.4 "Agios Intellectual Property" means Agios Know-How and Agios Patent Rights, collectively.
- Section 1.5 "Agios Know-How" means any Know-How that is (a) Controlled by Agios or AIS as of the Effective Date or during the Term, and (b) necessary or useful for the Development, Manufacture and/or Commercialization of the Licensed Products, but excluding Collaboration Know-How.
- Section 1.6 "Agios Patent Rights" means any Patent Rights that (a) are Controlled by Agios or AIS as of the Effective Date or during the Term, and (b) Cover, or are otherwise necessary or useful for the Development, Manufacture and/or Commercialization of, the Licensed Products (including the composition of matter, manufacture or any use thereof); but excluding Collaboration Patent Rights. Agios Patent Rights as of the Effective Date are as set forth on Exhibit B to this Agreement.
 - Section 1.7 "Business Day" means a day other than a Saturday or Sunday or federal holiday in Cambridge, Massachusetts or Summit, New Jersey.
- Section 1.8 "Calendar Quarter" 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 June following the Effective Date.
- Section 1.9 "Calendar Year" 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, 2015.
- Section 1.10 "Celgene Collaboration Intellectual Property", "Celgene Collaboration Know-How" and "Celgene Collaboration Patent Rights" means, respectively, the Collaboration Intellectual Property Controlled by Celgene or CIS II, the Collaboration Know-How Controlled by Celgene or CIS II and the Collaboration Patent Rights Controlled by Celgene or CIS II.
 - Section 1.11 "Celgene Intellectual Property" means Celgene Know-How and Celgene Patent Rights, collectively.
- Section 1.12 "<u>Celgene Know-How</u>" means any Know-How that is (a) Controlled by Celgene or CIS II as of the Effective Date or during the Term; (b) necessary for the Development, Manufacture and/or Commercialization of the Licensed Products; and (c) contributed by Celgene or CIS II, in Celgene's or CIS II's sole discretion, to the Collaboration, as evidenced by written notice from Celgene or CIS II to Agios; but excluding Collaboration Know-How.

- Section 1.13 "Celgene Patent Rights" means any Patent Rights that (a) are Controlled by Celgene or CIS II as of the Effective Date or during the Term; (b) Cover the Licensed Products (including the composition of matter, manufacture or any use thereof); and (c) are contributed by Celgene or CIS II, in Celgene's or CIS II's sole discretion, to the Collaboration, as evidenced by written notice from Celgene or CIS II to Agios; but excluding Collaboration Patent Rights.
- 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, the AGI-23088 ROW Agreement, and the activities performed by a Party or the Parties relating to the Development and Manufacturing of AGI-23088 under the 2010 Agreement before the Effective Date, collectively.
 - Section 1.17 "Collaboration Intellectual Property" means Collaboration Know-How and Collaboration Patent Rights, collectively.
- Section 1.18 "Collaboration Know-How" means any Know-How or interest therein that was, before the Effective Date, or is, on or after the Effective Date, developed or generated, either solely by or on behalf of Celgene, CIS II, Agios or AIS or jointly by or on behalf of any of such Persons in the conduct of the Collaboration, including Joint Inventions.
- Section 1.19 "Collaboration Patent Rights" means any Patent Rights or interest therein that was, before the Effective Date, or is, on or after the Effective Date, Controlled solely by Celgene, CIS II, Agios or AIS or Controlled jointly by any of such Persons and that Cover Collaboration Know-How, including Joint Patents and any such Patent Rights filed before or after the Effective Date.
- Section 1.20 "Commercialization" or "Commercialize" 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 and any Phase IV Studies).
- Section 1.21 "Commercially Reasonable Efforts" means, with respect to the performing Party, the carrying out of obligations of such Party in a diligent, expeditious and sustained manner, including the allocation of a commercially reasonable level of personnel and financial resources, but in no event less than such level of resources that an established biopharmaceutical company typically devotes to products of similar market potential at a similar stage in its development or product life, taking into account scientific and commercial factors, including commercial Manufacturing, issues of safety and efficacy, product profit, difficulty in developing or manufacturing the Licensed Products, competitiveness of alternative Third Party products in the marketplace, the patent or other proprietary position of the Licensed Products, the regulatory requirements involved and the potential profitability for the performing Party of the Licensed Products, marketed or to be marketed.

Section 1.22 "<u>Companion Diagnostic</u>" means a biomarker or diagnostic test that may be used with a Licensed Product, or may be developed by the Parties pursuant to Section 3.4, 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 type of cancer or to predict which patients are suitable candidates for a specific form of chemotherapy.

Section 1.23 "Compound" means AGI-23088 and any polymorph, isotopologue, stereoisomer, prodrug, solvate, co-crystal or salt of AGI-23088.

Section 1.24 "Confidential Information" 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, the AGI-23088 ROW Agreement or the 2010 Agreement relating to the Licensed Products and all proprietary biological materials of a Party.

Section 1.25 "Control" or "Controlled" means, with respect to any (a) Know-How or other information or materials, (b) compound, 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.

Section 1.26 "Core Patent Rights" means Patent Rights comprising [**] claims.

Section 1.27 "Cover," "Covering" or "Covered" means that, with respect to a product or technology, but for a Person's ownership of Patent Rights or a license granted to a Person under a Valid Claim included in the Patent Rights under which such license is granted, the Development, Manufacture, Commercialization and/or other use of such product or practice of such technology by such Person would infringe any Valid Claim of any patent included in such Patent Rights or, with respect to a Valid Claim included in any patent application, would infringe such Valid Claim if such patent application were to issue as a patent.

Section 1.28 "<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 1.29 "<u>Develop</u>" or "<u>Development</u>" means research, preclinical, non-clinical and clinical development activities, including activities relating to assays, test method development and stability testing, toxicology, pharmacology, formulation, quality assurance/quality control

development, Clinical Trials (including any Phase IV Study), technology transfer, statistical analysis, process development and scale-up, pharmacokinetic studies, data collection and management, report writing, and other pre-Regulatory Approval activities.

- Section 1.30 "<u>Development Plan</u>" means a development plan and related budget approved by the JSC by Mutual Consent after the Effective Date, as amended from time to time by the JSC by Mutual Consent.
- Section 1.31 "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 1.32 "Existing Third Party Agreement" means any agreement listed on Exhibit D to this Agreement.
 - Section 1.33 "FDA" means the United States Food and Drug Administration, or any successor agency thereof.
- Section 1.34 "FDCA" means the United States Federal Food, Drug, and Cosmetic Act, and the regulations promulgated thereunder, each as amended from time to time.
 - Section 1.35 "Field" means the treatment, control, mitigation, prevention or cure or diagnosis of any Indications.
- Section 1.36 "First Commercial Sale" means the first commercial sale of a Licensed Product by a Party, its Affiliates, distributors and/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 1.37 "Generic Competition" means, with respect to a Licensed Product in a given country in a given Calendar Year, that, during such Calendar Year [**] Generic Products shall be commercially available in such country.
- Section 1.38 "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 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," "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 1.39 "IDH1" means (alias PICD, IDPC; UniProt identifier O75874) the persoxisomal/cytosolic form of isocitrate dehydrogenase that catalyzes the NADP+ dependent conversion of isocitrate to alpha-ketoglutarate.
- Section 1.40 "<u>IDH2</u>" means (alias ICD-M, IDPM; UniProt identifier P48735) the mitochondrial form of isocitrate dehydrogenase that catalyzes the NADP+ dependent conversion of isocitrate to alpha-ketoglutarate.
- Section 1.41 "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.
- Section 1.42 "IND Acceptance Date" means thirty (30) days following the filing of an IND with the FDA; provided that the FDA has not provided any communication indicating that the conduct of clinical activities described in such IND may not begin within thirty (30) days after such filing. In the event that any such communication is provided by the FDA, "IND Acceptance Date" means the date that the Parties are permitted by the FDA to begin clinical activities. If the Parties both agree, "IND Acceptance Date" means the date, following filing of an IND with a Regulatory Authority (other than the FDA), that Agios receives a written communication from such Regulatory Authority pursuant to which the conduct of clinical activities described in the appropriate submissions is permitted to begin.
 - Section 1.43 "Indication" means any human disease, condition or syndrome, or sign or symptom of, or associated with, a human disease or condition.
- Section 1.44 "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.
- Section 1.45 "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.

Section 1.46 "Licensed Products" means (a) a Compound, and (b) any product that contains a Compound as an active ingredient.

Section 1.47 "<u>Licensee Partner</u>" means any Third Party to whom a Party or any of its Affiliates grants a sublicense or license with respect to the Development, Manufacture or Commercialization of Licensed Products in the Field in the US Territory under the rights to Agios Intellectual Property, Celgene Intellectual Property or Collaboration Intellectual Property, as the case may be, granted to such Party or Affiliate hereunder, in each case excluding (a) any Person that is granted a sublicense in accordance with Section 8.2(a), 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.

- Section 1.48 "Major European Countries" means France, Germany, Italy, Spain and the United Kingdom.
- Section 1.49 "Major Market" means each of the United States of America, Japan, and the Major European Countries.
- Section 1.50 "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.
- Section 1.51 "Manufacturing Technology" means copies of all Celgene Know-How, Agios Know-How or Collaboration Know-How, as applicable, which are necessary or useful for Manufacturing preclinical, clinical and/or commercial supply, as applicable, of the Licensed Products, including specifications, assays, batch records, quality control data, and transportation and storage requirements.

Section 1.52 "Mutual Consent" means with respect to any matter specified as requiring "Mutual Consent", that each Party must consent in writing to the action to be taken (or not taken), or if the matter is one referred to the JSC, that the JSC must approve the action to be taken (or not taken) by unanimous vote, with each Party (or its voting member of the JSC), in its/his/her sole discretion, being entitled to withhold its/his/her consent to or approval of the matter; provided, however, that a Party may take any such action as required by applicable Law or order of any governmental authority in the absence of the consent of the other Party or the approval of the JSC, as applicable.

Section 1.53 "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 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, and (c) all supplements and amendments that may be filed with respect to the foregoing.

Section 1.54 "Party" means Agios or Celgene; "Parties" means Agios and Celgene.

Section 1.55 "Patent Rights" 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, supplemental protection certificates, or extensions of any of the foregoing anywhere in the world.

Section 1.56 "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.

Section 1.57 "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).

Section 1.58 "Phase II Study" means a human clinical trial of a product, the principal purpose of which is a preliminary determination of safety and efficacy or appropriate dosage ranges in the target patient population or a 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(b), as amended (or the non-United States equivalent thereof).

Section 1.59 "Phase III Study" means a pivotal human clinical trial of a product, the principal purpose of which is to gain evidence with statistical significance of the efficacy of a product in a target population, to obtain expanded evidence of safety for such product that is needed to evaluate the overall benefit-risk relationship of such product, and to provide an adequate basis 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 or maintain Regulatory Approval for such product, including all tests and studies prescribed by the applicable Regulatory Authority, from time to time, pursuant to applicable Law or otherwise, including for example the trials referred to in 21 C.F.R. §312.21(c), as amended (or the non-United States equivalent thereof).

Section 1.60 "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 1.61 "Prosecution" or "Prosecute" means the filing, preparation, prosecution and maintenance of Patent Rights, including any and all pre-grant and post-grant ex-parte or *inter partes* proceedings before any patent authority, such as interferences, reissue proceedings, reexaminations, oppositions or other challenges to the patentability or validity of any Patent Rights not initiated through a court or other tribunal that determines infringement.

Section 1.62 "<u>Publication</u>" means any publication in a scientific journal or other scientific periodical, publication in any government clinical trial reporting website, any abstract to be presented to any scientific audience, any presentation at any scientific conference, including slides and texts of oral or other public presentations, any other public presentation directed to a scientific audience that pertains to any Licensed Product, the use of any Licensed Product, or the data or result from any work under the Collaboration.

Section 1.63 "Regulatory Approval" 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.

Section 1.64 "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 of a product in a country or territory.

Section 1.65 "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 1.66 "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 1.67 "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 1.68 "ROW Territory" means all countries in the world other than the US Territory.

Section 1.69 "Sole" means, with respect to the license of any Patent Rights or Know-How, that such license is an exclusive license, except for the rights reserved by the licensor for itself and its Affiliates (a) to continue to practice the subject Patent Rights and Know-How and (b) to license or sublicense, as applicable, the subject Patent Rights and Know to Third Parties as reasonably necessary for such licensor or its Affiliates to exercise their rights or fulfill their obligations under the Collaboration.

- Section 1.70 "Target" means IDH1 or IDH2.
- Section 1.71 "Territory" means the US Territory and the ROW Territory.
- Section 1.72 "Third Party" means any Person other than Agios or Celgene or each Party's respective Affiliates.
- Section 1.73 "Third Party Agreement" means (a) the Existing Third Party Agreement and (b) any other Third Party agreements which either Party may enter into, during the Term in accordance with the terms of this Agreement, to acquire or license Third Party Patent Rights or Know-How that are necessary or useful for the Development, Manufacture and/or Commercialization of the Licensed Products.
- Section 1.74 "Third Party Rights" 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 1.75 "US Territory" means the United States of America, including its territories, possessions and Puerto Rico.

Section 1.76 "Valid Claim" 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 [**] years from the earliest filing date to which such patent application or claim is entitled.

Section 1.77 Additional Definitions. Each of the following definitions is set forth in the section of this Agreement indicated below:

| DEFINITION | SECTION |
|---|--------------|
| 2010 Agreement | Introduction |
| AAA | 15.1(b) |
| Accounting Standards | Exhibit E |
| Acquired Party | 15.4(b) |
| Acquired Party Activity | 15.4(c) |
| Acquired Third Party | 15.4(c) |
| Acquirer | 15.4(b) |
| Acquisition | 15.4(b) |
| Additional Development Activities | 3.3 |
| Additional Development Opt-In Date | 3.3(e)(i) |
| Additional Development Opt-In Notice | 3.3(e) |
| Additional Development Proposal | 3.3(a) |
| Additional Development Party | 3.3(c) |
| Additional Revenue | Exhibit E |
| Advertising and Market Research Expenses | Exhibit E |
| AGI-23088 ROW Agreement | Recitals |
| Agios | Preamble |
| Agios Clinical-Scale Manufacturing Responsibilities | 4.1(a) |
| Agios Commercial-Scale Manufacturing Responsibilities | 4.1(a) |
| Agios Indemnified Parties | 13.1(a) |
| Agios Opt-Out Notice | 2.12(a) |
| Agios Opt-Out Date | 2.12(a) |
| Agreement | Preamble |
| AIS | Recitals |
| Alliance Manager | 2.6 |
| Annual Net Sales | Exhibit E |
| Arbitrable Matters | 15.1(b) |
| Audit Team | 9.8(a) |
| Audit Rights Holder | 9.8(f) |
| Auditee | 9.8(f) |
| Bankruptcy Code | 8.8 |
| Breaching Party | 14.2(b)(i) |
| CA 23088 US Partnership | 15.16 |
| Celgene | Preamble |
| Celgene Controlled Agios Patent Rights | 10.2(b) |
| Celgene Indemnified Parties | 13.2(a) |
| Celgene Manufacturing Responsibilities | 4.1(c) |
| Challenge | 10.8(a) |
| Change of Control | 15.5(c) |
| CIS II | Recitals |
| Combination Product | Exhibit E |
| Commercialization Expenses | Exhibit E |
| Commercialization Budget | 6.2(a)(i) |
| Commercialization Plan | 6.2(a)(i) |
| Committee | 2.1(a) |
| | . () |

| DEFINITION | SECTION |
|----------------------------------|---------------|
| Competitive Infringement | 10.3(b) |
| Cooperating Party | 11.3(b)(iii) |
| CPI | Exhibit E |
| CREATE Act Patent | 10.7 |
| Development Budget | 3.1(a) |
| Development Costs | Exhibit E |
| Disclosing Party | 11.1 |
| Dispute | 15.1(a) |
| Distribution Costs | Exhibit E |
| DOJ | 15.17(c)(i) |
| [**] Agreement | Exhibit D |
| Earlier Patent | 10.7 |
| Effective Date | Preamble |
| Excess Amounts | 9.2(b) |
| Expert | 15.1(b)(i) |
| Finance Working Group | 2.1(a) |
| Financial Exhibit | 2.9(b) |
| FTC | 15.17(c)(ii) |
| FTE | Exhibit E |
| FTE Costs | Exhibit E |
| FTE Rate | Exhibit E |
| Global Safety Database | 5.3 |
| Health Care Reform Fees | Exhibit E |
| [**] | 15.12 |
| HSR Act | 15.17(c)(iii) |
| Initial Enforcement Party | 10.3(b) |
| Invalidity Claim | 10.4(b) |
| JCC | 2.1(a) |
| JDC | 2.1(a) |
| Joint Inventions | 10.1(c) |
| Joint Patents | 10.1(c) |
| JPC | 2.1(a) |
| JPC Designee | 2.8(e) |
| JSC | 2.1(a) |
| Manufacturing Costs | Exhibit E |
| Manufacturing Scale-Up Costs | Exhibit E |
| Marketing Activities | 6.3(a) |
| Marketing Expenses | Exhibit E |
| Marketing Management Expenses | Exhibit E |
| Medical Education Expenses | Exhibit E |
| Net Sales | Exhibit E |
| Non-Additional Development Party | 3.3(c) |
| Non-Breaching Party | 14.2(b)(i) |
| Objecting Party | 6.1(b) |
| Other Commercialization Costs | Exhibit E |

| DEFINITION | SECTION |
|--|--------------|
| Out-of-Pocket Costs | Exhibit E |
| Patent and Trademark Prosecution and Enforcement Costs | Exhibit E |
| Patent Prosecution Expenses | 10.2(e) |
| Payments | 9.9(a) |
| Pharmacovigilance Agreement | 5.3 |
| Phase IV Trial Expenses | Exhibit E |
| PPACA | Exhibit E |
| Product Liabilities | Exhibit E |
| Product Trademarks | 6.4(a) |
| Proposing Party | 6.1(b) |
| Prosecuting Party | 10.2(f)(i) |
| Recall Expenses | Exhibit E |
| Receiving Party | 11.1 |
| Reconciliation Procedures | 2.9(b) |
| Redacted Version | 11.3(b)(i) |
| Regulatory Interactions | 5.1(b) |
| Regulatory Expenses | Exhibit E |
| Regulatory Maintenance Costs | Exhibit E |
| Requesting Party | 11.3(b)(iii) |
| Royalty Term | 9.5(b) |
| Selling Expenses | Exhibit E |
| Step-In Enforcement Party | 10.3(d) |
| Term | 14.1 |
| Third Party Activity | 15.4(b) |
| Third Party Contractors | 8.2(a)(ii) |
| Third Party Infringement | 10.3(a) |
| Third Party Infringement Action | 10.4(a) |
| Third Party Patent Costs | Exhibit E |
| Third Party Products Liability Action | 13.4(a) |
| US Territory Loss | Exhibit E |
| US Territory Profit | Exhibit E |
| US Territory Profit or Loss | Exhibit E |
| | |

Article II Governance; Collaboration

Section 2.1 General.

(a) <u>Governance Committees</u>. The Parties hereby establish (i) a Joint Steering Committee ("<u>JSC</u>") to oversee and coordinate the overall conduct of all further activities concerning the Collaboration after the Effective Date; (ii) a Joint Development Committee ("<u>JDC</u>") to oversee and coordinate Development (including Manufacturing of clinical supply) of the Licensed Product(s); (iii) a Joint Commercialization Committee ("<u>JCC</u>") to oversee the Commercialization (including Manufacturing of commercial supply) of the

Licensed Products; (iv) the Joint Patent Committee ("<u>JPC</u>") to coordinate the Prosecution of Agios Patent Rights, Agios Collaboration Patent Rights, Celgene Patent Rights and Celgene Collaboration Patent Rights (the JSC, the JDC, the JCC and JPC shall each be referred to as a "<u>Committee</u>"); and (v) a joint Finance Working Group ("<u>Finance Working Group</u>") to coordinate financial aspects of the Collaboration and to act as a resource for all financial matters for each Committee as needed. Each Committee may from time to time establish subcommittees or project teams to handle matters within the scope of its authority. 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.

- (b) <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):
- (i) All activities regarding Development, Manufacturing and Commercialization of a Compound or Licensed Product containing AGI-23088 shall cease under the 2010 Agreement and all future such activities shall be conducted solely under this Agreement and the AGI-23088 ROW Agreement.
- (ii) 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 8.8 of the 2010 Agreement.
- (iii) Neither AGI-23088 nor any other Compound or Licensed Product is or can be (A) included as an "Agreement Compound" or in any of the classes of compounds comprising "Agreement Compounds", (B) part of the "Compound List," (C) included in any of the "Picks", or (D) part of an "Agios Reverted Program," or "Celgene Reverted Program".
- (iv) 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 the Licensed Products.
- (v) 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. Each meeting of a Committee or working group under this Agreement shall be conducted separately from any meeting of a "Committee" or working group under the 2010 Agreement.
- (vi) All "Confidential Information" disclosed under the 2010 Agreement that solely relates to AGI-23088, Compound or any Licensed Product 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, AGI-23088, Compound or any Licensed Product 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 the 2010 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.

Section 2.2 Joint Steering Committee.

(a) <u>Establishment</u>. The initial members of the JSC for each Party will be determined by each Party, respectively, within [**] days after the Effective Date, and the Parties will complete <u>Exhibit H</u> to reflect such appointments. The Parties intend that the JSC shall have the responsibility for general oversight over the Collaboration for the US Territory and for coordinating with the JSC from the AGI-23088 ROW Territory Agreement on such matters.

(b) <u>Duties</u>. The JSC shall:

- (i) oversee and coordinate the conduct of the Collaboration and related matters within the responsibilities of the Committees hereunder;
- (ii) by Mutual Consent provide strategic guidance, and coordinate efforts between the Parties, with respect to any Publications and by Mutual Consent approve requests for Publication, from either Party, according to Section 11.4 hereof;
 - (iii) serve as a forum for dispute resolution in accordance with Section 2.8 with respect to matters that are not resolved at the JDC or JCC;
- (iv) approve the initial Development Plan (as provided in Section 1.30) and any changes thereto proposed by the JDC, in all cases by Mutual Consent; and
 - (v) perform such other duties as are specifically assigned to the JSC under this Agreement.

Section 2.3 Joint Development Committee.

(a) <u>Establishment</u>. The initial members of the JDC for each Party will be determined by each Party, respectively, within [**] days after the Effective Date, and the Parties will complete <u>Exhibit H</u> to reflect such appointments. The Parties intend that the JDC shall have the responsibility for overseeing the Development of Licensed Products under the Collaboration for the US Territory and for coordinating with the JDC from the AGI-23088 ROW Territory Agreement on such matters.

(b) Duties. The JDC shall:

(i) review and recommend to the JSC approval of the initial Development Plan (as provided in Section 1.30) and any proposed updates or amendments to the Development Plan (and applicable Development Budget) as needed;

- (ii) oversee, review, coordinate and provide strategic guidance to the Parties on the Development of the Licensed Products in the US Territory, including assigning activities to be performed by each Party, subject to the provisions of Section 3.1;
- (iii) in conjunction with any committees under the AGI-23088 ROW Agreement responsible for Development of the Licensed Products, review and coordinate such committees' activities with respect to the Development of the Licensed Products with the Parties activities under this Agreement;
- (iv) subject to and within the parameters of each Development Plan (A) 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 (B) oversee and approve the overall strategy and positioning of all material submissions and filings with the applicable Regulatory Authorities;
 - (v) manage the Development of any Companion Diagnostics, including the Development of any biomarkers;
- (vi) oversee, review and coordinate the studies required for the preparation of the CMC section of an IND for filing with Regulatory Authorities for the Licensed Products, including studies relating to analytical methods and purity analysis, and (in conjunction with the JCC) formulation and Manufacturing development studies, together with associated regulatory activities;
 - (vii) oversee, review and coordinate Manufacturing of Licensed Product for Development purposes;
 - (viii) review and approve the content of any IND for a Licensed Product;
- (ix) develop and approve a publication plan for any Publications made prior to the First Commercial Sale of a Licensed Product in the US Territory;
- (x) in conjunction with the JCC, oversee and coordinate the Parties' activities with respect to the Manufacture of pre-clinical and clinical supply of the Licensed Products; and
 - (xi) perform such other duties as are specifically assigned to the JDC under this Agreement.

Section 2.4 <u>Joint Commercialization Committee</u>. Upon initiation of the [**] Study with respect to a Licensed Product or within [**] days 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 Licensed Products under the Collaboration for the US Territory and for coordinating with the JCC from the AGI-23088 ROW Territory Agreement on such matters.

(a) <u>Duties.</u> The JCC shall:

- (i) oversee, review and coordinate the Commercialization of the Licensed Products by the Parties in the US Territory;
- (ii) in conjunction with any committees under the AGI-23088 ROW Agreement responsible for Commercialization of the Licensed Products, review and coordinate such committees' activities with respect to the Commercialization of the Licensed Products with the Parties activities under this Agreement;
 - (iii) develop and oversee a pricing and branding strategy for the Licensed Products;
 - (iv) set overall strategic objectives and plans related to Commercialization of the Licensed Products in the US Territory;
- (v) review and approve the annual Commercialization Plan for the Licensed Products, and any updates or amendments thereto, and propose revisions to the Commercialization Plan as needed;
 - (vi) review and approve all sales, promotional and communication materials for the Licensed Products;
- (vii) develop and approve a publication plan for any Publications made after the First Commercial Sale of a Licensed Product in the US Territory;
 - (viii) provide a forum for the Parties to share information with respect to the Commercialization of the Licensed Products;
 - (ix) review and provide strategic guidance on all Marketing Activities with respect to the Licensed Products worldwide;
 - (x) subject to and within the parameters of the Commercialization Plan, oversee the implementation of such plan;
 - (xi) confirm that both Parties' have approved all promotional materials in accordance with the Parties' internal copy review procedures;
 - (xii) oversee, review and coordinate Manufacturing of commercial supply of the Licensed Products; and
 - (xiii) perform such other duties as are specifically assigned to the JCC under this Agreement.

Section 2.5 Joint Patent Committee.

(a) <u>Establishment</u>. The initial members of the JPC for each Party will be determined by each Party, respectively, within [**] days after the Effective Date, and the Parties

will complete Exhibit H to reflect such appointments. The Parties intend that the JPC shall have the responsibility for sharing information and coordinating Patent Prosecution matters involving Agios Patent Rights, Celgene Patent Rights, and Collaboration Patent Rights for the US Territory and for coordinating with the JPC from the AGI-23088 ROW Territory Agreement on such matters.

(b) <u>Duties</u>. The JPC shall:

- (i) discuss the current status of all Agios Patent Rights, Celgene Patent Rights and Collaboration Patent Rights in the US Territory;
- (ii) discuss filing and claiming strategies involving Agios Patent Rights, Celgene Patent Rights and Collaboration Patent Rights in the US Territory for all those existing as of the Effective Date as well as any new applications for the foregoing to be filed after the Effective Date;
- (iii) in conjunction with the JPC from the AGI-23088 ROW Territory Agreement, coordinate the timing and conduct of the Parties' respective activities assigned to each of them under this Agreement with respect to Prosecution;
- (iv) in conjunction with the JPC from the AGI-23088 ROW Territory Agreement, coordinate the Parties' respective activities in preparation for potential litigation involving the assertion of the Agios Patent Rights, Agios Collaboration Patent Rights, Celgene Patent Rights and Celgene Collaboration Patent Rights in the US Territory under Section 10.3(c); and
 - (v) perform such other duties as are specifically assigned to the JPC under this Agreement.

Section 2.6 <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, JDC and JCC 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.

Section 2.7 General Committee Membership and Procedures.

(a) Committee Membership. Each Committee shall each be composed of three (3) representatives from Celgene, on the one hand, and (3) representatives from Agios, on the other hand, 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 and Commercialization of the Licensed 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. [**] shall appoint an initial chairperson from its members for the JDC, and [**] shall appoint an initial chairperson for each

Committee shall alternate each Calendar Year between a representative of Agios and a representative of Celgene. The initial chairperson for each Committee is indicated on Exhibit H. Within fifteen (15) Business Days 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 Consent, such minutes within fifteen (15) Business Days following circulation.

(b) Committee Meetings.

(i) The JSC, JPC and JDC shall hold an initial meeting within [**] days of the Effective Date or as otherwise agreed by the Parties. Thereafter, each Committee shall meet at least once every Calendar Quarter, unless the respective Committee members otherwise agree. All Committee meetings shall be conducted in person, unless otherwise determined by the applicable Committee by Mutual Consent.

(ii) 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 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 XI; 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.

Section 2.8 Decision Making.

- (a) Committee Voting. All decisions of a Committee 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 [**] Business Days 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) Referrals from JDC or JCC to JSC. 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 [**] Business Days 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) Referrals from the JSC to Executive Officers. 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 [**] Business Days 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 [**] Business Days after the matter is referred to them, then, subject to Section 2.8(c):
- (i) if the unresolved matter relates to the Development of the Licensed Products, including Agios Clinical-Scale Manufacturing Responsibilities and Celgene Manufacturing Responsibilities during Development and Regulatory Interactions in a geography until Regulatory Approval for such geography, neither Party shall have final decision-making rights with respect to such matter and neither Party may take action with respect to the unresolved matter unless and until resolved by Mutual Consent;
- (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, provided that 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), Agios shall have the right to decide the unresolved matter for the US Territory except for the matters specified in subsection (ii)(B) above, provided that Agios shall give due consideration to any comments or preferences expressed by Celgene with respect to such matter and (B) Celgene, if applicable pursuant to Section 6.3(f), shall have the right to decide the unresolved matter for the US Territory.
- (e) <u>JPC</u>. If the JPC is unable to decide, by unanimous vote, on any matter within [**] Business Days after the matter is first raised with the JPC, then the matter will be referred to the Vice President of Intellectual Property, Chief Patent Counsel of Celgene and the Vice President of Legal of Agios (each, a "<u>JPC Designee</u>") for resolution. If such matter is not resolved by such JPC Designees of the Parties within [**] Business Days after the matter was referred to them, then the JPC Designees shall submit such matter for attempted resolution by agreement of the Executive Officers. If the Executive Officers are unable to resolve any matter referred to them by the JPC Designees within [**] Business Days after the matter is referred to them, then, subject to Section 2.8(f), a Party may exercise its rights to decide the matter as provided in Article X. 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 Patent Rights 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. Notwithstanding the foregoing, neither Party shall have the right to finally resolve a dispute pursuant to Section 2.8(d)(ii) or (iii) or 2.8(e):
 - (i) in a manner that excuses such Party from any of its obligations specifically enumerated under this Agreement;
 - (ii) in a manner that negates any consent rights or other rights specifically allocated to the other Party under this Agreement;
 - (iii) to resolve any dispute involving the breach or alleged breach of this Agreement;
 - (iv) to resolve any dispute regarding whether a milestone event set forth in Section 9.3 has been achieved;
- (v) to resolve a matter if the provisions of this Agreement specify that mutual agreement of the Parties or a Mutual Consent is required for such matter; or
 - (vi) in a manner that would require the other Party to perform any act that is inconsistent with any Law.

Section 2.9 Finance Working Group.

- (a) Establishment. Within [**] days after the Effective Date, the Parties shall establish the Finance Working Group. The Finance Working Group shall include individuals from each Party with reasonable expertise in the areas of accounting, cost allocation, budgeting financial reporting and tax. Membership and governance of the Finance Working Group shall be as set forth in Section 2.7 as if the Finance Working Group were a Committee for the limited purpose of such Section. The Parties intend that the Finance Working Group shall have the responsibility for the matters set forth in subsection (b) of this Section 2.9 with respect to the US Territory and for coordinating with the Finance Working Group from the AGI-23088 ROW Territory Agreement on such matters.
- (b) <u>Duties</u>. The purpose of the Finance Working Group is to provide financial information as requested to the JDC and JSC with respect to the Development of the Licensed Products, to the JCC and JSC with respect to the Commercialization of the Licensed Products, and to the JSC with respect to the preparation and approval of US Territory Profit or Loss statements in accordance with the provisions of Section 9.4 and <u>Exhibit E</u> to this Agreement (the "<u>Financial Exhibit</u>"). The Finance Working Group will also develop procedures for quarterly reporting of actual results and review and discussion of potential discrepancies, quarterly reconciliation, reasonable forecasting and for each Party's review of the applicable books and records of the other Party, as well as other finance, tax and accounting matters, to the extent not set forth in the provisions below or in the Financial Exhibit (the "<u>Reconciliation Procedures</u>"). Such procedures must be established in a manner that provides the ability to comply with financial reporting requirements of each Party. The Finance Working Group shall be responsible for:
- (i) coordinating and conducting the accounting, reporting, reconciliation and other related activities set forth in this Agreement and the Financial Exhibit;

- (ii) advising and providing support to the JSC and the other Committees with respect to financial, accounting, tax, budgeting, reporting and other issues that may arise in connection with the various plans and corresponding budgets for activities thereunder;
 - (iii) reviewing relevant FTE Costs and Out-of-Pocket Costs incurred by the Parties and their Affiliates hereunder;
 - (iv) recommending for approval by the JSC any changes to reporting procedures;
- (v) coordinating or performing the budgeting, consolidation, completion and review of Development Cost and US Territory Profit or Loss statements in accordance with the Reconciliation Procedures and the Financial Exhibit, including budgeting and calculation of expenses not covered in the Development Budget or the Commercialization Budget;
- (vi) establishing the overall FTE Rate to be applied to each FTE devoted to Commercialization on a country-by-country basis at least [**] months prior to commencement of Commercialization activities (including pre-launch activities) and annually thereafter in connection with updates to the Commercialization Plan; such overall FTE Rate for a country to be set in consideration of the wages and salaries, employee benefits, bonus, automobile allowance, meal expenses, travel/housing for meetings, dues, subscriptions, meetings and purchased services (including training, recruitment, communications, repairs and maintenance, and contractors), and other incidental expenses incurred by each such FTE in the ordinary course of employment and other things as may be determined by the JCC;
- (vii) performing and reviewing calculations for the reconciliation of payments, and controlling and performing such other accounting functions as provided in the Financial Exhibit;
- (viii) coordinating audits pursuant to Section 9.8 by Audit Teams, and discussing and attempting to resolve discrepancies or issues arising from such audits;
- (ix) performing such other functions as are specifically designated to the Finance Working Group in this Agreement or the Financial Exhibit, or as the Parties otherwise agree are appropriate to further the purposes of this Agreement;
- (x) working with the JSC, JDC and JCC to assist in financial, accounting, tax, budgeting and planning matters if and as requested by the respective Committee, and providing periodic updates to the JSC, JDC (if requested) and JCC on financial matters relating to this Agreement, and performing such other financial matters as are delegated to it under this Agreement or by the JSC, JDC and JCC; and
 - (xi) making such decisions and determinations as are assigned to it under this Agreement.

Section 2.10 Scope of Governance. Notwithstanding the creation of each of the Committees and the Finance Working Group, each Party shall retain the rights, powers and discretion granted to it under this Agreement, and neither any Committee nor the Finance Working Group 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, and (except with respect to Section 2.9(b)(vi)) that the Finance Working Group has no decision making authority whatsoever.

Section 2.11 Agios Participation. Notwithstanding anything in this Article II to the contrary, at any time, Agios shall have the right, but not the obligation, to participate in, and may elect not to appoint members to, any given Committee, the Finance Working Group, subcommittee or project team. If Agios elects not to participate in, or does not appoint members to, any Committee, 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, including decisions requiring Mutual Consent; provided that Celgene's sole discretion all decisions of such Committee, subcommittee, or project team, including decisions requiring Mutual Consent; provided that Celgene shall not unilaterally discharge the roles of such Committee, subcommittee or project team, as applicable, as permitted under this Article II unless Agios has not appointed any members within [**] days 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; provided that such Committee, subcommittee or project team shall not thereafter repeal prior decisions made by Celgene when Celgene was unilaterally discharging such role.

Section 2.12 Agios Opt-Out.

(a) Opt-Out Notice and Date. Without it being a breach of Article VII, following the first anniversary of the Effective Date, Agios shall have the right, effective upon twelve (12) months' prior written notice (which notice shall may not be given prior to the first anniversary of the Effective Date), to elect to opt-out of its Development, Manufacturing and Commercialization rights and the sharing of Development Costs and US Territory Profit or Loss under both this Agreement and the AGI-23088 ROW Agreement (such notice, the "Agios Opt-Out Notice", the effective date of such Agios Opt-Out Notice, subject to Section 2.12(b), being the expiration of such 12-month period, the "Agios Opt-Out Date"; provided, however, that Agios may not, without consent of Celgene, provide any such notice (x) within [**] months after any Regulatory Authority or the other Party has provided to any Committee or Agios any notification under Section 5.4 that a recall, market withdrawal or similar action may be required with respect to any Licensed Product or (y) within [**] months after any Committee or Agios receives knowledge of any Third Party Products Liability Action.

(b) Effects of Agios Opt-Out Notice or 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;
- (ii) effective as of the Agios Opt-Out Date, all decisions relating to Development, Manufacturing or Commercialization that require decision by a Committee or that are subject to Mutual Consent shall be made solely by Celgene and all decisions for which Agios was provided with final decision-making authority under Section 2.8 or Article 10 shall be made solely by Celgene; provided that Celgene shall exercise any such decision-making authority in a manner consistent with a commitment of Commercially Reasonable Efforts to the Development and Commercialization of the Licensed Products in the US Territory; provided, further, that if Celgene or its Affiliate propose(s) to take or take(s) any action not contemplated by the Development Plan in effect on the Agios Opt-Out Date, and that Agios reasonably determines is reasonably likely to have a material adverse impact on the Commercialization of any of the "Licensed Products," as such term is defined in the 2010 Agreement, then Agios shall provide written notice to such effect to Celgene specifying in reasonable detail which actions by Celgene or its Affiliates would have such an effect, and what such effect would be. The Parties shall use good faith efforts to discuss the pertinent actions and resolve the matter. If Celgene concurs with Agios' determination, Celgene and its Affiliates shall not proceed with, or shall cease as quickly as reasonably possible, as applicable, such action without the written consent of Agios. If Celgene does not concur with Agios' determination, Celgene may present the issue to the Executive Officers for resolution pursuant to Section 15.1(a) and, if agreement is not reached, may seek resolution of such matter in accordance with Section 15.1(b);
- (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 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 Sections 5.4, 13.3 and 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 and cease to incur any further Development Costs or Commercialization Expenses except as approved by Celgene or as provided in Sections 5.4, 13.3 and 13.4;

(vii) within [**] days 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 Sections 9.2 and 9.4;

- (viii) within [**] days 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, and Agios shall provide to Celgene an update to such summary within [**] days after the Agios Opt-Out Date;
- (ix) 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 Agios' sole expense, including those activities referenced in Section 14.3(b)(viii), all of which must be completed 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 Celgene requests that any contracts or agreements that extend beyond the Agios Opt-Out Date be terminated, Agios and Celgene shall share all costs associated with such termination, and, (B) if Celgene requests that any such contract or agreement remain in effect, Celgene shall be responsible for all Development Costs and Commercialization Expenses under such contract or agreement following the Agios Opt-Out Date or, if Celgene requests assignment of such contract or agreement prior to the Agios Opt-Out Date, following such assignment (whichever is earlier);
- (x) 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;
- (xi) 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;
- (xii) 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 or AIS within Agios Intellectual Property that is both 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 shall be completed before the Agios Opt-Out Date;

(xiii) 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 US Territory Profit or Loss under Section 9.4;

(xiv) as quickly as reasonably possible but in no event later than the Agios Opt-Out Date, Agios shall transition to Celgene Agios' initial Prosecution and enforcement responsibilities with respect to Agios Patent Rights, Agios Collaboration Patent Rights, Joint Inventions and Joint Patents, and provide reasonable assistance to Celgene and cooperation in connection therewith, including execution of such documents as may be necessary to effect such transition, provided that Agios shall retain step-in rights under Section 10.2(b) as well as comparable step-in rights on Prosecution matters relating to Agios Patent Rights and Agios Collaboration Patent Rights that are not Joint Patents but not under Section 10.3; and

(xv) The AGI-23088 ROW Agreement will be affected in a corresponding manner as provided therein.

Article III Development

Section 3.1 Development of Licensed Products.

- (a) <u>Development Plan and Changes</u>. Once the Development Plan has been mutually agreed, the Parties shall undertake the Development of Licensed Products on a worldwide basis in accordance with the Development Plan, including the [**] budget of Development Costs ("<u>Development Budget</u>"). The JDC may propose changes to the Development Plan to the JSC. The Development Plan may be amended from time to time only by Mutual Consent of the JSC.
- (b) <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, <u>provided that</u> if Agios so desires, the Development Plan shall specify that Agios shall be responsible for conducting all Phase I Studies of the Licensed Product in the Territory. For purposes of clarity, except as provided in Section 3.3, neither Party shall undertake any Development activities relating to the Licensed Products that are not specifically allocated to such Party in the Development Plan.
- (c) <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 Development Activities 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 all other Major Markets and such other countries as the JSC deems appropriate.
- (d) Coordination and Reports. 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 [**] 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 [**]), 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; provided that, 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 in accordance with Section 9.2.
- Section 3.3 <u>Additional Development Activities</u>. Subject to Section 2.12, each Party shall be permitted (i) to undertake Development activities (including Clinical Trials) not contemplated by the Development Plan (for example, a Clinical Trial for an Indication not included in such plans) or (ii) to repeat any Clinical Trial previously conducted under the Development Plan that failed to meet its primary endpoints (collectively, "<u>Additional Development Activities</u>"); <u>provided that</u> such Party complies with the provisions of this Section 3.3.
- (a) Additional Development Proposals. If a Party desires to undertake Additional Development Activities, such Party shall submit to the JDC a proposal for the addition of such Additional Development Activities to the Development Plan (an "Additional Development Proposal"). Each Additional Development Proposal for Additional Development Activities shall include a general description of the Development activities including, as applicable, study design, clinical study endpoints, clinical methodology and monitoring requirements, and the funding budget. If the JDC approves an Additional Development Proposal, such Additional Development Proposal shall, within [**] days, be submitted to the JSC for review and approval.

(b) Inclusion of Additional Development Activities in the GDP. If the JSC approves an Additional Development Proposal, the Development Plan shall be deemed to be amended to include the Additional Development Activities and associated budget upon approval of such Additional Development Proposal by the JSC. For the sake of clarity, all Development Costs incurred by the Parties and their Affiliates in performing such Additional Development Activities shall be shared by the Parties in accordance with Section 9.2.

(c) Independent Performance of Additional Development Activities. If the JDC does not approve an Additional Development Proposal within [**] days after its submission to the JDC, or the JSC does not approve an Additional Development Proposal within [**] days after its submission to the JSC, then the Party that submitted the Additional Development Proposal (the "Additional Development Party") may, upon notice to the other Party, conduct the relevant Additional Development Activities in accordance with the Additional Development Proposal at its own expense; provided, however, that, if the other Party (the "Non-Additional Development Party") determines reasonably and in good faith that any of the proposed Additional Development Activities is reasonably likely to adversely affect the Development, Manufacturing or Commercialization of any of the Licensed Products or "Licensed Products" as such term is defined in the 2010 Agreement, then the Additional Development Party shall not undertake such Additional Development Activities unless and until the JDC or JSC determines that such Additional Development Activities should be permitted. Additional Development Activities undertaken by the Additional Development Party shall be subject to the oversight of the JDC and, except as expressly set forth in this Section 3.3(c), subject to all terms and conditions of this Agreement relating to Development of Licensed Products (including the license grants in Article VIII). For clarity, a Licensed Product that is the subject of Additional Development Activities shall continue to be a "Licensed Product" for all purposes of this Agreement. The Additional Development Party shall provide informal reports of its progress with regard to the Additional Development Activities at each meeting of the JDC and shall provide formal written reports of the results and budgeted costs of the Additional Development Activities to the JDC at least [**] during the first [**] months in which any Clinical Trial within the Additional Development Activities is being performed, and otherwise in the same manner and frequency as the Parties provide reports to the JDC with respect to activities covered by the Development Plan. If, at any time after the commencement of an Additional Development Activity, the Non-Additional Development Party determines reasonably and in good faith that any Additional Development Activity is reasonably likely to adversely affect the Development or Commercialization of the Licensed Products or "Licensed Products" as such term is defined in the 2010 Agreement, the Non-Additional Development Party shall so notify the Additional Development Party and such Additional Development Activity shall be promptly discontinued (subject to such ethical obligations to continue support of patients already enrolled in Clinical Trials, as the Additional Development Party may in good faith determine) unless and until the JDC or JSC determines that such Additional Development Activities should be permitted to continue.

(d) <u>Costs of Additional Development Activities</u>. The Additional Development Party shall bear all costs associated with the Additional Development Activities it

undertakes and such costs shall not be taken into account as Development Costs for purposes of Section 9.2. If the JSC determines, by Mutual Consent, to include Data generated from such Additional Development Activities (excluding only safety Data) for label expansion purposes in a submission for Regulatory Approval for a Licensed Product or for other specific commercial purposes, the Non-Additional Development Party shall reimburse the Additional Development Party an amount equal to [**] percent ([**]%) of the costs incurred by the Additional Development Party for the Additional Development Activities (to the extent not previously reimbursed pursuant to Section 3.3(e)). Such costs will be determined using the same manner of calculating Development Costs under the Development Plan.

- (e) Opt-In for Additional Development Activities. In the event that the Non-Additional Development Party elects, in its discretion and upon written notice to the Additional Development Party (an "Additional Development Opt-In Notice"), on a Clinical Trial-by-Clinical Trial basis, to opt in with respect to a given Clinical Trial within the Additional Development Activities, then:
- (i) such Clinical Trial shall be deemed to be included in the Development Plan from and after the date on which such Additional Development Opt-In Notice is received by the Additional Development Party (the "Additional Development Opt-In Date");
- (ii) the then-current plan and budget of the Additional Development Party with respect to such Clinical Trial shall be deemed to be included within and part of the Development Plan from the Additional Development Opt-In Date, and shall control with respect to such Clinical Trial unless and until an amendment to the Development Plan providing for a different or modified plan and budget is approved by the JSC;
- (iii) the Out-of-Pocket Costs and FTE Costs associated with such Clinical Trial incurred after the Additional Development Opt-In Date shall be treated as Development Costs and shared by the Parties in accordance with Section 9.2; and
- (iv) the Non-Additional Development Party shall reimburse the Additional Development Party an amount equal to [**] percent ([**]%) of the costs incurred prior to the Additional Development Opt-In Date by the Additional Development Party and its Affiliates for such Clinical Trial (to the extent not previously reimbursed pursuant to Section 3.3(d)). Such costs will be determined using the same manner of calculating Development Costs under the Development Plan.

Section 3.4 Companion Diagnostics.

(a) <u>Development of Companion Diagnostic</u>. The Parties may mutually agree to Develop and/or Commercialize a Companion Diagnostic for use with the Licensed Products; <u>provided that</u>, 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 Patent Rights, Celgene Patent Rights and Collaboration Patent Rights, and each of the licenses granted to a Party under Section 8.1 or 8.2; and (ii) all costs and profits with respect to such Development or Commercialization of the Companion Diagnostic shall be shared equally by the Parties 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 Sections 9.3 through 9.5 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 14.3, 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 Patent Rights necessary for the Development, Manufacture and/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 Patent Rights otherwise associated with such Licensed Products are transferred.
- (c) No Other Diagnostics. 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 and/or Commercialize any biomarker or diagnostic product for use with the Licensed Products, other than a Companion Diagnostic pursuant to this Section 3.4.

Section 3.5 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 [**] years (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 [**]-year 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[**] copies of all Agios Know-How and Agios 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[**] copies of all Celgene Know-How and Celgene 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) Agios Responsibilities. Agios shall be responsible for Manufacturing, or having Manufactured by its designee, (i) all pre-clinical supply of Licensed Products, (ii) all supply of Licensed Products for Phase I Studies, (iii) all active pharmaceutical ingredients for all Phase II Studies and Phase III Studies (collectively, items (i), (ii) and (iii), the "Agios Clinical-Scale Manufacturing Responsibilities"), and (iv) all active pharmaceutical ingredients for Commercialization of Licensed Products (the "Agios Commercial-Scale Manufacturing Responsibilities"). Agios shall fulfill a substantial portion of the Agios Commercial-Scale Manufacturing Responsibilities from within, and ship all such Licensed Products and active pharmaceutical ingredients to Celgene from, Agios' or its designee's manufacturing facility located in Switzerland or another country mutually agreed in writing by the Parties such that the Licensed Products are treated as manufactured in Switzerland or such other country 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 Celgene disagrees that the fulfillment of the Agios Manufacturing Responsibilities is such that the Licensed Products are so treated, Agios shall deliver to Celgene an opinion of an independent nationally recognized law or accounting firm that the Licensed Products should be so treated.

(b) Agios Commercial-Scale Manufacturing Responsibilities. 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 upon which Celgene and Agios are Affiliates, and (ii) a Change of Control of Celgene, Agios shall notify Celgene at least [**] months 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 Section 4.1(a).

- (c) Celgene Responsibilities. Celgene shall be responsible for Manufacturing, or having Manufactured by its designee, all supply of Licensed Products not included within Agios Clinical-Scale Manufacturing Responsibilities and Agios Commercial-Scale Manufacturing Responsibilities, including drug product manufacturing and processing, filling, packaging, labeling, shipping and storage of Licensed Products for all Clinical Trials (other than Phase I Studies) and for Commercialization of Licensed Products (collectively, the "Celgene Manufacturing Responsibilities"). Celgene shall fulfill a substantial portion of the Celgene Manufacturing Responsibilities from within Celgene's or its designee's manufacturing facility located in Switzerland or another country mutually agreed in writing by the Parties such that the Licensed Products are treated as manufactured in Switzerland or such other country 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 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 if Agios disagrees that the fulfillment of the Celgene Manufacturing Responsibilities is such that the Licensed Products are so treated, Celgene shall deliver to Agios an opinion of an independent nationally recognized law or accounting firm that the Licensed Products should be so treated.
- (d) <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.
- Section 4.2 <u>Third Party Manufacturers</u>. If either Party uses any Third Party to fulfill its Manufacturing obligations or rights under Section 4.1 with respect to 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 2.8.
- 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 or AIS 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, if deemed necessary by the JDC or JCC, as applicable, the establishment of an alternative supply source. Such Party 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 and/or Commercialize, as applicable, such Licensed Products as contemplated under the applicable Development Plan and/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) <u>Lead Responsibility</u>. Agios shall have the initial lead responsibility for all Regulatory Interactions with Regulatory Authorities in the US Territory with respect to each Licensed Product unless and until there is a transfer thereof to Celgene as provided in Section 5.1(c). Celgene shall have lead responsibility for all Regulatory Interactions with Regulatory Authorities in the US Territory for the applicable Licensed Product after any such transfer to the extent set forth in Section 5.1(c). The JDC may propose to the JSC a different allocation for the roles of each Party for all Regulatory Interactions in the US Territory but such roles may only be changed by Mutual Consent of the JSC.
- (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 in the US Territory with respect to the Licensed Products and (ii) interfacing, corresponding and meeting with the Regulatory Authorities in the US Territory with respect to the Licensed Products.
- (c) <u>Transfer of Regulatory Responsibility in US Territory</u>. At any time after either an Agios Opt-Out Notice or the date that is [**] days prior to the expected commencement of a Phase III Study for a Licensed Product, Celgene may notify Agios that Celgene desires to take over lead responsibility for the Regulatory Interactions in the US Territory for such Licensed Product. Upon and after such notice from Celgene:
- (i) Agios shall (1) at Celgene's option, either close or inactivate Agios' IND(s) for such Licensed Product, or transfer such IND(s) to Celgene, and (2) with Celgene input, complete all relevant activities related to such IND as required for Celgene to assume regulatory ownership, as applicable, all within [**] days 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.

If Celgene does not provide notice to Agios in accordance with this Section 5.1(c) that Celgene desires to take over lead responsibility for the Regulatory Interactions in the US Territory associated with a Licensed Product, Agios shall retain lead responsibility for all Regulatory Interactions in the US Territory with respect to such 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 (*i.e.*, initially the US Territory if the responsible Party is Agios, or the ROW Territory if the responsible Party is Celgene), 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, Agios shall initially be responsible for the Global Safety Database for the Licensed Products, and Celgene 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 Celgene pursuant to Section 5.1(c). 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 together with

CIS II and AIS 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 together with CIS II and AIS no later than the completion of the first Phase I Study of a Licensed Product.

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 US 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 US 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 [**] hours advise the other Party thereof by telephone or facsimile. The JSC shall decide whether to conduct a recall, market withdrawal or similar action in any portion of the US 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 Parties, 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 US Territory shall be taken into account in determining US Territory Profit or Loss as, and to the extent, provided in the Financial Exhibit. 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 US 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 and the costs and expenses for such recall, market withdrawal or similar action and (ii) the event, incident or circumstance and 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 US Territory shall be borne fifty per cent (50%) by each of the Parties 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 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 [**] days of receipt of invoice.

Article VI Commercialization

Section 6.1 Commercialization Responsibilities for Licensed Products.

(a) <u>Responsibility</u>. Subject to oversight by the JCC and to Sections 2.8, 2.12 and 6.3(f), each Party shall have the responsibility for the Commercialization of Licensed Products in the US Territory as specified in the Commercialization Plan.

- (b) Effects on Licensed Product and "Licensed Products" Under 2010 Agreement. If (i) either Party or its Affiliate (the "Proposing Party") proposes to take or take(s) any Commercialization action (or make any business decision) that is not contemplated by the Commercialization Plan in effect at such time, that the other Party (the "Objecting Party") reasonably determines is reasonably likely to have a material adverse impact on the Commercialization of any of the "Licensed Products," as such term is defined in the 2010 Agreement or (ii) Agios or its Affiliate proposes to take any such action that Celgene or its Affiliate reasonably determines is reasonably likely to have an adverse impact on Commercialization of the "Licensed Products," as such term is defined in the AGI-23088 ROW Agreement, in the ROW Territory, such Objecting Party (and its Affiliate, if applicable) shall provide written notice to such effect to the Proposing Party specifying in reasonable detail which actions by such Proposing Party or its Affiliates would have such an effect, and what such effect would be. The Parties shall use good faith efforts to discuss the pertinent actions and resolve the matter. If the Proposing Party concurs with the Objecting Party's determination, the Proposing Party and its Affiliates shall not proceed with, or shall cease as quickly as reasonably possible, as applicable, such action without the written consent of the Objecting Party. If the Proposing Party does not concur with the Objecting Party's determination, the Objecting Party may present the issue to the Executive Officers for resolution of such matter in accordance with Section 15.1(b). If the Objecting Party does present the issue to the Executive Officers for resolution, then Proposing Party and its Affiliates shall not proceed with, or shall cease as quickly as reasonably possible, as applicable, such action until the dispute is resolved by agreement of the Executive Officers or in accordance with Section 15.1(b).
- (c) <u>Sales</u>. Celgene will book all sales of the Licensed Products in the US 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 Commercialization Plan.

(a) Initial Commercialization Plan.

- (i) Subject to Sections 2.8 and 2.12, Commercialization of Products shall be governed by a Commercialization Plan (the "Commercialization Plan") that describes the Commercialization activities (including pre-launch and launch activities, if applicable) to be undertaken with respect to the Licensed Products in the US Territory, which shall include an [**] budget of Commercialization Expenses ("Commercialization Budget") and anticipated timelines for performance.
- (ii) Commencing no later than [**] months prior to the anticipated commercial launch of the first Licensed Product in the US Territory and thereafter at least [**] days prior to the start of each Calendar Year, Agios shall prepare the initial Commercialization Plan for each Licensed Product, with input and guidance from the JDC, JCC and the Finance Working Group. Such Commercialization Plan shall describe Commercialization activities to be undertaken by the Parties in the US Territory.

(b) JCC Approval; Amendments. The JCC shall approve the first Commercialization Plan for each Licensed Product no later than [**] prior to the anticipated commercial launch of each such Licensed Product in the US Territory. Thereafter, the JCC shall review the Commercialization Plan not less frequently than [**] and shall propose updates to the Commercialization Plan for [**]. Either Party may also develop and submit to the JCC for review from time to time other proposed amendments to the applicable Commercialization Plan. The initial Commercialization Plan, and any amendments and updates to the Commercialization Plan, shall be effective upon the approval of the JCC (subject to resolution of any dispute involving such approval as provided in Section 2.8).

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 US Territory (*e.g.*, sales force (and the number of physicians to be called on and call frequency), field-based medical affairs, advertising, and field-based market access resources) (collectively, "<u>Marketing Activities</u>"), and the Commercialization Plan for each Licensed Product in the US Territory shall set forth such Marketing Activities for each Indication which is marketed in the US Territory.
- (b) Allocation of Activities. The Commercialization Plan will allocate to each Party its portion of the total Marketing Activities for each Licensed Product in the US Territory; provided that, unless otherwise agreed to by the Parties, each Party will be allocated fifty percent (50%) of the Marketing Activities in the US Territory, 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 US Territory in a manner reasonably consistent with the distribution of the population in the US Territory 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 customer base and call volume measured against the customer base, geographic scope of activities, and the competitive market for the Licensed Product.
- (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 US Territory for each Licensed Product. Each Party, in its sole discretion, shall create a field management structure for its sales effort. Each Party shall use Commercially Reasonable Efforts to have hired, no later than [**] months before the applicable PDUFA date, the full sales force planned to be available for the launch of the Licensed Products in the US Territory and to have the sales force trained within [**] months of hiring. 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 but avoiding sales representatives detailing the same persons). 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; provided that the Commercialization Plan shall identify the portion of the detailing effort to be undertaken by each Party in the US Territory no later than [**] months before the planned date of the NDA submission in the US Territory.

- (d) <u>Training Materials and Sessions</u>. 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 US Territory. The JCC will develop a sales training program directed towards the Licensed Products use in the US Territory. 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. 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 US Territory. As requested by Agios, Celgene shall make its management, marketing, training and other personnel reasonably available to participate in Agios' national and regional sales meetings and Licensed Product training events for the US Territory.
- (e) Other Obligations. Subject to Section 2.12, in conducting the Marketing Activities in the US Territory, the Parties will comply with all applicable Laws, applicable industry professional standards and compliance policies of Celgene, and, subject to Section 6.3(f), Agios, 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 or otherwise approved by the JCC.
- (f) <u>Termination of Marketing Activities</u>. Agios shall have the right to terminate its Marketing Activities obligations in the US Territory with respect to any Licensed Product by providing at least [**] months' 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 [**]-month (or, if applicable, shorter) notice period, Agios' obligations to perform Marketing Activities under this Section 6.3 in the US Territory shall terminate, and Celgene's obligation under the first sentence of Section 6.3(e) to comply with Agios compliance policies, shall terminate (but, for clarity, Celgene's other obligations under such first sentence shall not 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 Trademarks.

(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 US 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 US Territory hereunder, to the extent permitted by Law.

- (b) Ownership. Agios shall own all Product Trademarks for any Licensed Product in the US Territory. Effective as of the Agios Opt-Out Date, Agios hereby assigns to Celgene all right, title and interest in and to the Product Trademarks in the US Territory 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>Agios Acknowledgement and License</u>. In connection with all packaging, literature, labels and other printed matters used in the US Territory, to the extent permitted by Law, the Parties shall include an expression to the effect that the Licensed Products were developed under license from Agios, together with the Agios logo. Agios hereby grants Celgene a license to use Agios' name and logo to comply with such obligation and in the Product Trademarks for the US Territory as reasonably required for Celgene to exercise its rights and perform its obligations under this Agreement in the US Territory.

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 Diligence Obligations.

- (a) In addition to the diligence obligations set forth in Section 7.1, the Parties shall use Commercially Reasonable Efforts to Develop and achieve Regulatory Approval for the Licensed Products in each of the Major Markets and, following such Regulatory Approval, to Commercialize such Licensed Products in each of the Major Markets.
- (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 14.2(b)(i). Notwithstanding the foregoing, the Parties acknowledge that it might be commercially reasonable, under certain circumstances, for the Party having lead responsibility for Marketing Activities in any portion of the Major Markets to determine not to launch a Licensed Product in [**] Major Markets, 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 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 License Grants. Subject to the terms and conditions of this Agreement:

- (a) <u>Licenses Granted to Celgene</u>. Agios hereby grants to Celgene a non-transferable (except as set forth in Section 15.4), right and license in the Field, with the right to grant sublicenses as set forth in Sections 8.2(a) and 8.2(b), under Agios' rights in Agios Intellectual Property and Agios Collaboration Intellectual Property, to Develop, Manufacture and/or Commercialize Licensed Products in the US Territory. Such license is a Sole license until the Agios Opt-Out Date; upon and after the Agios Opt-Out Date, such license automatically converts to an exclusive license (including exclusive of Agios and its Affiliates).
- (b) <u>Licenses Granted to Agios</u>. Celgene hereby grants to Agios a Sole, non-transferable (except as set forth in Section 15.4), right and license in the Field, with the right to grant sublicenses as set forth in Sections 8.2(a) and 8.2(b), under Celgene's rights in Celgene Intellectual Property and Celgene Collaboration Intellectual Property, to Develop, Manufacture and/or Commercialize Licensed Products in the US Territory.
 - Section 8.2 Sublicense Rights. 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 engaging Third Parties as contract research organizations, contract manufacturers, contract sales forces, consultants, academic researchers and the like ("<u>Third Party Contractors</u>") in connection with Development, Manufacturing or Commercialization activities on behalf of such Party or its Affiliates with respect to the Collaboration under this Agreement, subject to the following:
- (A) unless otherwise agreed by the JSC by Mutual Consent, 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 agreed by the JSC by Mutual Consent, each Party will obligate such Third Party to agree in writing to [**] 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 in the US Territory; and such Party shall structure such [**] 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 to research either or both of the Targets, each Party will only be required to obligate such academic collaborator to agree in writing to grant [**] to, and a right to negotiate for [**] to, any such inventions, which must be sublicensable 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 agreed by the JSC by Mutual Consent, each Party will require any such Third Party to grant to the other Party access to [**] 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 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 Sublicense Requirements. Any sublicense granted by a Party pursuant to this Agreement shall be subject to the following:

(a) each sublicense granted hereunder by a Party 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; provided that such Party shall remain responsible for the activities of its Affiliate;
- (c) a Party's or its Affiliates' Third Party sublicensees 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 sublicensees to comply with all relevant restrictions, limitations and obligations in this Agreement;
- (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 [**] days after the execution of such sublicense agreement; provided that any such copy may be 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
- (f) except as otherwise provided in the sublicense agreement, if this Agreement terminates for any reason, any Third Party sublicensee of a Party shall, from the effective date of such termination, automatically become a direct licensee of the other Party with respect to the rights licensed to such Party hereunder and sublicensed to the sublicensee by such Party; provided, however, that such sublicensee is not in breach of its sublicense agreement and continues to perform thereunder.
- Section 8.4 Affiliates and Third Party Contractors. 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 Existing Third Party Agreement.

(a) <u>Acknowledgement</u>. Except as provided in Section 8.5(b), Agios acknowledges that it is responsible for the fulfillment of its obligations under the 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 nature of such rights, subject to Celgene's compliance with its obligations hereunder. In the event of any conflict between the terms of this Agreement and the Existing Third Party Agreement, the Parties will discuss in good faith how to address the conflict; <u>provided that</u>, if the Parties are unable to agree on how to address the conflict, the terms of this Agreement shall govern.

(b) Incorporation of Certain Provisions. Celgene acknowledges and agrees that it shall be bound by the following provisions of the Existing Third Party Agreement, as a sublicensee of the rights licensed to Agios thereunder but only to the extent applicable to the rights sublicensed to Celgene hereunder: Sections 1.3 (as described in Section 8.7(b) hereof), 2.1, 2.3, 5.2, 5.3, 5.4, 5.5, 6.2, 7.1, 8.1 (with respect to information of the licensors under the [**] Agreement or with respect to the licensors' obligation to keep information of either Party confidential), 10.1 and 10.4 of the [**] Agreement. Furthermore, Celgene acknowledges that Agios is required to share certain reports and copies of sublicense agreements provided by Celgene to Agios hereunder with the licensors under the 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(b) (ii)(B) hereunder; provided that any such copies of sublicense agreements must be redacted to the extent permitted under such Existing Third Party Agreement.

(c) Covenants Regarding the Existing Third Party Agreement. Agios agrees that during the Term:

- (i) Agios shall not modify or amend the Existing Third Party Agreement in any way without Celgene's prior written consent;
- (ii) Agios shall not terminate the Existing Third Party Agreement, in whole or in part, without Celgene's prior written consent;
- (iii) Agios 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 the licensors under and pursuant to the Existing Third Party Agreement;
- (iv) Agios shall not exercise or fail to exercise any of Agios' rights, or fail to perform any of Agios' obligations, under the 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 the 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 the Existing Third Party Agreement;
- (v) Agios shall promptly furnish Celgene with copies of all reports and other communications that Agios furnishes to the licensors under the Existing Third Party Agreement to the extent that such reports relate to this Agreement;
- (vi) Agios shall promptly furnish Celgene with copies of all reports and other communications that Agios receives from the licensors under the Existing Third Party Agreement that relate to the subject of this Agreement (including notices relating to improvements under the Existing Third Party Agreement);
- (vii) Agios shall furnish Celgene with copies of all notices received by Agios relating to any alleged breach or default by Agios under the Existing Third Party Agreement within [**] Business Days after Agios' receipt thereof; in addition, if Agios should at any time breach the Existing Third Party Agreement or become unable to timely perform its obligations thereunder, Agios shall immediately notify Celgene;

(viii) If Agios cannot or chooses not to cure or otherwise resolve any alleged breach or default under the Existing Third Party Agreement, (A) Agios shall so notify Celgene within [**] Business Days of such decision, which shall not be less than [**] Business Days prior to the expiration of the cure period under the 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 the Existing Third Party Agreement in accordance with the terms and conditions of the Existing Third Party Agreement or otherwise resolve such breach directly with the licensors under the Existing Third Party Agreement; and (C) if Celgene pays any such licensor any amounts owed by Agios under the Existing Third Party Agreement, Celgene may deduct 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

(ix) Agios shall not provide any Licensed Products to the licensors under the 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 the 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 licensors under such Existing Third Party Agreement and Agios shall use Commercially Reasonable Efforts to assist Celgene in exercising such rights; <u>provided that</u> Celgene 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 the licensors under the Existing Third Party Agreement for a direct license. In the event of any such direct license following any termination of the Existing Third Party Agreement without Celgene's consent, Celgene shall be entitled to deduct from any payments owed to Agios hereunder [**] percent ([**]%) of 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 the Existing Third Party Agreement.
- (e) <u>Termination of Existing Third Party Agreement</u>. The Parties agree that termination, without Celgene's prior written consent, of the Existing Third Party Agreement with respect to any Patent Right 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 the Existing Third Party Agreement, Celgene agrees to use Commercially Reasonable Efforts to assist Agios in curing such breach of the Existing Third Party Agreement, and (ii) if Celgene's breach of this Agreement results in a termination of the Existing Third Party Agreement, such termination of the Existing Third Party Agreement shall not be deemed a material breach by Agios of this Agreement or AIS of the AGI-23088 ROW Agreement.

Section 8.6 Exclusivity.

- (a) <u>Agios Exclusivity Obligations</u>. During the Term, Agios and, subject to Sections 15.4(b) and 15.4(c), its Affiliates shall not, directly or indirectly, Develop, Manufacture or Commercialize any therapeutic modality (including any small molecule or biologic) in any field or application that [**], except for the following:
- (i) Licensed Products pursuant to the Collaboration under this Agreement (including those activities specifically permitted upon and after termination);
- (ii) Collaboration Compounds, Development Candidates, Licensed Compounds, Independent Compounds and products that contain any of the foregoing pursuant to the 2010 Agreement (as such terms are defined in the 2010 Agreement); and
- (iii) Agios Reverted Compounds (other than Agios Reverted Compounds that [**]) and Agios Reverted Products that contain any such Agios Reverted Compound, in each case pursuant to the 2010 Agreement (as such terms are defined in the 2010 Agreement).
- (b) <u>Celgene Exclusivity Obligations</u>. During the Term, Celgene and, subject to Sections 15.4(b) and 15.4(c), its Affiliates shall not, directly or indirectly, Develop, Manufacture or Commercialize any therapeutic modality (including any small molecule or biologic) in any field or applications that [**], except for the following:
 - (i) Licensed Products pursuant to this Agreement (including those activities specifically permitted upon and after termination); and
- (ii) Collaboration Compounds, Development Candidates, Licensed Compounds, Independent Compounds, Celgene Reverted Compounds and products that contain any of the foregoing in each case pursuant to the 2010 Agreement (as such terms are defined in the 2010 Agreement).
- (c) Exception. A Party shall not be deemed to be, directly or indirectly, Developing, Manufacturing or Commercializing in violation of the provisions of Section 8.6(a) or 8.6(b) as a result of conducting a research program or discovery effort (or 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 [**], as applicable, that are subject to the prohibitions of Section 8.6(a) or 8.6(b).
- (d) <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 2010 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) the [**]; (ii) the [**]; (iii) [**]; (iv) [**]; or (vi) [**].

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 Collaboration Intellectual Property and any other Patent Rights or Know-How of Agios and its Affiliates, are hereby retained by Agios and its Affiliates. Except as expressly provided in Sections 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 Patent Rights 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 the rights retained by the licensors under the [**] Agreement pursuant to Sections 1.3 and 2.3 of the [**] 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. 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>Initial Payment</u>. In consideration of Agios' discovery of AG-23088 and the rights and licenses granted hereunder, Celgene shall make an initial, non-refundable payment to Agios of [**] Dollars (US \$[**]) within [**] days following the Effective Date.

Section 9.2 Development Costs.

(a) Sharing of Development Costs. Subject to Section 2.12:

- (i) The Development Costs to be shared by the Parties under this Agreement and the parties to the AGI-23088 ROW Agreement are those (A) Development Costs that are incurred after the IND Acceptance Date and (B) Manufacturing Costs associated with clinical supply of Licensed Products (even if incurred before the Effective Date), and, in either case, that are within [**] percent ([**]%) of the approved Development Budget under the Development Plan. Any Development Costs in excess of [**] percent ([**]%) of the approved Development Budget 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. The Parties have determined the reasonably anticipated benefits share for purposes of Section 482 of the Code between the US Territory and ROW Territory to be derived from the Development activities and as a result each Party agrees to have it and its Affiliates allocate [**] percent ([**]%) of the Development Costs to the US Territory under this Agreement and the remainder of their portion of the Development Costs to the ROW Territory under the AGI-23088 ROW Agreement. Each Party shall be responsible for fifty percent (50%) of the Development Costs allocated to this Agreement.
- (ii) Within [**] days following the beginning of the [**], each Party shall prepare and deliver to the Finance Working Group a [**] report detailing its and its Affiliates' Development Costs incurred during the first [**], estimated to be incurred during the [**], and actually incurred in the [**] 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 [**] days after the other Party's receipt of such request. The Parties, with the assistance of the Finance Working Group, shall conduct a reconciliation of Development Costs for the subject [**] within [**] days 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 [**]. Such reconciliation shall balance the actual amount of Development Costs incurred during the [**] (to correct for any differences between the estimates and actual amount of such costs) together with the amounts incurred during the first [**] and those estimated to be incurred during the [**]. The paying Party shall pay all amounts payable under any such invoice within [**] days after its receipt of such invoice.
- (b) Annual Cost Cap. In the event that Agios' share of aggregate Development Costs in any given Calendar Year, including any such Development Costs that become due from Agios pursuant to Section 3.3(d) or 3.3(e) in such Calendar Year, plus Agios' share of US Territory Loss and AIS's share of ROW Territory Loss (as defined in the AGI-23088 ROW Agreement) for any Calendar Quarter in such Calendar Year, less Agios' share of US Territory Profit (if any) and AIS's share of ROW Territory Profit (if any) (as defined in the AGI-23088 ROW Agreement) for any Calendar Quarter in such Calendar Year, exceed a total of \$[**], then any such amounts for such Calendar Year that are in excess of \$[**] (the "Excess Amounts") shall be borne initially by Celgene and CIS II, and not by Agios or AIS, and the reimbursement calculations set forth in Section 9.2(a) for such Calendar Year shall be adjusted accordingly with [**] percent ([**]%) of the Excess Amounts being applied to the AGI-23088 ROW Agreement (and the reimbursement calculations in Section 9.2(a) of the AGI-230889 ROW Agreement) also being adjusted accordingly. Celgene may recoup the [**] percent ([**]%) of the Excess Amounts due under this Agreement, together with interest thereon

calculated at the rate set forth in Section 9.11, calculated on the number of days from the date on which Agios' payment of such Excess Amounts would otherwise be due to Celgene if this Section 9.2(b) did not apply until the date reimbursed to Celgene, from any milestone payments owed under Section 9.3 and Agios' share of US Territory Profits (if any) and AIS's share of ROW Territory Profits (if any) (as defined in the AGI-23088 ROW Agreement) in the Calendar Year in which the Excess Amounts accrued or thereafter until such Excess Amounts and applicable interest have been fully recouped (and the other [**] percent ([**]%) of such Excess Amounts, together with interest, will be recouped as provided in the AGI-23088 ROW Agreement). Excess Amounts and interest thereon shall be reimbursable only from such milestone payments and Agios' share of US Territory Profits (if any) and AIS's share of ROW Territory Profits (if any) (as defined in the AGI-23088 ROW Agreement), and shall not otherwise be owed from Agios to Celgene; provided, however, that in the event that the Development and Commercialization of all Licensed Products are permanently discontinued by Mutual Consent or this Agreement is terminated for any reason, then all Excess Amounts due under this Agreement shall be paid by Agios to Celgene in equal annual installments over the next [**]. Agios may in its discretion elect to pre-pay any portion of outstanding Excess Amounts or associated interest upon written notice to Celgene.

Section 9.3 <u>Milestone Payments</u>. Celgene shall pay Agios the following amounts after the first achievement by or on behalf of the Parties or their respective Affiliates or sublicensees of the corresponding milestone events set forth below with respect to the first Licensed Product to achieve such milestone events.

| Milestones | Amount |
|--|----------|
| (1) Filing of first NDA in a Major Market, whether such NDA is filed in the US Territory pursuant to | |
| this Agreement or in the ROW Territory pursuant to the AGI-23088 ROW Agreement | US\$[**] |
| (2) First Regulatory Approval in any Major Market, whether such Regulatory Approval is obtained in the US Territory pursuant to this Agreement or in the ROW Territory pursuant to the AGI-23088 | |
| ROW Agreement | US\$[**] |
| (3) Second Regulatory Approval in any Major Market, but only if received in a different country or | |
| region, as applicable, than the first Regulatory Approval, whether such Regulatory Approval is | |
| obtained in the US Territory pursuant to this Agreement or in the ROW Territory pursuant to the | |
| AGI-23088 ROW Agreement | US\$[**] |

(a) For purposes of determining the occurrence of milestones under item (1) in the table above, [**] shall be deemed to have occurred [**] days following [**]; provided that, if such [**]. For purposes of determining the occurrence of milestones under items (2) and (3) in the table above, the [**]. For purposes of clarity, no milestone amount shall be payable to Agios under item (3) if [**] for purposes of item (3).

- (b) Each milestone payment under this Section 9.3 shall be made within [**] days 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 [**] days following Celgene's receipt of written notice of the achievement of such milestone).
- (c) For clarity, (i) 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 and (ii) the milestone payments set forth in the table above shall be in addition to any milestones payable pursuant to the AGI-23088 ROW Agreement.

Section 9.4 <u>US Territory Profit or Loss</u>. Subject to Section 2.12:

- (a) <u>Profit or Loss</u>. The Parties shall share in US Territory Profit or Loss as follows: Agios shall bear (and be entitled to) fifty percent (50%), and Celgene shall bear (and be entitled to) fifty percent (50%). Each Party may include Commercialization Expenses in the US Territory Profit or Loss incurred by such Party that are within [**] percent ([**]%) of the approved Commercialization Budget under the Commercialization Plan. Any Commercialization Expenses in excess of [**] percent ([**]%) of the approved Commercialization Budget under the Commercialization Plan shall be borne solely by the Party incurring such costs and not included in US Territory Profit or Loss unless such Party has received the other Party's written approval to share such excess costs.
 - (b) [**] Reconciliation and Payments. Unless the Parties otherwise agree, the Reconciliation Procedures shall provide that:
- (i) Within [**] days following the end of [**], each Party shall prepare and deliver to the Finance Working Group a [**] report detailing its Net Sales made and Commercialization Expenses incurred, and other amounts necessary to calculate US Territory Profit or Loss, during such [**], with respect to which the Parties share US Territory 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 [**] days after the other Party's receipt of such request. The Parties, with the assistance of the Finance Working Group, shall conduct a reconciliation of US Territory Profit or Loss for the full [**] within [**] days 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 of the US Territory Profit or Loss identified in such reconciliation for such [**]. The paying Party shall pay all amounts payable under any such invoice within [**] days after its receipt of such invoice.

Section 9.5 Royalty Payments Following Agios Opt-Out. In the event of an Agios Opt-Out Date:

(a) Royalty Rate. Celgene shall pay to Agios royalties on Annual Net Sales of Licensed Products in the US Territory (i) at the royalty rate of [**] percent ([**]%), if acceptance for review of the first NDA for a Licensed Product occurred prior to the Agios Opt-Out Date, or (ii) at the following rates, if acceptance for review of the first NDA for a Licensed Product did not occur prior to the Agios Opt-Out Date:

| Annual Net Sales of Licensed Products | Royalty Rate |
|---|--------------|
| On the tranche of Annual Net Sales in the US Territory occurring until aggregate, worldwide Annual Net Sales reaches US\$[**] | [**]% |
| On the tranche of Annual Net Sales in the US Territory occurring so long as aggregate, worldwide Annual Net Sales is equal to or greater than US\$[**] and less than US\$[**] | [**]% |
| On the tranche of Annual Net Sales in the US Territory occurring upon and after aggregate, worldwide Annual Net Sales equals US\$[**] | [**]% |

- (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 of the US Territory with respect to which royalty payments are due, until the latest of:
- (i) the last to expire of any Valid Claim of Agios Patent Rights or Agios Collaboration Patent Rights (including Joint Patents), in each case Covering such Licensed Product in such country of the US Territory;
 - (ii) [**] years following the date of First Commercial Sale in such country of the US Territory; and
 - (iii) the expiration of Regulatory Exclusivity for such Licensed Product in such country of the US Territory;

(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 of the US Territory continues solely due to Section 9.5(b)(ii) above (i.e., the Licensed Product is not Covered by a Valid Claim of Agios Patent Rights or Agios Collaboration Patent Rights 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 of the US Territory, 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 of the US Territory, 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.

- (c) <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 9.5, 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 from and after the Agios Opt-Out Date (i) with respect to any license obtained prior to the Agios Opt-Out Date pursuant to Section 9.6(b)(i), and (ii) with respect to any other license obtained pursuant to Section 9.6(b) but only to the extent that the Patent Rights and/or Know-How licensed under such other license are necessary (A) to use the Targets to which the applicable Licensed Product is directed or (B) to the Development, Manufacture or Commercialization of such Licensed Product in a country(ies) in the US Territory, from royalty payments otherwise due and payable by Celgene to Agios under this Section 9.5 with respect to such Licensed Product in such country(ies), on a Licensed Product-by-Licensed Product and country-by-country basis; provided, however, that in no event shall the aggregate deductions permitted by this Section 9.5(c) reduce the royalties payable by Celgene to Agios with respect to any such Licensed Product in such country(ies) for any Calendar Quarter to less than [**] percent ([**]%) of the royalties otherwise due in the absence of any deduction pursuant to this Section 9.5(c); provided further 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) <u>Royalty Reports</u>: <u>Payments</u>. Within [**] calendar days after the end of any [**] 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, licensees and sublicensees, as applicable, in the US Territory, 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.

Section 9.6 Third Party Payments.

- (a) Existing Third Party Agreement. Except as otherwise provided in Section 14.3(b)(vii), [**] shall be [**] responsible for [**] amounts payable under the Existing Third Party Agreement with respect to the Licensed Products.
- (b) Additional Agreements. If Celgene at any time or Agios before an Agios Opt-Out Notice believes that a license under Third Party Patent Rights or Third Party Know-How could be [**] to Develop, Manufacture or Commercialize the Licensed Products in the US Territory, then such Party shall notify the (A) JDC if such notice is provided during Development or Manufacturing of Licensed Products for Development or (B) 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 2.8; provided that, if the JSC cannot agree on which Party should obtain such license, then until an Agios Opt-Out Notice, Agios shall have the first right to obtain such license for the US Territory and if Agios does not promptly exercise such right then Celgene shall have the right to do so, and after an Agios Opt-Out Notice, Celgene shall have the sole right to obtain such license.

(ii) The costs of each such license 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 in the US Territory and/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 Patent Rights and Third Party Know-How licensed pursuant to this Section 9.6 shall be deemed "Collaboration Intellectual Property" of the Party obtaining such license.

(iv) (1) The Party designated to pursue the license 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 license shall reasonably consider all comments and suggestions reasonably recommended by the other Party; and (3) the Party seeking the license 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 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 9.6), except for payment obligations, which will be treated as provided in this Section 9.6.

Section 9.7 Financial Records. 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 [**] years 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, US Territory Profit or Loss and, if applicable, Annual Net Sales.

Section 9.8 Audits.

- (a) <u>Audit Team</u>. 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 "<u>Audit Team</u>") 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 only [**], (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 [**] Calendar Years 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 [**] proposed dates of the audit not less than [**] days 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>Audit Report</u>. The audit report and basis for any determination by an Audit Team shall be made available first for review and comment by the Auditee, and the Auditee shall have the right, at its expense, to request a further determination by such Audit Team as to matters which the Auditee disputes (to be completed no more than [**] days after the first determination is provided to such Auditee and to be limited to the disputed matters). Such Audit Team shall not disclose to the Audit Rights Holder any information relating to the business of the Auditee except that which should properly have been contained in any report required hereunder or otherwise required to be disclosed to the Audit Rights Holder to the extent necessary to verify the payments required to be made pursuant to the terms of this Agreement.
- (e) <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 [**] days 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 [**] days after receiving appropriate invoices and other support for such audit-related costs.

(f) <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) Withholding Taxes. The milestones and other amounts payable by a Party to the other Party pursuant to this Agreement ("Payments") shall not be reduced on account of any taxes unless required by Law. The receiving Party alone shall be responsible for paying any and all taxes (other than withholding taxes required by Law to be deducted and paid on the receiving Party's behalf by the paying Party) levied on account of, or measured in whole or in part by reference to, any Payments it receives. The Parties will cooperate in good faith to obtain the benefit of any relevant tax treaties to minimize as far as reasonably possible any taxes which may be levied on any Payments. The paying Party shall deduct or withhold from the Payments any taxes that it is required by Law to deduct or withhold. If the receiving Party is entitled under any applicable tax treaty or any Law to a reduction of the rate of, or the elimination of, applicable withholding tax, it may deliver to the paying Party or the appropriate governmental authority (with the assistance of the paying Party to the extent that this is reasonably required and is expressly requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve the paying Party of its obligation to withhold tax, and the paying Party shall apply the reduced rate of withholding tax, or dispense with withholding tax, as the case may be; provided that the paying Party has received evidence of the receiving Party's delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) at least [**] days prior to the time that the Payment is due. If, in accordance with the foregoing, the paying Party withholds any amount, it shall make timely payment to the proper taxing authority of the withheld amount, and send to the receiving Party proof of such payment within [**] days following that latter payment.
- (b) Limited Gross-Up Obligation. Notwithstanding the foregoing, if the rights and obligations of a Party making payments hereunder are assigned to an Affiliate or Third Party outside of the United States or Switzerland pursuant to Section 15.4, and if such Affiliate or Third Party shall be required by Law to withhold any additional taxes from or in respect of any sum payable under this Agreement as a result of such assignment, then any such sum payable under this Agreement shall be increased to take into account the additional taxes withheld as may be necessary so that, after making all required withholdings, the receiving Party receives an amount equal to the sum it would have received had no such assignment been made; provided, however, that, if the rights and obligations of the paying Party hereunder are assigned to an Affiliate or Third Party outside of the United States or Switzerland pursuant to Section 15.4 and if at the time of such assignment such Affiliate or Third Party is not required by Law to withhold any additional taxes as a result of such assignment, the paying Party shall not be required to increase any such sum payable under this Agreement in the event of a change

in Law. In addition, if the rights and obligations of the receiving Party hereunder are assigned to an Affiliate or Third Party pursuant to Section 15.4, the paying Party shall not have an obligation to pay an additional sum pursuant to this Section 9.9(b) to the extent that the additional sum would not have been due pursuant to this Section 9.9(b) if the rights and obligations of the receiving Party hereunder had not been assigned to an Affiliate or Third Party pursuant to Section 15.4.

Section 9.10 Currency Exchange.

- (a) <u>Currency Conversion</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 made using the average of the buying and selling exchange rate for conversion of the applicable foreign currency into United States Dollars, quoted for current transactions reported in <u>The Wall Street Journal</u> (U.S., Eastern Edition) (or similarly recognized source for currency exchange rates agreed by the Parties) for the last [**] Business Days of the Calendar Quarter to which such payment pertains.
- (b) <u>Restrictions on Payments</u>. Where Payments are due in a country where, for reasons of currency, tax or other regulations, transfer of foreign currency out of such country is prohibited, the paying Party has the right to place Payments due to the other Party in a bank account in such country in the name of and under the sole control of such other Party; <u>provided</u>, <u>however</u>, <u>that</u> the bank selected be reasonably acceptable to such other Party and that the paying Party inform such other Party of the location, account number, amount and currency of money deposited therein. After such other Party has been so notified, those monies shall be considered as Payments duly paid to such Party and will be completely controlled by such Party.
- (c) <u>Prohibitions on Payments</u>. When in any country in the US 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 [**] month LIBOR plus [**] percent ([**]%), as reported by <u>The Wall Street Journal</u>, 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 9.12 <u>Payment by Affiliates</u>. Notwithstanding anything in this Agreement to the contrary, all payments made by or on behalf of a Party or its Affiliates to the other Party under this Agreement shall be paid to the other Party directly by such first Party or one of its Affiliates that is incorporated in the United States.

Article X Intellectual Property Ownership, Protection and Related Matters

Section 10.1 Ownership of Inventions

- (a) Non-Collaboration Know-How. 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 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 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 ("<u>Joint Inventions</u>" and, any Patent Rights 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) Notice. Each Party agrees to provide regular [**] written reports disclosing to the other Party all 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(d).
- (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 [**] to resolve such dispute. The decision of such [**] 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 Patent Rights</u>. Subject to the terms and conditions of the Existing Third Party Agreement to the extent such agreement applies to the Agios Patent Rights or Agios Collaboration Patent Rights in the US Territory, the following provisions shall apply with respect to the Agios Patent Rights, Celgene Patent Rights and Collaboration Patent Rights in the US Territory:

- (a) Agios Patent Rights. Subject to the provisions of Section 10.2(h) and coordination with the JPC, Agios shall have the initial right and option to Prosecute the Agios Patent Rights and Agios Collaboration Patent Rights (excluding Joint Patents) in the US Territory with respect to which Celgene does not have the initial right to Prosecute pursuant to Section 10.2(b). In the event that Agios declines to Prosecute such Patent Rights, it shall give Celgene reasonable notice to this effect, sufficiently in advance to permit Celgene to undertake such Prosecution in such country without a loss of rights, and thereafter Celgene may, upon written notice to Agios, Prosecute such Patent Rights in Agios' name subject to coordination with the JPC.
- (b) Agios Patent Rights Prosecuted by Celgene. Subject to coordination with the JPC, Celgene shall have the initial right and option to Prosecute the Core Patent Rights within any of the Agios Patent Rights or Agios Collaboration Patent Rights in the US Territory that specifically Cover a Compound or a Licensed Product ("Celgene Controlled Agios Patent Rights"). Certain of the Agios Patent Rights and Agios Collaboration Patent Rights may from time to time Cover some Celgene Controlled Agios Patent Rights and other Agios Patent Rights or Agios Collaboration Patent Rights in the same application. Each Party will cooperate reasonably with any requests of the other Party from time to time to attempt to isolate Celgene Controlled Agios Patent Rights, on the one hand, from applications containing other Agios Patent Rights and Agios Collaboration Patent Rights, on the other hand. In the event that Celgene declines to Prosecute such Patent Rights, Celgene shall give Agios reasonable notice to this effect, sufficiently in advance to permit Agios to undertake such Prosecution in such country without a loss of rights, and thereafter Agios may, upon written notice to Celgene, Prosecute such Patent Rights in Agios' name subject to coordination with the JPC.
- (c) <u>Celgene Patent Rights</u>. Celgene shall have the sole right and option to Prosecute the Celgene Patent Rights in the US Territory and, subject to coordination with the JPC, the initial right and option to Prosecute the Celgene Collaboration Patent Rights (excluding Joint Patents) in the US Territory. In the event Celgene declines to Prosecute any such Celgene Collaboration Patent Right, Celgene shall give Agios reasonable notice to this effect, sufficiently in advance to permit Agios to undertake such Prosecution for such Celgene Collaboration Patent Right in such country without a loss of rights, and thereafter Agios may, upon written notice to Celgene, Prosecute such Patent Rights in Celgene's name.
- (d) <u>Joint Patents</u>. The JPC shall determine which Party shall have the initial right and option to Prosecute Joint Patents in the US Territory; <u>provided that</u> (i) if the JPC cannot make such determination by unanimous vote, then (x) Celgene shall have such initial right and option with respect to such Joint Patents that (A) are Core Patent Rights and that specifically Cover a Compound or Licensed Product or (B) claim or embody an improvement to technology claimed or embodied in Celgene Intellectual Property, and (y) Agios shall have such initial right and option with respect to all other such Joint Patents; and (ii) in the event that the Party with the initial right to Prosecute Joint Patents declines the option to Prosecute any such Joint Patents in any country, such Party shall give the other Party reasonable notice to this effect, sufficiently in advance to permit such other Party to undertake such Prosecution in such

country without a loss of rights, and thereafter such other Party may, upon written notice to the first Party, Prosecute such Joint Patent in both Parties' names, with expenses shared as provided in Section 10.2(e).

(e) <u>Costs and Expenses</u>. The Parties shall jointly bear all costs and expenses in Prosecuting Agios Patent Rights, Agios Collaboration Patent Rights, Celgene Collaboration Patent Rights and Joint Patents (collectively, "<u>Patent Prosecution Expenses</u>") in the US Territory as either Development Costs (to the extent incurred for any country of the US Territory prior to the First Commercial Sale of the Licensed Product in the country to which the Patent Rights relate) or Commercialization Expenses (if incurred after First Commercial Sale of the Licensed Product in the US Territory); <u>provided</u>, <u>however</u>, <u>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.

(f) 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 Patent Rights, Collaboration Patent Rights and Joint Patents in the US Territory, including the scope and priority of the claims to be pursued within such Patent Rights and to maximize the value of such Patent Rights, together with their foreign counterparts in the ROW Territory, 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 2.8(e), and if such attempt fails, then as follows: Prosecution matters involving (A) Agios Patent Rights (other than Celgene Controlled Agios Patent Rights therein) may be resolved by Agios; (B) Agios Collaboration Patent Rights (other than Celgene Controlled Agios Patent Rights and Joint Patents therein) may be resolved by Agios; (C) Celgene Controlled Agios Patent Rights and Celgene Collaboration Patent Rights (other than Joint Patents) may be resolved by Celgene; (D) all Core Patent Rights within the Joint Patents may be resolved by Celgene; and (E) all other Joint Patents may be resolved only by Mutual Consent. The Party conducting Prosecution (the "Prosecuting Party") with respect to each such Patent Right shall follow such strategy in connection with all Prosecution of such Patent Rights 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 2.8(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), (b), (c), and (d). Each Party agrees to cooperate with the other with respect to the Prosecution of such Patent Rights 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 Patent Rights that such other Party is entitled, and has elected, to Prosecute, as provided for in Sections 10.2(a), 10.2(b), 10.2(c), and 10.2(d) and (y) giving consideration to the proper scope of Patent Rights. The Prosecuting Party shall:

(A) regularly provide the JPC in advance with reasonable information relating to the Prosecuting Party's Prosecution of Patent Rights 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 at least [**] days prior to any filing or response deadlines, or within [**] Business Days of the Prosecuting Party's receipt of any official correspondence if such correspondence only allows for [**] days or less to respond; provided that, if the foregoing time periods are not practicable under the circumstances, the Prosecuting Party shall provide such copies as far in advance as is practicable but with sufficient time for the non-Prosecuting party to provide meaningful input;

- (B) 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 Patent Rights or Collaboration Patent Rights (including the Joint Patents), as applicable.
- (iii) The JPC shall determine the countries in which Agios Patent Rights and Collaboration Patent Rights (including Joint Patents) shall be Prosecuted, with the understanding that the countries set forth on Exhibit F of this Agreement shall generally form the basis for the overall Prosecution strategy for such Patent Rights 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(f). Further, Agios shall consult with the JPC well in advance of [**] and [**] deadlines as to additional countries (if any) in which the JPC or Celgene desires that the Agios Patent Rights and Collaboration Patent Rights be Prosecuted.
- (iv) The Prosecuting Party agrees not to abandon the subject matter of a claim in an Agios Patent Right, Collaboration Patent Right or Joint 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; provided that, prior to such abandonment or narrowing, if feasible, the Parties will co-operate to file divisional or continuation applications to separate such claim.
- (g) <u>Third Party Rights</u>. Agios covenants and agrees that it shall not grant any Third Party any right to control the Prosecution of the Agios Patent Rights or Agios Collaboration Patent Rights or to approve or consult with respect to any Patent Rights licensed to Celgene hereunder, in any case, that is more favorable to the Third Party than the rights granted to Celgene hereunder or that otherwise conflicts with Celgene's rights hereunder.
- (h) Existing Third Party Agreement. Each Party acknowledges that, pursuant to the Existing Third Party Agreement, the applicable licensors thereunder Prosecute the Agios Patent Rights 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 licensors under the Existing Third Party Agreement or their patent counsel relating to the Agios Patent Rights covered by such agreements. To the extent that Agios is permitted to proceed with Prosecution or provide comments or suggestions to patent documents under the Existing Third Party Agreement, then the Agios Patent Rights under such Existing Third Party Agreement shall be treated in the same manner as other Agios Patent Rights under this Section 10.2, and Agios shall exercise all such rights with respect to such Agios Patents Rights 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 Patent Rights and Collaboration Patent Rights</u>. Subject to the terms and conditions of the Existing Third Party Agreement to the extent such agreement applies to the Agios Patent Rights or Agios Collaboration Patent Rights in the US Territory, the following provisions shall apply with respect to the Agios Patent Rights, Agios Collaboration Patent Rights, Celgene Collaboration Patent Rights, Agios Know-How, Agios Collaboration Know-How, and Celgene Collaboration Know-How in the US Territory:

- (a) Notice. Each Party shall immediately provide the other Party with written notice reasonably detailing any (i) known or alleged infringement of any Agios Patent Rights or Collaboration Patent Rights, or known or alleged misappropriation of any Agios Know-How or 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) First Right to Initiate Infringement Actions. Until an Agios Opt-Out Notice, Agios shall have the initial right throughout the US Territory, but not the obligation, to initiate a suit or take other appropriate action in the US Territory that Agios believes is reasonably required to protect the Agios Intellectual Property or Agios Collaboration Intellectual Property against the infringement, including Third Party Infringement, unauthorized use or misappropriation by a Third Party that relates to a Licensed Product ("Competitive Infringement"). Celgene shall have the sole right throughout the US Territory, but not the obligation, to initiate a suit or take other appropriate action in the US Territory that Celgene believes is reasonably required to protect the Celgene Collaboration Patent Rights from Competitive Infringement. Upon and after an Agios Opt-Out Notice, Celgene also shall have the initial right throughout the US Territory, but not the obligation, to initiate a suit or take other appropriate action in the US Territory that Celgene believes is reasonably required to protect the Agios Patent Rights and Agios Collaboration Patent Rights from Competitive Infringement. The Party having such initial or sole right under the preceding three sentences ("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 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, subject to coordination with the JPC, the Initial Enforcement Party shall use reasonable efforts to prepare for the possibility of suit for Competitive Infringement starting [**] years after such First Commercial Sale. Such preparation includes identifying and retaining experts, selecting and retaining outside counsel, having outside counsel conduct a prelitigation 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.
- (d) Step-in Rights. If Agios, as the Initial Enforcement Party, fails to initiate a suit or take such other appropriate action under Section 10.3(b) above within [**] days after becoming aware of the Competitive Infringement, then Celgene may, in its discretion, provide Agios with written notice of Celgene's intent to initiate a suit or take other appropriate action to combat such Competitive Infringement. If Celgene, as the Initial Enforcement Party for the Agios Patent Rights and Agios Collaboration Patent Rights after the Agios Opt-Out Notice, fails to initiate a suit or take such other appropriate action under Section 10.3(b) above within [**] days after becoming aware of the Competitive Infringement, then Agios may, in its discretion, provide Celgene with written notice of Agios' intent to initiate a suit or take other appropriate action to combat such Competitive Infringement. If the Party with such step-in rights under either of the two preceding sentences ("Step-In Enforcement Party") provides such notice and the Initial Enforcement Party fails to initiate a suit or take such other appropriate action within [**] days after receipt of such notice from the Step-In Enforcement Party, then 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 or Agios Collaboration Intellectual Property from Competitive Infringement. The Step-In Enforcement Party shall give the Initial Enforcement Party advance notice of the Step-In Enforcement Party's intent to file any such suit or take any such action and the reasons therefor and shall provide the Initial 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. For the avoidance of any doubt, this Section 10.3(d) shall not be applicable to any of the Celgene Collaboration Patent Rights, so Agios shall not have any right to be the Step-In Enforcement Party for Celgene Collaboration Patent Rights without the written agreement of Celgene.

- (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 and/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 of the Territory prior to the First Commercial Sale of a Licensed Product in the Country) or Commercialization Expenses (if incurred after the First Commercial Sale of a Licensed Product in the US Territory). 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 US Territory Profit or Loss). For clarity, if required under applicable Law in order for AIS or CIS II to initiate and/or maintain a suit pursuant to which it has the right to initiate and/or maintain under Section 10.3 of the AGI-23088 ROW Agreement, each Party, as applicable, shall join as a party to such suit.
- (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) Existing Third Party Agreement. In the event that (i) a Patent Right covered by the 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 Patent Rights 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 licensors' consent under the 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.

Section 10.4 Claimed Infringement; Claimed Invalidity.

- (a) Infringement of Third Party Rights. 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, in the US Territory, 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 ("Third Party Infringement Action"), 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 US Territory 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 an Agios Opt-Out Notice or the failure of the Parties to so mutually agree, Celgene 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 US Territory 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 US Territory 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 and the AGI-23088 ROW Agreement, in each case (A) (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 (if approved by the non-controlling Party) shall be deemed Patent and Trademark Enforcement Costs that are factored into the calculation of US Territory 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 Right or Agios Collaboration Patent Right (including Joint 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 the Existing Third Party Agreement to the extent such agreement applies to such Agios Patent Right or Agios Collaboration Patent Right, 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 Right or Agios Collaboration Patent Right before any such right 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 Patent Rights, Agios Collaboration Patent Rights and Celgene Collaboration Patent Rights that Cover Licensed Products. If the JPC is unable to agree upon which of such Patent Rights should be extended, and the matter remains unresolved after the procedure described in Section 2.8(e), then the Initial Enforcement Party shall have the right to resolve the dispute, subject in each case to the terms and conditions of the Existing Third Party Agreement to the extent such agreement applies to such Agios Patent Right or Agios Collaboration Patent Right.

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>CREATE Act Application</u>. It is agreed and acknowledged that this Agreement establishes a qualifying collaboration within the scope of the U.S. CREATE Act and, accordingly, shall be deemed to constitute a "Joint Research Agreement" for all purposes under the CREATE Act. Neither Party shall invoke the provisions of the CREATE Act, or file this Agreement, in connection with the prosecution of any patent application claiming, in whole or in part, any CREATE Act 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 CREATE Act invention (a "<u>CREATE Act Patent</u>"), 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 "<u>Earlier Patent</u>"), then, if the Parties agree, the Parties shall coordinate the filing of such terminal disclaimer in good faith, and, to the extent required under the CREATE

Act, both Parties shall agree, in such terminal disclaimer, that they shall not separately enforce the CREATE Act Patent independently from the Earlier Patent. To this end, to the extent required under the CREATE Act, following the filing of such terminal disclaimer, the Parties shall, in good faith, coordinate all enforcement actions with respect to the CREATE Act Patent.

Section 10.8 Challenges to Patent Rights.

- (a) Certain Consequences of Celgene Challenges. Without limiting Celgene's obligations pursuant to Section 8.5(b), if Celgene or any of its Affiliates or any of its sublicensees under the licenses granted to Celgene in this Agreement (i) initiates or requests an interference or opposition proceeding with respect to any Agios Patent Right or Agios Collaboration Patent Right that Covers a Target or Licensed Product, (ii) makes, files or maintains any claim, demand, lawsuit, or cause of action to challenge the validity or enforceability of any Agios Patent Right or Agios Collaboration Patent Right that Covers a Target or Licensed Product, or (iii) funds or otherwise provides material assistance to any other Person with respect to any of the foregoing (any of the actions described in the foregoing clauses (i), (ii) and (iii), a "Challenge"), and if the outcome of such Challenge is that any claim of an Agios Patent Right or Agios Collaboration Patent Right that Covers a Target or Licensed Product and that is subject to such Challenge remains valid and enforceable, then (A) Celgene shall [**] Agios in connection with such Challenge (which amounts shall not be deemed to constitute Development Costs or Commercialization Expenses), and (B) thereafter, if the Agios Opt-Out Date has not occurred before such outcome, then Agios' share of US Territory Profit or Loss hereunder with respect to any Licensed Product Covered by any remaining such valid and enforceable claim of a Challenged Agios Patent Right or Agios Collaboration Patent Right or Agios Collaboration Patent Right shall [**], notwithstanding Section 9.4(a), and if the Agios Opt-Out Date has occurred before such outcome, then all royalty amounts payable by Celgene to Agios hereunder with respect to any Licensed Product Covered by any remaining such valid and enforceable claim of a Challenged Agios Patent Right or Agios Collaboration Patent Right or Agios Coll
- (b) No Use of Confidential Information. Without limiting Celgene's obligations pursuant to Section 10.8(a), Celgene shall not, and shall ensure that its Affiliates and its sublicensees under the licenses granted to Celgene in this Agreement do not, use or disclose any Confidential Information of Agios or any nonpublic information regarding the Prosecution or enforcement of any Agios Patent Rights or Agios Collaboration Patent Rights to which Celgene or any of its Affiliates or sublicensees are or become privy as a consequence of the rights granted to Celgene pursuant to this Article X, in initiating, requesting, making, filing or maintaining, or in funding or otherwise assisting any other Person with respect to, any Challenge.
- (c) <u>Certain Consequences of Agios Challenges</u>. The provisions of Sections 10.8(a) and 10.8(b) shall apply with respect to Celgene Patent Rights and Celgene Collaboration Patent Rights licensed to Agios pursuant to Section 8.1, in each case, substituting "Celgene" for "Agios" and vice versa with respect to all obligations and definitions, and otherwise *mutatis mutandis*.

Section 10.9 <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 10.4, all recoveries with respect to any such action, by settlement or otherwise, shall be [**] by Celgene.

Article XI Confidentiality

- Section 11.1 <u>Confidential Information</u>. All Confidential Information of a Party ("<u>Disclosing Party</u>") shall not be used by the other Party (the "<u>Receiving Party</u>") except in performing its obligations or exercising rights explicitly granted under this Agreement and shall be maintained in confidence by the Receiving Party and shall not otherwise be disclosed by the Receiving Party to any Third Party, without the prior written consent of the Disclosing Party with respect to such Confidential Information, 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; 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 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 and have an obligation to treat such information and materials as confidential;
- (b) to patent offices in order to seek or obtain Patent Rights 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 Patent Rights or Regulatory Approvals; or
- (c) if such disclosure is required by judicial order or applicable Law or to defend or prosecute litigation or arbitration; provided that, 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 [**] Business Days 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 G 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 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) Permitted Disclosures. 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), 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 Securities and Exchange Commission, 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) Either Party may disclose the existence and terms of this Agreement in confidence:

(A) to (1) its attorneys, professional accountants, and auditors, and (2) bankers or other financial advisors in connection with a public offering, other strategic transaction, or corporate valuation for internal purposes; <u>provided that</u> any such disclosure to such professional accountants, auditors, bankers or other financial advisors is under an agreement to keep the terms of confidentiality and non-use no less rigorous than the terms contained in this Agreement and to use such information solely for the applicable purpose permitted pursuant to this Section 11.3(b)(ii)(A);

(B) to the licensors under the Existing Third Party Agreement; provided that such disclosure is under the confidentiality and non-use provisions of such agreement;

(C) to potential acquirers (and their respective attorneys and professional advisors), in connection with a potential merger, acquisition or reorganization; provided that (1) the Party making the disclosure has a bona fide offer from such Third Party for such a transaction, and (2) such disclosure is under an agreement to keep the terms of confidentiality and non-use no less rigorous than the terms contained in this Agreement and to use such information solely for the purpose permitted pursuant to this Section 11.3(b)(ii)(C);

(D) to existing investors, lenders or permitted assignees of such Party (and their respective attorneys and professional advisors); provided that such disclosure is under an agreement to keep the terms of confidentiality and non-use no less rigorous than the terms contained in this Agreement; and

(E) to potential investors, lenders or permitted assignees of such Party, or to potential licensees or sublicensees of such Party (and their respective attorneys and professional advisors); provided that (1) such disclosure shall not be made prior to [**] Business Days prior to the good faith anticipated closing date for the investment, loan, assignment or license, as applicable, and shall be made only if such Party reasonably concludes that such transaction with such disclosee is likely to be consummated; (2) the disclosure shall be limited to the Redacted Version plus such additional terms and conditions reasonably requested by the disclosing Party and consented to by the other Party (for purposes of clarity, the disclosing Party shall not be obligated to disclose the identity of the disclosee in order to request such consent); and (3) such disclosure is under an agreement to keep the terms of confidentiality and non-use no less rigorous than the terms contained in this Agreement.

(iii) The Parties acknowledge the importance of supporting each other's efforts to publicly disclose results and significant developments regarding the Licensed Products and other activities in connection with this Agreement that may include information that is not otherwise permitted to be disclosed under this ARTICLE XI, and that may be beyond what is required by applicable Law, and each Party may make such disclosures from time to time. Such disclosures may include achievement of milestones, significant events in the development and regulatory process, commercialization activities and the like. Except for the initial press release described in Section 11.3(a), whenever a Party (the "Requesting Party") elects to make any such public disclosure, 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 [**] Business Days 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 [**] Business Days 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 decisions regarding the timing and content of Publications shall be subject to the oversight and approval by Mutual Consent 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, by Mutual Consent, shall then have [**] days prior to submission for any Publication ([**] days 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 Patent Rights or Know-How belonging (whether through ownership or license, including under this Agreement) in whole or in part to the non-publishing Party.
- (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 the 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; provided that, 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 by Mutual Consent delegate its responsibilities under this Section 11.4 to one or more representatives of Agios and Celgene.
 - Section 11.5 Term. All obligations under this Article XI shall expire [**] years following termination or expiration of this Agreement.

Section 11.6 Return of Confidential Information.

- (a) Obligations to Return or Destroy. 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 Mutual Representations. Agios and Celgene each represents, warrants and covenants to the other Party, as of the Effective Date, that:
 - (a) Authority. It has full corporate right, power and authority to enter into this Agreement and to perform its obligations under this Agreement.
- (b) <u>Consents</u>. Except as provided in Section 15.17, 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 have been or shall be obtained by the Effective Date.
- (c) No Conflicts. 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 Effective Date and (ii) do not and will not conflict with, violate, breach or constitute a default under any contractual obligations of such Party or any of its Affiliates existing as of the Effective Date. It has not used, and during the Term will not knowingly use, any Know-How 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 the other Party hereunder. It has not granted, and during the Term it will not grant, any right or license, to any Third Party relating to any of the intellectual property rights it Controls, that conflicts with the rights or licenses granted or to be granted to the other Party hereunder.
 - (d) Enforceability. This Agreement is a legal and valid obligation binding upon it and is enforceable in accordance with its terms.
- (e) Employee Obligations. 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, non-competition or non-solicitation.

- Section 12.2 Additional Agios Representations. Agios represents, warrants and covenants to Celgene, as of the Effective Date, as follows:
- (a) Agios possesses sufficient rights to enable Agios to grant all rights and licenses it purports to grant to Celgene with respect to the Agios Intellectual Property under this Agreement.
- (b) The Agios Patent Rights existing as of the Effective Date constitute all of the Patent Rights Controlled by Agios or AIS as of such date that are necessary or useful for the Development, Manufacture or Commercialization of the Licensed Products.
- (c) There is no pending litigation, and Agios has not received any written notice of any claims or litigation, seeking to invalidate or otherwise challenge the Agios Patent Rights or Agios' rights therein.
- (d) There is no pending litigation, and Agios has not received any written notice of any claims or litigation, that alleges that Agios' activities with respect to IDH1 or IDH2 have infringed or misappropriated any intellectual property rights of any Third Party.
- (e) [**] practice of the Agios Intellectual Property as contemplated under this Agreement does not (i) infringe any claims of any Patent Rights of any Third Party, or (ii) misappropriate any Know-How of any Third Party.
- (f) None of (i) the Agios Patent Rights owned by Agios or both Controlled by and Prosecuted by Agios and (ii) [**], the Agios Patent Rights Controlled but not Prosecuted by Agios are subject to any pending re-examination, opposition, interference or litigation proceedings.
- (g) All of (i) the Agios Patent Rights owned by Agios or both Controlled by and Prosecuted by Agios and (ii) [**], the Agios Patent Rights Controlled but not Prosecuted by Agios have been filed and diligently Prosecuted in accordance with all applicable Laws in the Territory and have been maintained, with all applicable fees with respect thereto having been paid.
- (h) True and correct copies of the Existing Third Party Agreement have been provided to Celgene, and such agreement is in full force and effect and have not been modified or amended. Neither Agios nor, [**], any licensor under the Existing Third Party Agreement 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 Agreement.
- (i) [**] Agios Patent Rights Controlled by Agios pursuant to the Existing Third Party Agreement were not and are not subject to any restrictions or limitations except as set forth in the Existing Third Party Agreement.

- (j) Agios has not waived or allowed to lapse any of its rights under the Existing Third Party Agreement with respect to the Licensed Products, and no such rights have lapsed or otherwise expired or been terminated.
- (k) Agios has and, [**], the applicable licensor under the Existing Third Party Agreement has complied with any and all obligations under [**] to perfect rights to the applicable Patent Rights or Know-How licensed thereunder.
- (l) Agios has not employed and, to its knowledge, has not used a contractor or consultant that has employed, any individual or entity (i) debarred by the FDA (or subject to a similar sanction of another applicable Regulatory Authority), (ii) who is the subject of an FDA debarment investigation or proceeding (or similar proceeding of another applicable Regulatory Authority), or (iii) has been charged with or convicted under United States Law for conduct relating to the development or approval, or otherwise relating to the regulation of any Licensed Product under the Generic Drug Enforcement Act of 1992, in each case, in the conduct of its activities prior to the Effective Date.
 - Section 12.3 Additional Celgene Representations. Celgene represents, warrants and covenants to Agios, as of the Effective Date, as follows:
- (a) Celgene possesses sufficient rights to enable Celgene to grant all rights and licenses it purports to grant to Agios with respect to the Celgene Intellectual Property under this Agreement.
- (b) Celgene has not employed and, to its knowledge, has not used a contractor or consultant that has employed, any individual or entity (i) debarred by the FDA (or subject to a similar sanction of another applicable Regulatory Authority), (ii) who is the subject of an FDA debarment investigation or proceeding (or similar proceeding of another applicable Regulatory Authority), or (iii) has been charged with or convicted under United States Law for conduct relating to the development or approval, or otherwise relating to the regulation of any Licensed Product under the Generic Drug Enforcement Act of 1992, in each case, in the conduct of its activities prior to the Effective Date.
- Section 12.4 Employee Obligations. Agios and Celgene each covenants to the other Party that all of its and its Affiliates' employees, officers, consultants and advisors who have been, are or will be involved in the Collaboration have executed (or, prior to becoming involved in the Collaboration, will have executed agreements) or have existing obligations under Law requiring assignment to such Party of all intellectual property made during the course of and as the result of their association with such Party, and obligating the individual to maintain as confidential such Party's Confidential Information, to the extent required to support such Party's obligations under this Agreement.
- Section 12.5 No Warranties. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH HEREIN, THE PARTIES MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY REPRESENTATIONS OR WARRANTIES AS TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NONINFRINGEMENT.

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; 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 [**] Business Days, notify Celgene in writing of the claim. Celgene shall have the right, exercisable by notice to Agios within [**] Business Days 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 (including the right to settle the claim solely for monetary consideration) 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.

Section 13.2 By Agios.

- (a) Agios Indemnification Obligation. 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 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; or
 - (ii) the gross negligence, willful misconduct or violation of Law of Agios or its Affiliates.

(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 [**] Business Days, notify Agios in writing of the claim. Agios shall have the right, exercisable by notice to Celgene within [**] Business Days 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 (including the right to settle the claim solely for monetary consideration) 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 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.

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 shall be taken into account in determining US Territory Profit or Loss as, and to the extent, provided in the Financial Exhibit.
- (b) All such costs and expenses incurred after the Agios Opt-Out Date relating to Licensed Products in the US Territory shall be borne solely by Celgene if and only to the extent such Product Liabilities were caused by the occurrence after the Agios Opt-Out Date of the event, incident or circumstance that led to the Third Party Liability Action.
- (c) All such costs and expenses incurred after the Agios Opt-Out Date relating to Licensed Products in the US Territory shall be borne fifty per cent (50%) by each of the Parties to the extent such Product Liabilities were caused by the occurrence before the Agios Opt-Out Date of an event, incident or circumstance that is the subject of the Third Party Liability Action. If Agios is invoiced for its portion of such costs and expenses incurred after the Agios Opt-Out Date, payment is due within [**] days of receipt of invoice.

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 in the US Territory 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; provided that, in the event of an Agios Opt-Out Notice or the failure of the Parties to mutually agree otherwise, 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. Subject to Section 13.3, each Party shall be responsible for its own Out-of-Pocket Costs incurred in connection with any litigation or proceedings related to such Third Party Products Liability Action, including the fees and expenses of the counsel selected by the controlling Party. 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 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 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 \$[**] per claim and annual aggregate. Celgene may elect to self-insure all or parts of the limits described above. Within [**] days 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 2.12(b) or 14.2, in full force and effect as long as the Parties continue to Develop and/or Commercialize Licensed Products in accordance with the terms and conditions of this Agreement, or, in the event of an Agios Opt-Out Date, until expiration of the Royalty Term for all Licensed Products.

Section 14.2 Termination.

(a) <u>Termination for Convenience</u>. Celgene shall have the right to terminate this Agreement in its entirety for convenience upon ninety (90) days' prior written notice to Agios; <u>provided that</u> Celgene shall not have the right to terminate this Agreement until twelve (12) months following the Effective Date.

(b) Termination for Material Breach or Insolvency.

- (i) If either Party (the "Non-Breaching Party") believes that the other Party (the "Breaching Party") is in material breach of this Agreement, then the Non-Breaching Party may deliver written notice of such breach to the Breaching Party. If the Breaching Party fails to cure such breach, or take such steps as would be considered reasonable to effectively cure such breach, within the [**] day period after delivery of such notice, the Non-Breaching Party may terminate this Agreement upon written notice to the Breaching Party. Notwithstanding the foregoing, if such breach is capable of being cured, but is not reasonably capable of being cured within the [**]-day cure period, if the Breaching Party (A) proposes within such [**]-day period a written plan to cure such breach within a defined time frame extending for a period not to exceed an additional [**] days, and (B) makes good faith efforts to cure such default and to implement such written cure plan, then the Non-Breaching Party may not terminate this Agreement until the earlier of such time as the Breaching Party is no longer diligently pursuing such cure in accordance with such plan or the end of such additional period.
- (ii) 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; provided, however, that, in the event of any involuntary bankruptcy or receivership proceeding such right to terminate shall only become effective if the Party consents to the involuntary bankruptcy or receivership or such proceeding is not dismissed within ninety (90) days after the filing thereof.
- (c) <u>Termination of AGI-23088 ROW Agreement</u>. This Agreement terminates automatically if the AGI-23088 ROW Agreement terminates for any reason. The AGI-23088 ROW Agreement terminates if this Agreement terminates for any reason.

Section 14.3 Effects Of Termination.

- (a) Effects of Celgene Termination for Convenience or Agios Termination for Celgene Breach or Insolvency. Upon termination of this Agreement by Celgene under Section 14.2(a), by Agios under Section 14.2(b), as a result of termination of the AGI-23088 ROW Agreement by CIS II under Section 14.2(a) for Celgene CIS II convenience therein, or as a result of termination of the AGI-23088 ROW Agreement by AIS under Section 14.2(b) for CIS II breach therein, the following shall apply:
- (i) all licenses granted by Agios to Celgene under Section 8.1(a) shall terminate, and all licenses granted by Celgene to Agios under Section 8.1(b) shall remain in effect and, from and after such termination, Agios shall pay Celgene royalties on Annual Net Sales of Licensed Products in the US Territory pursuant to Section 9.5 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;
- (ii) each Party shall be released from its Development, Manufacture and Commercialization obligations (except as set forth in Section 14.3(a)(vii) and (viii) below with respect to Celgene's transfer of Manufacturing to Agios hereunder);
- (iii) within [**] days 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 Sections 9.2 and 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 [**] days after the other Party's receipt of such request. The Parties, with the assistance of the Finance Working Group, shall conduct a final reconciliation of such costs and payments within [**] days 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 Sections 9.2 and 9.4, as applicable. The paying Party shall pay all amounts payable under any such invoice within [**] days after its receipt of such invoice; provided, however, that, Celgene shall remain responsible for its applicable share of the Developments Costs of any Clinical Trials or other Development activities committed and not cancelable by Agios with respect to the Licensed Products prior to the effective date of termination to the extent such Development Costs are within an approved Development Budget under an approved Development Plan in place prior to termination;
- (iv) within [**] days 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 US Territory;

(vi) Celgene shall as soon as reasonably practicable transfer and assign to Agios all Regulatory Approvals of the Licensed Products in the US Territory, 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; and provided further that, if such Regulatory Approvals or Regulatory Documentation are necessary or useful for the Development, Manufacture and/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 US Territory;

(vii) Agios shall have the option, exercisable within [**] days following the effective date of such termination of this Agreement, to obtain Celgene's inventory of the Licensed Products at a price equal to one hundred five percent (105%) 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 [**]day 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 [**] months 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 one hundred five percent (105%) 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 [**] months 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 manufacture 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 or CIS II 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) 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, provided, however, that in the event of a termination under Section 14.2(a) by Celgene, if Agios or any of its Affiliates propose(s) to take or take(s) any action not contemplated by the Development Plan in effect at the time of such termination, and that Celgene reasonably determines is reasonably likely to have a material adverse impact on the Commercialization of any of the "Licensed Products," as such term is defined in the 2010 Agreement, then Celgene shall provide written notice to such effect to Agios specifying in reasonable detail which actions by Agios or its Affiliates would have such an effect, and what such effect would be. The Parties shall use good faith efforts to discuss the pertinent actions and resolve the matter. If Agios concurs with Celgene's determination, Agios and its Affiliates shall not proceed with, or shall cease as quickly as reasonably possible, as applicable, such action without the written consent of Celgene. If Agios does not concur with Celgene's determination, Celgene may present the issue to the Executive Officers for resolution pursuant to Section 15.1(a) and, if agreement is not reached, may seek resolution of such matter in accordance with Section 15.1(b). If Celgene does present the issue to the Executive Officers for resolution, then Agios and its Affiliates shall not proceed with, or shall cease as quickly as reasonably possible, as applicable, such action until the dispute is resolved by agreement of the Executive Officers or in accordance with Section 15.1(b); and

(x) 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 Rights and Collaboration Patent Rights then being Prosecuted or enforced by Celgene, including execution of such documents as may be necessary to effect such transition.

- (b) Effects of Celgene Termination for Agios Breach. Upon any termination of this Agreement by Celgene under Section 14.2(b) or as a result of termination of the AGI-23088 ROW Agreement by CIS II under Section 14.2(b) for breach by AIS therein:
- (i) all future milestones payable by Celgene under Section 9.3 shall be reduced by fifty percent (50%) of the otherwise applicable payment amounts; provided that, if the termination of this Agreement is as a result of Agios' breach of Section 8.6, all future milestones payable by Celgene under Section 9.3 shall terminate;
- (ii) from and after such termination, if the Agios Opt-Out Date has not occurred before the effective date of termination, then Celgene shall pay Agios royalties on

Annual Net Sales of Licensed Products in the US Territory pursuant to Section 9.5, with the Agios Opt-Out Date, as used therein, deemed to be the effective date of termination, and if the Agios Opt-Out Date has occurred before the effective date of termination, then Celgene shall continue to pay to Agios royalties on Annual Net Sales of Licensed Products in the US Territory but the applicable royalty rate(s) shall be reduced by fifty percent (50%) of the otherwise applicable rate(s);

- (iii) all licenses granted by Celgene to Agios under Sections 8.1(b) with respect to the Licensed Products shall terminate;
- (iv) each Party shall be released from its Development, Manufacture and Commercialization obligations (except as set forth in clause (viii) 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 9.4; provided, however, that, Agios shall remain responsible for its applicable share of the Developments Costs of any Clinical Trials or other Development activities committed by the Parties with respect to the Licensed Products prior to the effective date of termination to the extent such Development Costs are within an approved Development Budget under an approved Development Plan in place prior to termination;
- (vi) within [**] days 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) the license granted by Agios to Celgene in Section 8.1(a) shall immediately become an exclusive (even as to Agios) license for the entire US Territory, which license shall continue in full force in perpetuity; provided that Celgene shall be solely responsible for any payments owed by Agios to any Third Party licensors of Agios Intellectual Property or Agios Collaboration Intellectual Property 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;
- (viii) the provisions of Section 14.3(a)(v), (vi), (vii) and (viii), shall apply, in each case, substituting "Agios" for "Celgene" and vice versa with respect to all obligations and definitions, and otherwise *mutatis mutandis*;
- (ix) notwithstanding anything to the contrary in Section 8.6, Celgene shall have the right to pursue the Development, Manufacture and Commercialization of the Licensed Products, provided, however, that if Celgene or any of its Affiliates propose(s) to take or take(s) any action not contemplated by the Development Plan in effect at the time of such termination, and that Agios reasonably determines is reasonably likely to have a material adverse impact on the Commercialization of any of the "Licensed Products," as such term is defined in the 2010 Agreement, then Agios shall provide written notice to such effect to Celgene specifying

in reasonable detail which actions by Celgene or its Affiliates would have such an effect, and what such effect would be. The Parties shall use good faith efforts to discuss the pertinent actions and resolve the matter. If Celgene concurs with Agios' determination, Celgene and its Affiliates shall not proceed with, or shall cease as quickly as reasonably possible, as applicable, such action without the written consent of Agios. If Celgene does not concur with Agios' determination, Celgene may present the issue to the Executive Officers for resolution pursuant to Section 15.1(a) and, if agreement is not reached, may seek resolution of such matter in accordance with Section 15.1(b). If Agios does present the issue to the Executive Officers for resolution, then Celgene and its Affiliates shall not proceed with, or shall cease as quickly as reasonably possible, as applicable, such action until the dispute is resolved by agreement of the Executive Officers or in accordance with Section 15.1(b); and

- (x) 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 Rights and Agios Collaboration Patent Rights and all Joint Inventions and Joint Patents, including execution of such documents as may be necessary to effect such transition.
- (c) <u>Sell-Down</u>. Unless Agios exercises its option under Section 14.3(a)(vii), if Celgene, its Affiliates or sublicensees at termination of this Agreement possess Licensed Product, have started the manufacture thereof or have accepted orders therefor, Celgene, its Affiliates or sublicensees shall have the right, for up to [**] following the date of termination, to sell their inventories thereof, complete the manufacture thereof and Commercialize such fully-manufactured Licensed Product, in order to fulfill such accepted orders or distribute such fully-manufactured Licensed Product, subject to the obligation of Celgene to pay Agios any and all payments as provided in this Agreement.
- (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</u>, <u>however</u>, <u>that</u> Sections 2.1(b), 3.4(b), 8.3(f), 8.7, 8.8, 9.2(b), 9.5(b) (v), 9.7, 9.8, 9.9, 10.1, 12.5, 13.6 (for at least [**]) and this Section 14.3 and Articles IX (to the extent any amounts are due but unpaid), XI, XIII (other than Section 13.6 (Insurance)) and XV, 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 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.
- (f) <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.

Article XV Miscellaneous

Section 15.1 Dispute Resolution.

- (a) 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 2.8), 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(a) after in-person discussions between the Executive Officers within [**] Business Days after referring such dispute to the Executive Officers, either Party may, at its sole discretion, seek resolution of such matter in accordance with Section 15.1(b) or Section 15.2, as applicable.
- (b) If the Parties do not resolve a Dispute with respect to any Arbitrable Matter after referring such matter to the Executive Officers pursuant to Section 15.1(a), then either Party may request that such Dispute be resolved by binding arbitration in accordance with the expedited procedures applicable to the Commercial Arbitration Rules of the American Arbitration Association (the "AAA") and the provisions of this Section 15.1(b). Dispute resolution pursuant to this Section 15.1(b) shall apply only to the following Disputes if the Parties cannot agree by Mutual Consent ("Arbitrable Matters"): (x) whether an action proposed to taken by a Party or its Affiliate pursuant to Section 2.12(b)(ii), 6.1(b)(i), 14.3(a)(ix) or 14.3(b)(ix) is reasonably likely to have a material adverse impact on the Commercialization of any of the "Licensed Products," as such term is defined in the 2010 Agreement; or (y) whether an action proposed to be taken by Agios or its Affiliate pursuant to Section 6.1(b)(ii) is reasonably likely to have an adverse impact on Commercialization of any of the "Licensed Products," as such term is defined in the AGI-23088 ROW Agreement.
- (i) The Party desiring to initiate an arbitration proceeding with respect to an Arbitrable Matter will send a written notice to the other Party requesting the commencement of the arbitration proceeding and specifying the issue to be resolved. Within [**] days after the date such notice is sent, the Parties shall negotiate in good faith to appoint a mutually acceptable independent person, with scientific, technical, and regulatory experience with respect to the development of pharmaceutical products in the Field necessary to resolve such Dispute and with availability to comply with the time periods in this Section 15.1(b) (an "Expert"). If the Parties fail to choose an Expert within the foregoing time period, the AAA shall choose an Expert (with such experience and availability) on behalf of the Parties within [**] days after receipt of written request by a Party to the AAA. Disputes about arbitration procedure will be resolved by the Expert or, failing agreement, by the AAA in New York, New York. Unless otherwise agreed by the Parties, the arbitration proceedings will be conducted in New York, New York. The fees and costs of the Expert and the AAA, if applicable, shall be shared equally by the Parties.

(ii) Within [**] days after selection of the Expert, each Party shall simultaneously deliver to the Expert and the other Party a written statement: (A) stating each of the issues that is the subject of the Arbitrable Matter dispute, (B) setting forth such Party's position on each issue in dispute, and (C) setting forth such Party's final position with respect to each such issue. With such statement, each Party may also submit supporting documentation, if any, for such Party's final position. Each Party shall have [**] days after the other Party's submission to submit to the Expert and the other Party a written response thereto, which may include any scientific and technical information in support thereof. The Expert shall have the right to meet with the Parties, either alone or together, as necessary to make a determination.

(iii) In resolving the dispute, the Expert will have no authority to make a decision on any issue other than by selecting the final position of one of the Parties. An arbitration decision with respect to the Arbitrable Matter will be rendered in writing the designation of the Expert, which decision will be final and binding on the Parties. For all purposes under this Agreement, any decision made pursuant to this Section 15.1(b) shall be deemed to be the decision of the Parties, by Mutual Consent.

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 15.7 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) Right to Assign. Neither Party may assign this Agreement, in whole or in part, without the consent of the other Party, except that either Party may assign this Agreement without the consent of the other Party, (i) in whole or in part, to any Affiliate of such Party, or (ii) in whole as part of a Change of Control of such Party; provided that the assigning Party provides the other Party with written notice of such assignment and such assignee agrees in writing to be bound by the terms and conditions of this Agreement. The terms of this

Agreement shall be binding upon and shall 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 shall be null and void.

- (b) Acquisition of a Party. Each Party agrees that in the event that a Party (the "Acquired Party") is acquired by Change of Control (an "Acquisition") by a Third Party (the "Acquirer"), (i) the non-Acquired Party shall not obtain any rights or access under this Agreement to any Know-How or Patent Rights Controlled by such Acquirer which were not already within Agios Intellectual Property (if the Acquired Party is Agios) or Celgene Intellectual Property (if the Acquired Party is Celgene) immediately prior to the consummation of such Acquisition; and (ii) the provisions of Section 8.6 shall not apply to any activity otherwise prohibited therein if a Party's involvement in such prohibited activity results from the Acquirer's activities but only if (A) such Acquirer, prior to such acquisition or merger, was already engaged in such prohibited activity (the "Third Party Activity"), and (B) no Celgene Intellectual Property, Agios Intellectual Property, or Collaboration Intellectual Property is used in connection with such Third Party Activity.
- (c) Acquisition by a Party. Each Party agrees that in the event that a Party acquires (whether by way of merger, acquisition, sale of all or substantially all of its business or assets to which this Agreement pertains, or otherwise) a Third Party (the "Acquired Third Party"), the provisions of Section 8.6 shall not apply to any activity otherwise prohibited therein if a Party's involvement in such prohibited activity results from such acquisition, but only if (i) such Acquired Third Party, prior to such acquisition, was already engaged in such prohibited activity (the "Acquired Party Activity"), and (ii) the Party acquiring such Acquired Third Party shall, within [**] days after the date of the consummation of such acquisition, notify the other Party of such acquisition and comply with the other provisions of this Section 15.4(c). Following consummation of such an acquisition, the acquiring Party shall, at its option, either (A) use good faith efforts to identify a Third Party purchaser to whom such Party will divest its interest in the Acquired Party Activity and to enter into a definitive agreement with such Third Party for such divestiture as soon as reasonably practicable under the circumstances, but such divestiture must be completed no later than [**] months after the closing of such Party's acquisition of the Acquired Party Activity, or (B) promptly discontinue such Acquired Party Activity; provided that notwithstanding which option is chosen, such divesture or discontinuation must be accomplished no later than [**] months after the closing of such Party's acquisition of the Acquired Party Activity, the acquiring Party shall not use any Celgene Intellectual Property, Agios Intellectual Property, or Collaboration Intellectual Property in connection with such Acquired Party Activities. So long as the acquiring Party divests of, or discontinues, the Acquired Party Activity in accordance with this Section 15.4(c), such acquisition shall not be deemed a violation of Section 8.6.

Section 15.5 <u>Certain Additional Matters Relating to Change of Control of a Party.</u> In the event that either Party is subject to a Change of Control, such Party shall notify the other Party at least [**] Business Days prior to the consummation of such Change of Control (or such lesser period of time as is practicable under the circumstances), and shall thereafter provide written notice to the other Party promptly following consummation of such Change of Control.

- (a) Agios Change of Control. Upon consummation of a Change of Control of Agios, the Collaboration shall continue in effect as provided in this Agreement except that:
 - (i) the license and sublicense granted to Agios under Section 8.1(b) shall terminate;

- (ii) all decisions relating to Development, Manufacturing and Commercialization that require decision by a Committee or that are subject to Mutual Consent shall be made solely by Celgene and all decisions for which Agios was provided with final decision-making authority under Section 2.8 shall be made solely by Celgene; <u>provided</u>, <u>however</u>, <u>that</u> Celgene shall not exercise such decision-making authority in any manner that diminishes Agios' rights with respect to Marketing Activities pursuant to Section 6.3;
- (iii) except as otherwise directed by Celgene and except with respect to Marketing Activities allocated to Agios pursuant to Section 6.3, Agios shall cease to conduct any further Development or Commercialization activities with respect to any Licensed Products and cease to incur any further Development Costs or Commercialization Expenses except as approved by Celgene or as provided in Sections 5.4, 13.3 and 13.4;
- (iv) 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;
- (v) 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 US Territory (other than Marketing Activities allocated to Agios pursuant to Section 6.3), at Agios' sole expense, including those activities referenced in Section 14.3(b)(viii); 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 Celgene requests that any contracts or agreements that extend beyond consummation of the Change of Control be terminated, Agios shall be responsible for all costs associated with such termination, and (B) if Celgene requests that any such contract or agreement remain in effect, Celgene shall be responsible for all Development Costs and Commercialization Expenses under such contract or agreement following consummation of the Change of Control;
- (vi) Celgene shall have the option to obtain Agios' inventory of the Licensed Products and their active pharmaceutical ingredients at a price equal to their Manufacturing Costs;
- (vii) 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;

- (viii) Agios shall 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 or AIS within Agios Intellectual Property that is both 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;
- (ix) notwithstanding anything to the contrary in Section 2.8 or otherwise herein, Celgene shall have the right to resolve all disputes within any Committee and final decision making authority on all unresolved matters throughout the US Territory;
- (x) all of Agios' rights under Article X (other than Section 10.1) shall terminate, and Agios shall transition to Celgene all of Agios' Prosecution and enforcement responsibilities with respect to Agios Patents Rights, Agios Collaboration Patent Rights, Joint Inventions and Joint Patents, and provide reasonable assistance to Celgene and cooperation in connection therewith, including execution of such documents as may be necessary to effect such transition, and Agios' rights under Sections 10.2(a) and 10.2(d) on Prosecution matters all terminate notwithstanding anything to the contrary in Article X, provided that Agios shall retain step-in rights under Sections 10.2(b) and Section 10.3(d) as well as comparable step-in rights on Prosecution matters relating to Agios Patent Rights and Agios Collaboration Patent Rights; and
 - (xi) the AGI-23088 ROW Agreement will be affected in a corresponding manner as provided therein.
- (b) <u>Celgene Change of Control</u>. Upon consummation of a Change of Control of Celgene before the Agios Opt-Out Notice, the Collaboration shall continue in effect as provided in this Agreement, except that:
 - (i) the license and sublicense granted to Celgene under Section 8.1(a) shall terminate;
- (ii) all decisions relating to Development, Manufacturing and Commercialization that require decision by a Committee or that are subject to Mutual Consent shall be made solely by Agios and all decisions relating to Commercialization for which Celgene was provided with final decision-making authority under Section 2.8 shall be made solely by Agios; provided, however, that Agios shall not exercise such decision-making authority in any manner that diminishes Celgene's rights with respect to Marketing Activities pursuant to Section 6.3;
- (iii) except as otherwise directed by Agios and except with respect to Marketing Activities allocated to Celgene pursuant to Section 6.3, Celgene shall cease to conduct any further Development or Commercialization activities with respect to any Licensed Products and cease to incur any further Development Costs or Commercialization Expenses except as approved by Agios or as provided in Sections 5.4, 13.3 and 13.4;

- (iv) Celgene shall provide to Agios a reasonably detailed summary of Development and Commercialization activities undertaken by Celgene under the Collaboration, including any Clinical Trials committed but not yet completed as of such date;
- (v) Celgene shall undertake, and coordinate with Agios with respect to, any wind-down or transitional activities reasonably necessary to transfer to Agios all Development, Manufacturing (including all Celgene Manufacturing Responsibilities) and Commercialization responsibility for the Licensed Products throughout the Territory (other than Marketing Activities allocated to Celgene pursuant to Section 6.3), at Celgene's sole expense, including those activities referenced in Section 14.3(b)(viii); 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 Agios requests that any contracts or agreements that extend beyond the consummation of the Change of Control be terminated, Celgene shall be responsible for all costs associated with such termination, and (B) if Agios requests that any such contract or agreement remain in effect, Agios shall be responsible for all Development Costs and Commercialization Expenses under such contract or agreement following the consummation of the Change of Control;
- (vi) Agios shall have the option to obtain Celgene's inventory of the Licensed Products and their active pharmaceutical ingredients at a price equal to their Manufacturing Costs;
- (vii) in the event Celgene is utilizing a Third Party manufacture to Manufacture the Licensed Products or their active pharmaceutical ingredients, to the extent permitted by the terms of such contract, Celgene shall, if requested by Agios, promptly assign to Agios the manufacturing agreements with such Third Party with respect to such products and ingredients;
- (viii) 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 or CIS II within Celgene Intellectual Property that is both necessary to Manufacture the Licensed Products or their active pharmaceutical ingredients as Manufactured by or on behalf of Celgene and its Affiliates, 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 deemed Development Costs:
- (ix) notwithstanding anything to the contrary in Section 2.8 or otherwise herein, Agios shall have the right to resolve all disputes within any Committee and final decision making authority on all unresolved matters throughout the US Territory;
- (x) all of Celgene's rights under Article X (other than Section 10.1) with respect to the Agios Patent Rights, Agios Collaboration Intellectual Property, and Joint Patents shall terminate, and Celgene shall transition to Agios all of Celgene's Prosecution and enforcement responsibilities with respect to Agios Patents Rights, Agios Collaboration Patent Rights, Joint Inventions and Joint Patents, and provide reasonable assistance to Agios and cooperation in connection therewith, including execution of such documents as may be necessary to effect such transition, and Celgene's rights under Sections 10.2(b) and 10.2(d) on Prosecution

matters all terminate notwithstanding anything to the contrary in Article X, <u>provided that</u> Celgene shall retain its step-in rights under Section 10.2(a) and 10.3(d) and shall be extended comparable step-in rights under Celgene-Controlled Agios Patent Rights as those Agios had under Section 10.2(b) and 10.2(d); and

(xi) the AGI-23088 ROW Agreement will be affected in a corresponding manner as provided therein.

(c) <u>Definition</u>. For purposes of this Agreement, "<u>Change of Control</u>" of a Party means any of the following, in a single transaction or a series of related transactions: (i) the sale or disposition of all or substantially all of the assets of such Party to a Third Party, (ii) 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 fifty percent (50%) of the then-outstanding common shares or voting power of such Party, or (iii) the merger or consolidation of such Party with or into a Third Party, unless, following such merger or consolidation, the stockholders of such Party immediately prior to such merger or consolidation beneficially own directly or indirectly more than fifty percent (50%) of the then-outstanding common shares or voting power of the entity resulting from such merger or consolidation.

Section 15.6 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 15.7 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. 38 Sidney Street Cambridge, MA 02139 Attention: J. Duncan Higgons Telephone: (617) 649-8634 Facsimile: (617) 649-8618

To Celgene:

Celgene Corporation 86 Morris Avenue Summit, NJ 07901 Attention: George S. Golumbeski Telephone: (908) 673-9043 Facsimile: (908) 673-2769 With copies to:

WilmerHale LLP 60 State Street Boston, MA 02109

Attention: Steven D. Singer, Esq. Telephone: (617) 526-6000 Facsimile: (617) 526-5000

Agios Pharmaceuticals, Inc. 38 Sidney Street Cambridge, MA 02139 Attention: Legal Department Telephone: (617) 649-8600 Facsimile: (617) 649-8618 With a copy to:

Celgene Corporation 86 Morris Avenue Summit, NJ 07901

Attention: Legal Department Telephone: (908) 673-9000 Facsimile: (908) 673-2162

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

Section 15.8 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 15.9 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 15.10 Entire Agreement. This Agreement (including the Exhibits attached hereto) 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 solely with respect to AGI-23088. 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 15.11 <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 15.12 <u>Independent Contractors</u>; No <u>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 Sections 13.1 and 13.2, and (b) except that [**] are intended third party beneficiaries of certain provisions of this Agreement, as specifically referred to herein. Notwithstanding the provisions of this Section 15.12, the provisions of Section 15.16 shall control for U.S. federal income tax purposes, as applicable.

Section 15.13 <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; (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 15.14 <u>Performance by Affiliates</u>. To the extent that this Agreement imposes obligations on Affiliates of a Party, such Party agrees to cause its Affiliates to perform such obligations.

Section 15.15 <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.

Section 15.16 <u>Certain U.S. Federal Income Tax Treatment</u>. Pursuant to Section 15.12, 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; <u>provided however</u>, the Parties hereby acknowledge and agree that the Collaboration shall

be treated as a partnership for U.S. 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 and Celgene shall be treated as partners in such partnership (the "CA 23088 US 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 U.S. federal and state income tax purposes for such time. For so long as the tax partnership remains in existence, (a) Celgene shall control all tax matters with respect to the CA 23088 US Partnership (including the preparation of returns and making of elections) and shall be the "tax matters partner" of the CA 23088 US Partnership (as that term is defined in Section 6231(a)(7) of the Code), (b) Agios shall cooperate as reasonably requested by Celgene in furtherance of (a), (c) the CA 23088 US Partnership shall comply with the provisions of Subchapter K of the Code and the Treasury Regulations thereunder, including the requirements of Section 704 of the Code and the Treasury Regulations thereunder with respect to the maintenance of capital accounts and allocation of items, and (d) each payment made by Celgene in connection with this Agreement (including the initial payment pursuant to Section 9.1 and each milestone payment pursuant to Section 9.3) shall be reported for U.S. federal income tax purposes so as to maximize the amount deductible to Celgene in respect of any such payment (including as a result of the allocation of an amortization deduction) to the full extent permitted by the Code. Exhibit I of this Agreement sets for the Parties' intentions regarding allocations and other tax matters related to the tax partnership. Exhibit I shall be interpreted in a manner consistent with this Section 15.16.

Section 15.17 HSR Clearance; Cooperation.

- (a) HSR Filing. Notwithstanding anything in this Section to the contrary, the Parties shall use Commercially Reasonable Efforts to promptly obtain any necessary clearance under the HSR Act with respect to the transactions contemplated by this Agreement, including the prompt filing of a copy of this Agreement and each Party's respective premerger notification and report forms with the FTC and the DOJ pursuant to the HSR Act, and shall keep each other apprised of the status of any communications with, and any inquiries or requests for additional information from, the FTC and the DOJ and shall comply with any such inquiry or request; provided, however, that neither Party shall be required to consent to the divestiture or other disposition of any of its assets or assets of its Affiliates or to consent to any other structural or conduct remedy, and each Party and its Affiliates shall have no obligation to consent, administratively or in court, to any ruling, order or other action of the FTC or DOJ or any Third Party respecting the transactions contemplated by this Agreement.
- (b) <u>Cooperation</u>. The Parties commit to instruct their respective counsel to cooperate with each other and use Commercially Reasonable Efforts to facilitate and expedite the identification and resolution of any such issues and, consequently, the expiration of the applicable HSR Act waiting period. Each Party's counsel will undertake (A) to keep each other appropriately informed of communications from and to personnel of the reviewing antitrust authority, and (B) to confer with each other regarding appropriate contacts with and response to personnel of the FTC or DOJ. Celgene shall be responsible for the filing fee in connection with any HSR Act filing relating to the transactions contemplated in this Agreement.
 - (c) <u>Definitions</u>. For purposes of this Section 15.17, the following definitions shall apply:
 - (i) "DOJ" means the United States Department of Justice.

(ii) "FTC" means the United States Federal Trade Commission.

(iii) "HSR Act" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (15 U.S.C. §18a), and the rules and regulations promulgated thereunder.

 $[Remainder\ of\ page\ intentionally\ left\ blank]$

IN WITNESS WHEREOF, the Parties have executed this Collaboration and License Agreement as of the Effective Date.

AGIOS PHARMACEUTICALS, INC.

By: /s/ David Schenkein

Name: David Schenkein

Title: CEO

CELGENE CORPORATION

 By:
 /s/ Thomas Daniel

 Name:
 Thomas Daniel

 Title:
 President, R&D

Exhibit A

AGI-23088 (Also known as AG-881)

[**]

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Exhibit B

<u>Agios Patent Rights and Agios Collaboration Patent Rights</u> (as of the Effective Date)

| AGIOS DOCKET NO. | APPLICATION NO. | FILING DATE | PUBLICATION NO. | PATENT NO. |
|------------------|-----------------|-------------|-----------------|------------|
| [**] | [**] | [**] | [**] | [**] |

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of two pages were omitted. [**]

Exhibit C

[Exhibit no longer used]

C-1

Exhibit D

Existing Third Party Agreement

[**]

Exhibit E

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.

"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 US 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 or the AGI-23088 ROW Agreement (as the term "Licensed Products" is defined therein), 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 or the AGI-23088 ROW 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 US Territory, and shall consist of the following expenses: (a) Distribution Costs; (b) Health Care Reform Fees; (c) Manufacturing Costs for commercial supply in the US Territory; (d) Marketing Expenses; (e) Other Commercialization Costs; (f) Patent and Trademark Prosecution and Enforcement Costs incurred in any country of the US 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 of the US Territory 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 US 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).

"<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 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;
- (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 Trial 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 US 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 a full-time equivalent person year (consisting of a total of [**] hours per year) of scientific, technical or commercialization work undertaken by a Party's employees.

"FTE Costs" means, for any period, the FTE Rate multiplied by the number of FTEs in such period.

"FTE Rate" means \$[**] per FTE for each FTE devoted to Development and the overall rate as established from time to time by the Finance Working Group pursuant to Section 2.9(b)(vi) for each FTE devoted to Commercialization. On January 1, 2016 and on January 1st of each subsequent Calendar Year, the foregoing rates shall be increased for the Calendar Year then commencing by the percentage increase, if any, in the Consumer Price Index ("CPI") as of December 31 of the then most recently completed Calendar Year with respect to the level of the CPI on December 31, 2014. 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 Vital Statistics (or its successor equivalent index).

"Health Care Reform Fees" means Out-of-Pocket Costs representing the annual fee paid to the U.S. 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:

- (a) 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
- (b) 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 US 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 and/or promotion of a Licensed Product in the Territory; provided, that, 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; provided, further, that 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 US Territory with respect to a Licensed Product in the US 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; and education grant programs.

"Net Sales" means, with respect to any Licensed Product, gross amounts invoiced by the Parties, their respective Affiliates or sublicensees to Third Parties (that are not sublicensees) for the sale or other commercial disposition of such Licensed Product anywhere within the US Territory, including sales to wholesale distributors, less deductions from such amounts calculated in accordance with the Accounting Standards so as to arrive at "net sales" under the Accounting Standards, and further reduced by write-offs of accounts receivables or increased for collection of accounts that were previously written off.

Net Sales, and any and all set-offs against gross amounts invoiced, shall be determined from books and records maintained in accordance with the Accounting Standards, consistently applied throughout the organization and across all products of the entity whose sales of any Product are giving rise to Net Sales. Sales or other commercial dispositions of Licensed Products between a Party and its Affiliates and its sublicensees, and Licensed Products provided to Third Parties without charge, in connection with research and development, clinical trials, compassionate use, humanitarian and charitable donations, or indigent programs or for use as samples shall be excluded from the computation of Net Sales, and no payments will be payable on such sales or such other commercial dispositions, except where such an Affiliate or sublicensee is an end user of the Licensed Product.

If a Licensed Product is sold or otherwise commercially disposed of for consideration other than cash or in a transaction that is not at arm's length between the buyer and the seller, then the gross amount to be included in the calculation of Net Sales shall be the amount that would have been invoiced had the transaction been conducted at arm's length and for cash. Such amount that would have been invoiced shall be determined, wherever possible, by reference to the average selling price of the relevant Product in arm's length transactions in the relevant country.

In the event of an Agios Opt-Out Date, then, notwithstanding the foregoing, in the event a Licensed Product is sold as a Combination Product following the Agios Opt-Out Date, then Net Sales shall be calculated by multiplying the Net Sales of the Combination Product by the fraction A/(A+B), where A is the gross invoice price of the Licensed Product if sold separately in a country and B is the gross invoice price of the other product(s) included in the Combination Product if sold separately in such country. If no such separate sales are made by the relevant Party, its Affiliates or sublicensees in a country, Net Sales of the Combination Product shall be calculated in a manner to be negotiated and agreed upon by the Parties, reasonably and in good faith, prior to any sale of such Combination Product, which shall be based upon the relative value of the active components of such Combination Product.

As used in this definition, "Combination Product" means any product that comprises a Licensed Product sold in conjunction with another active ingredient so as to be a combination product (whether packaged together or in the same therapeutic formulation). Pharmaceutical dosage form vehicles, adjuvants and excipients shall be deemed not to be "active ingredients."

"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 Sections 10.2(e), 10.3(e) and 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 Trial Expenses" means all Out-of-Pocket Costs incurred for the US Territory related to a Phase IV Study for any Licensed Product in the US Territory, including expenses arising from: (a) the activities related to the performance of the Phase IV Trial; (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, 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 Trial 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.

"Product Liabilities" 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 and/or Commercialization) in the US 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 and/or the voluntary or involuntary withdrawal of the Licensed Product.

"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 in the US Territory and 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 in the US Territory, 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 US 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 in the US Territory, and (b) Out-of-Pocket Costs and FTE Costs directly attributable to selling the Licensed Products in the US Territory, 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(b) of this Agreement.

"US Territory 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, "US Territory Profit" refers to a Calendar Quarter or Calendar Year in which a profit exists, and "US Territory Loss" refers to a Calendar Quarter or Calendar Year in which a loss exists.

Exhibit F

Countries for Filing Agios Patent Rights and Collaboration Patent Rights

[**]

Exhibit G

Press Release



Agios Pharmaceuticals Selects Third Novel IDH Mutant Inhibitor, AG-881, for Clinical Development

- Brain-penetrant, pan-IDH mutant inhibitor broadens pipeline for treatment of patients with IDH mutant positive cancers
- New worldwide development and profit share collaboration for AG-881 entered into by Agios and Celgene
- Expect to initiate clinical development for AG-881 in second quarter 2015

CAMBRIDGE, Mass., April 28, 2015 — Agios Pharmaceuticals, Inc. (NASDAQ: AGIO), a leader in the fields of cancer metabolism and rare genetic disorders of metabolism, today announced that it plans to advance into clinical development AG-881, a small molecule that has shown in preclinical studies to fully penetrate the blood brain barrier and inhibit isocitrate dehydrogenase-1 (IDH1) and IDH2 mutant cancer cells, in collaboration with its cancer metabolism partner Celgene Corporation. The companies have entered into a new joint worldwide development and profit share collaboration for AG-881, and plan to initiate clinical development of AG-881 in the second quarter of 2015. AG-881 will be the third IDH mutant inhibitor discovered by Agios to enter clinical development.

"The addition of our third IDH mutant inhibitor to our growing pipeline is an exciting milestone for Agios and underscores our goals to lead the scientific understanding of cancer metabolism and help as many patients as possible with an IDH mutant positive cancer," said David Schenkein, M.D., chief executive officer of Agios. "AG-221 and AG-120 remain our lead medicines in clinical development and are advancing rapidly. We believe the addition of AG-881 given its unique profile provides added flexibility to our portfolio of IDH inhibitors. Based on our preclinical findings, it has the potential to support our ongoing development effort to provide treatment options to patients with glioma, and it represents a possible second-generation molecule for both AG-221 and AG-120 in IDH mutant tumors. We look forward to generating data for AG-881 to inform our future development plans."

Under the terms of the new AG-881 collaboration, Agios will receive an initial payment of \$10 million in the second quarter of 2015 and is eligible to receive regulatory milestone payments of up to \$70 million. Agios and Celgene will jointly collaborate on the worldwide development program for AG-881, sharing development costs 50/50 worldwide. The two companies have agreed to share any worldwide profits 50/50, with Celgene booking worldwide commercial sales. Agios would lead commercialization in the U.S. with both companies sharing equally in field-based commercial activities, and Celgene would lead commercialization ex-U.S. with Agios providing one third of field-based commercial activities in the major E.U. markets.

Summary of Agios and Celgene Collaboration on IDH Mutant Inhibitors

Agios and Celgene entered a global, strategic collaboration in April 2010 and, to date, three potential new distinct investigational medicines have emerged – the IDH2 mutant inhibitor, AG-221; the IDH1 mutant inhibitor, AG-120; and the pan-IDH mutant inhibitor, AG-881, which as described above is now part of a new collaboration between the companies. These three investigational medicines aim to improve the treatment outcomes for patients whose cancers carry these IDH mutations, including difficult to treat acute myelogenous leukemia and glioma, a type of aggressive brain tumor with poor prognosis. Each of these investigational medicines carries different financial terms and rights under the collaboration, including:

- AG-221: Celgene has worldwide development and commercialization rights for AG-221. Agios is eligible for up to \$120 million in milestone
 payments and royalties on any net sales.
- AG-120: Agios retains U.S. development and commercialization rights, while Celgene has development and commercialization rights outside the U.S. Agios is eligible to receive royalties on any net sales outside the U.S. and up to \$120 million in milestone payments. Celgene is eligible to receive royalties on any net sales in the U.S.
- AG-881: Joint worldwide development and 50/50 profit share agreement. Agios is eligible to receive regulatory milestone payments up to \$70 million.

About Agios Pharmaceuticals, Inc.

Agios Pharmaceuticals is focused on discovering and developing novel investigational medicines to treat cancer and rare genetic disorders of metabolism through scientific leadership in the field of cellular metabolism. In addition to an active research and discovery pipeline across both therapeutic areas, Agios has multiple first-in-class investigational medicines in clinical and/or preclinical development. All Agios programs focus on genetically identified patient populations, leveraging our knowledge of metabolism, biology and genomics. For more information, please visit the company's website at agios.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Such forward-looking statements include those regarding the potential benefits of, and plans relating to, the collaboration with Celgene; the potential benefits of AG-221, AG-120 and AG-881; and Agios' plans to generate data from AG-881 to inform its future development plans; and the benefit of Agios' strategic plans and focus. The words "anticipate," "believe," "estimate," "expect," "goal," "intend," "may," "plan," "possible," "potential," "predict," "project," "could," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from Agios' current expectations and beliefs. For example, there can be no guarantee that AG-881 or any other product candidate Agios is developing will successfully commence or complete necessary preclinical and clinical development phases, or that development of any of Agios' product candidates will successfully continue. There can be no guarantee that any positive developments in Agios' business will result in stock price appreciation. Management's expectations and, therefore, any forward-looking statements in this press release could also be affected by risks and uncertainties relating to a number of other important factors, including: Agios' results of clinical trials and preclinical studies, including subsequent analysis of existing data and new data received from ongoing and future studies; the content and timing of decisions made by the U.S. FDA and other regulatory authorities, investigational review boards at clinical trial sites and publication review bodies; Agios' ability to obtain and maintain requisite regulatory approvals and to enroll patients in its planned clinical trials; unplanned cash requirements and expenditures; competitive factors; Agios' ability to obtain, maintain and enforce patent and other intellectual property protection for any product candidates it is developing; Agios' ability to maintain key collaborations; and general economic and market conditions. These and other risks are described in greater detail under the caption "Risk Factors" included in Agios' Annual Report on Form 10-K for the year ended December 31, 2014, and other filings that Agios may make with the Securities and Exchange Commission in the future. Any forward-looking statements contained in this press release speak only as of the date hereof, and Agios expressly disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

###

Contact:

Agios Pharmaceuticals, Inc. Lora Pike, 617-649-8608 Senior Director, Investor Relations and Public Relations lora.pike@agios.com

Exhibit H

Initial JSC, JDC and JPC Appointments

Joint Steering Committee (JSC)

| Position | The Lot of | Celgene Appointee | Agios Appointee |
|----------|---------------------|-----------------------------|-----------------|
| | Initial Chairperson | [**] | [**] |
| | JSC Member | [**] | [**] |
| | JSC Member | [**] | [**] |
| | JSC Member | [**] | [**] |
| | | | |
| | | Joint Development Committee | (JDC) |
| Position | | Celgene Appointee | Agios Appointee |
| | Initial Chairperson | [**] | [**] |
| | JDC Member | [**] | [**] |
| | JDC Member | [**] | [**] |
| | JDC Member | [**] | [**] |
| | | | |
| | | Joint Patent Committee (JP | <u>C)</u> |
| Position | | Celgene Appointee | Agios Appointee |
| | Initial Chairperson | [**] | [**] |
| | JPC Member | [**] | [**] |
| | JPC Member | [**] | [**] |

Exhibit I

Partnership Tax Matters

(See attached.)

I-1

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

COLLABORATION

AND LICENSE AGREEMENT

by and between

AGIOS INTERNATIONAL SARL

and

CELGENE INTERNATIONAL II SARL

Re:

AGI-23088

for the

ROW Territory

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$\underline{Exhibits}$

Exhibit I

AGI-23088 Exhibit A Exhibit B Agios Patent Rights and Agios Collaboration Patent Rights $Exhibit \, C$ [Exhibit no longer used.] Exhibit D **Existing Third Party Agreement** Exhibit E Certain Financial Definitions Exhibit F Countries for Filing Agios Patent Rights and Collaboration Patent Rights Exhibit G Press Release Exhibit H Initial JSC, JDC and JPC Appointments

Partnership Tax Matters

COLLABORATION AND LICENSE AGREEMENT (AGI-23088 for the ROW Territory)

This Collaboration and License Agreement (this "Agreement") is entered into as of April 27, 2015 (the "Effective Date"), by and between Agios International Sarl, a limited liability company organized and existing under the laws of Switzerland ("Agios"), and Celgene International II Sarl, a limited liability company organized and existing under the laws of Switzerland and having its principal office in the Canton of Neuchatel, Switzerland ("Celgene").

INTRODUCTION

- 1. Agios Pharmaceuticals, Inc., a Delaware corporation ("Agios USA"), and Celgene Corporation, a Delaware corporation ("Celgene USA"), are parties to the Discovery and Development Collaboration and License Agreement, dated as of April 14, 2010, as amended (the "2010 Agreement").
- 2. Pursuant to the 2010 Agreement, Agios USA has discovered and is developing a compound referred to as AGI-23088 and as AG-881, which Agios USA and Celgene USA believe to be a potent inhibitor of IDH1 and IDH2 mutants and wild type, with the potential for penetration of the blood brain barrier
- 3. Agios USA and Celgene USA, along with Agios and Celgene, have agreed that the further Development and Commercialization of AGI-23088, which has potential overlaps with other programs currently being undertaken pursuant to the 2010 Agreement, should be conducted pursuant to the terms of this Agreement between the Parties for the ROW Territory and another agreement between Celgene USA and Agios USA for the US Territory ("AGI-23088 US Agreement") and that all further such activities related to AGI-23088 should cease under the 2010 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

When used in this Agreement, each of the following terms shall have the meanings set forth in this Article I:

Section 1.1 "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, "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.

- Section 1.2 "AGI-23088" means the compound described on Exhibit A to this Agreement. Such compound may also be referred to from time to time as AG-881.
- Section 1.3 "Agios Collaboration Intellectual Property," "Agios Collaboration Know-How" and "Agios Collaboration Patent Rights" means, respectively, the Collaboration Intellectual Property Controlled by Agios or Agios USA, the Collaboration Know-How Controlled by Agios or Agios USA, and the Collaboration Patent Rights Controlled by Agios or Agios USA.
 - Section 1.4 "Agios Intellectual Property" means Agios Know-How and Agios Patent Rights, collectively.
- Section 1.5 "Agios Know-How" means any Know-How that is (a) Controlled by Agios or Agios USA as of the Effective Date or during the Term, and (b) necessary or useful for the Development, Manufacture and/or Commercialization of the Licensed Products, but excluding Collaboration Know-How.
 - Section 1.6 "Agios Opt-Out Date" has the meaning set forth in the AGI-23088 US Agreement.
 - Section 1.7 "Agios Opt-Out Notice" has the meaning set forth in the AGI-23088 US Agreement.
- Section 1.8 "Agios Patent Rights" means any Patent Rights that (a) are Controlled by Agios or Agios USA as of the Effective Date or during the Term, and (b) Cover, or are otherwise necessary or useful for the Development, Manufacture and/or Commercialization of, the Licensed Products (including the composition of matter, manufacture or any use thereof); but excluding Collaboration Patent Rights. Agios Patent Rights as of the Effective Date are as set forth on Exhibit B to this Agreement.
 - Section 1.9 "Business Day" means a day other than a Saturday or Sunday or federal holiday in Cambridge, Massachusetts or Summit, New Jersey.
- Section 1.10 "Calendar Quarter" 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 June following the Effective Date.
- Section 1.11 "Calendar Year" 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, 2015.
- Section 1.12 "Celgene Collaboration Intellectual Property", "Celgene Collaboration Know-How" and "Celgene Collaboration Patent Rights" means, respectively, the Collaboration Intellectual Property Controlled by Celgene or Celgene USA, the Collaboration Know-How Controlled by Celgene or Celgene USA and the Collaboration Patent Rights Controlled by Celgene or Celgene USA.

- Section 1.13 "Celgene Intellectual Property" means Celgene Know-How and Celgene Patent Rights, collectively.
- Section 1.14 "Celgene Know-How" means any Know-How that is (a) Controlled by Celgene or Celgene USA as of the Effective Date or during the Term; (b) necessary for the Development, Manufacture and/or Commercialization of the Licensed Products; and (c) contributed by Celgene or Celgene USA, in Celgene's or Celgene USA's sole discretion, to the Collaboration, as evidenced by written notice from Celgene or Celgene USA to Agios; but excluding Collaboration Know-How.
- Section 1.15 "Celgene Patent Rights" means any Patent Rights that (a) are Controlled by Celgene or Celgene USA as of the Effective Date or during the Term; (b) Cover the Licensed Products (including the composition of matter, manufacture or any use thereof); and (c) are contributed by Celgene or Celgene USA, in Celgene's or Celgene USA's sole discretion, to the Collaboration, as evidenced by written notice from Celgene or Celgene USA to Agios; but excluding Collaboration Patent Rights.
- Section 1.16 "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 1.17 "Code" means the United States Internal Revenue Code of 1986, as amended.
- Section 1.18 "Collaboration" 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, the AGI-23088 US Agreement, and the activities performed by a Party or the Parties relating to the Development and Manufacturing of AGI-23088 under the 2010 Agreement before the Effective Date, collectively.
 - Section 1.19 "Collaboration Intellectual Property" means Collaboration Know-How and Collaboration Patent Rights, collectively.
- Section 1.20 "Collaboration Know-How" means any Know-How or interest therein that was, before the Effective Date, or is, on or after the Effective Date, developed or generated, either solely by or on behalf of Celgene, Celgene USA, Agios or Agios USA or jointly by or on behalf of any of such Persons in the conduct of the Collaboration, including Joint Inventions.
- Section 1.21 "Collaboration Patent Rights" means any Patent Rights or interest therein that was, before the Effective Date, or is, on or after the Effective Date, Controlled solely by Celgene, Celgene USA, Agios or Agios USA or Controlled jointly by any of such Persons and that Cover Collaboration Know-How, including Joint Patents and any such Patent Rights filed before or after the Effective Date.

Section 1.22 "<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 and any Phase IV Studies).

Section 1.23 "Commercially Reasonable Efforts" means, with respect to the performing Party, the carrying out of obligations of such Party in a diligent, expeditious and sustained manner, including the allocation of a commercially reasonable level of personnel and financial resources, but in no event less than such level of resources that an established biopharmaceutical company typically devotes to products of similar market potential at a similar stage in its development or product life, taking into account scientific and commercial factors, including commercial Manufacturing, issues of safety and efficacy, product profit, difficulty in developing or manufacturing the Licensed Products, competitiveness of alternative Third Party products in the marketplace, the patent or other proprietary position of the Licensed Products, the regulatory requirements involved and the potential profitability for the performing Party of the Licensed Products, marketed or to be marketed.

Section 1.24 "Companion Diagnostic" means a biomarker or diagnostic test that may be used with a Licensed Product, or may be developed by the Parties pursuant to Section 3.4, 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 type of cancer or to predict which patients are suitable candidates for a specific form of chemotherapy.

Section 1.25 "Compound" means AGI-23088 and any polymorph, isotopologue, stereoisomer, prodrug, solvate, co-crystal or salt of AGI-23088.

Section 1.26 "<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, the AGI-23088 US Agreement or the 2010 Agreement relating to the Licensed Products and all proprietary biological materials of a Party.

Section 1.27 "Controll" or "Controlled" means, with respect to any (a) Know-How or other information or materials, (b) compound, 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.

Section 1.28 "Core Patent Rights" means Patent Rights comprising [**] claims.

Section 1.29 "Cover," "Covering" or "Covered" means that, with respect to a product or technology, but for a Person's ownership of Patent Rights or a license granted to a Person under a Valid Claim included in the Patent Rights under which such license is granted, the Development, Manufacture, Commercialization and/or other use of such product or practice of

such technology by such Person would infringe any Valid Claim of any patent included in such Patent Rights or, with respect to a Valid Claim included in any patent application, would infringe such Valid Claim if such patent application were to issue as a patent.

- Section 1.30 "<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 1.31 "<u>Develop</u>" or "<u>Development</u>" means research, preclinical, non-clinical and clinical development activities, including activities relating to assays, test method development and stability testing, toxicology, pharmacology, formulation, quality assurance/quality control development, Clinical Trials (including any Phase IV Study), technology transfer, statistical analysis, process development and scale-up, pharmacokinetic studies, data collection and management, report writing, and other pre-Regulatory Approval activities.
- Section 1.32 "<u>Development Plan</u>" means a development plan and related budget approved by the JSC by Mutual Consent after the Effective Date, as amended from time to time by the JSC by Mutual Consent.
 - Section 1.33 "Excess Amount" has the meaning set forth in the AGI-23088 US Agreement.
- Section 1.34 "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 1.35 "Existing Third Party Agreement" means any agreement listed on Exhibit D to this Agreement.
 - Section 1.36 "FDA" means the United States Food and Drug Administration, or any successor agency thereof.
- Section 1.37 "FDCA" means the United States Federal Food, Drug, and Cosmetic Act, and the regulations promulgated thereunder, each as amended from time to time.
 - Section 1.38 "Field" means the treatment, control, mitigation, prevention or cure or diagnosis of any Indications.
- Section 1.39 "First Commercial Sale" means the first commercial sale of a Licensed Product by a Party, its Affiliates, distributors and/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 1.40 "Generic Competition" means, with respect to a Licensed Product in a given country in a given Calendar Year, that, during such Calendar Year [**] Generic Products shall be commercially available in such country.

Section 1.41 "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 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.

Section 1.42 "Global Safety Database" has the meaning set forth in the AGI-23088 US Agreement.

Section 1.43 "<u>IDH1</u>" means (alias PICD, IDPC; UniProt identifier O75874) the persoxisomal/cytosolic form of isocitrate dehydrogenase that catalyzes the NADP+ dependent conversion of isocitrate to alpha-ketoglutarate.

Section 1.44 "<u>IDH2</u>" means (alias ICD-M, IDPM; UniProt identifier P48735) the mitochondrial form of isocitrate dehydrogenase that catalyzes the NADP+ dependent conversion of isocitrate to alpha-ketoglutarate.

Section 1.45 "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.

Section 1.46 "IND Acceptance Date" means thirty (30) days following the filing of an IND with the FDA; provided that the FDA has not provided any communication indicating that the conduct of clinical activities described in such IND may not begin within thirty (30) days

after such filing. In the event that any such communication is provided by the FDA, "IND Acceptance Date" means the date that the Parties are permitted by the FDA to begin clinical activities. If the Parties both agree, "IND Acceptance Date" means the date, following filing of an IND with a Regulatory Authority (other than the FDA), that Agios receives a written communication from such Regulatory Authority pursuant to which the conduct of clinical activities described in the appropriate submissions is permitted to begin.

Section 1.47 "Indication" means any human disease, condition or syndrome, or sign or symptom of, or associated with, a human disease or condition.

Section 1.48 "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.

Section 1.49 "<u>Law</u>" 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.

Section 1.50 "Licensed Products" means (a) a Compound, and (b) any product that contains a Compound as an active ingredient.

Section 1.51 "<u>Licensee Partner</u>" means any Third Party to whom a Party or any of its Affiliates grants a sublicense or license with respect to the Development, Manufacture or Commercialization of Licensed Products in the Field in the ROW Territory under the rights to Agios Intellectual Property, Celgene Intellectual Property or Collaboration Intellectual Property, as the case may be, granted to such Party or Affiliate hereunder, in each case excluding (a) any Person that is granted a sublicense in accordance with Section 8.2(a), 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.

- Section 1.52 "Major European Countries" means France, Germany, Italy, Spain and the United Kingdom.
- Section 1.53 "Major Market" means each of the United States of America, Japan, and the Major European Countries.

Section 1.54 "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.

Section 1.55 "Manufacturing Technology" means copies of all Celgene Know-How, Agios Know-How or Collaboration Know-How, as applicable, which are necessary or useful for Manufacturing preclinical, clinical and/or commercial supply, as applicable, of the Licensed Products, including specifications, assays, batch records, quality control data, and transportation and storage requirements.

Section 1.56 "Mutual Consent" means with respect to any matter specified as requiring "Mutual Consent", that each Party must consent in writing to the action to be taken (or not taken), or if the matter is one referred to the JSC, that the JSC must approve the action to be taken (or not taken) by unanimous vote, with each Party (or its voting member of the JSC), in its/his/her sole discretion, being entitled to withhold its/his/her consent to or approval of the matter; provided, however, that a Party may take any such action as required by applicable Law or order of any governmental authority in the absence of the consent of the other Party or the approval of the JSC, as applicable.

Section 1.57 "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 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, and (c) all supplements and amendments that may be filed with respect to the foregoing.

Section 1.58 "Parent" means, with respect to Agios, Agios USA, and with respect to Celgene, Celgene USA.

Section 1.59 "Party" means Agios or Celgene; "Parties" means Agios and Celgene.

Section 1.60 "Patent Rights" 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, supplemental protection certificates, or extensions of any of the foregoing anywhere in the world.

Section 1.61 "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.

Section 1.62 "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).

Section 1.63 "Phase II Study" means a human clinical trial of a product, the principal purpose of which is a preliminary determination of safety and efficacy or appropriate dosage ranges in the target patient population or a 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(b), as amended (or the non-United States equivalent thereof)

Section 1.64 "Phase III Study" means a pivotal human clinical trial of a product, the principal purpose of which is to gain evidence with statistical significance of the efficacy of a product in a target population, to obtain expanded evidence of safety for such product that is needed to evaluate the overall benefit-risk relationship of such product, and to provide an adequate basis 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 or maintain Regulatory Approval for such product, including all tests and studies prescribed by the applicable Regulatory Authority, from time to time, pursuant to applicable Law or otherwise, including for example the trials referred to in 21 C.F.R. §312.21(c), as amended (or the non-United States equivalent thereof).

Section 1.65 "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 1.66 "Prosecution" or "Prosecute" means the filing, preparation, prosecution and maintenance of Patent Rights, including any and all pre-grant and post-grant *ex-parte* or *inter partes* proceedings before any patent authority, such as interferences, reissue proceedings, reexaminations, oppositions or other challenges to the patentability or validity of any Patent Rights not initiated through a court or other tribunal that determines infringement.

Section 1.67 "<u>Publication</u>" means any publication in a scientific journal or other scientific periodical, publication in any government clinical trial reporting website, any abstract to be presented to any scientific audience, any presentation at any scientific conference, including slides and texts of oral or other public presentations, any other public presentation directed to a scientific audience that pertains to any Licensed Product, the use of any Licensed Product, or the data or result from any work under the Collaboration.

Section 1.68 "Regulatory Approval" 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.

Section 1.69 "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 of a product in a country or territory.

Section 1.70 "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 1.71 "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 1.72 "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 1.73 "ROW Territory" means all countries in the world other than the US Territory.

Section 1.74 "Sole" means, with respect to the license of any Patent Rights or Know-How, that such license is an exclusive license, except for the rights reserved by the licensor for itself and its Affiliates (a) to continue to practice the subject Patent Rights and Know-How and (b) to license or sublicense, as applicable, the subject Patent Rights and Know to Third Parties as reasonably necessary for such licensor or its Affiliates to exercise their rights or fulfill their obligations under the Collaboration.

Section 1.75 "Target" means IDH1 or IDH2.

Section 1.76 "Territory" means the US Territory and the ROW Territory.

Section 1.77 "Third Party" means any Person other than Agios or Celgene or each Party's respective Affiliates.

Section 1.78 "Third Party Agreement" means (a) the Existing Third Party Agreement and (b) any other Third Party agreements which either Party may enter into, during the Term in

accordance with the terms of this Agreement, to acquire or license Third Party Patent Rights or Know-How that are necessary or useful for the Development, Manufacture and/or Commercialization of the Licensed Products.

Section 1.79 "Third Party Rights" 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 1.80 "US Territory" means the United States of America, including its territories, possessions and Puerto Rico.

Section 1.81 "Valid Claim" 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 [**] years from the earliest filing date to which such patent application or claim is entitled.

Section 1.82 Additional Definitions. Each of the following definitions is set forth in the section of this Agreement indicated below:

| DEFINITION | SECTION |
|---|--------------|
| 2010 Agreement | Introduction |
| AAA | 15.1(b) |
| Accounting Standards | Exhibit E |
| Acquired Party | 15.4(b) |
| Acquired Party Activity | 15.4(c) |
| Acquired Third Party | 15.4(c) |
| Acquirer | 15.4(b) |
| Acquisition | 15.4(b) |
| Additional Development Activities | 3.3 |
| Additional Development Opt-In Date | 3.3(e)(i) |
| Additional Development Opt-In Notice | 3.3(e) |
| Additional Development Proposal | 3.3(a) |
| Additional Development Party | 3.3(c) |
| Additional Revenue | Exhibit E |
| Advertising and Market Research Expenses | Exhibit E |
| AGI-23088 US Agreement | Recitals |
| Agios | Preamble |
| Agios Clinical-Scale Manufacturing Responsibilities | 4.1(a) |
| Agios Commercial-Scale Manufacturing Responsibilities | 4.1(a) |
| Agios Guarantor | 15.17 |
| Agios Indemnified Parties | 13.1(a) |
| | |

| DEFINITION | SECTION |
|--|--------------|
| Agios Non-Satisfaction Condition | 15.17 |
| Agios Obligations | 15.17 |
| Agios USA | Recitals |
| Agreement | Preamble |
| Alliance Manager | 2.6 |
| Annual Net Sales | Exhibit E |
| Arbitrable Matters | 15.1(b) |
| Audit Team | 9.8(a) |
| Audit Rights Holder | 9.8(f) |
| Auditee | 9.8(f) |
| Bankruptcy Code | 8.8 |
| Breaching Party | 14.2(b)(i) |
| CA 23088 ROW Partnership | 15.16 |
| Celgene | Preamble |
| Celgene Controlled Agios Patent Rights | 10.2(b) |
| Celgene Guarantor | 15.18 |
| Celgene Indemnified Parties | 13.2(a) |
| Celgene Manufacturing Responsibilities | 4.1(c) |
| Celgene Non-Satisfaction Condition | 15.18 |
| Celgene Obligations | 15.18 |
| Celgene USA | Recitals |
| Challenge | 10.8(a) |
| Change of Control | 15.5(c) |
| Combination Product | Exhibit E |
| Commercialization Expenses | Exhibit E |
| Commercialization Budget | 6.2(a)(i) |
| Commercialization Plan | 6.2(a)(i) |
| Committee | 2.1(a) |
| Competitive Infringement | 10.3(b) |
| Cooperating Party | 11.3(b)(iii) |
| CPI | Exhibit E |
| CREATE Act Patent | 10.7 |
| Development Budget | 3.1(a) |
| Development Costs | Exhibit E |
| Disclosing Party | 11.1 |
| Dispute | 15.1(a) |
| Distribution Costs | Exhibit E |
| [**] Agreement | Exhibit D |
| Earlier Patent | 10.7 |
| Effective Date | Preamble |
| Expert | 15.1(b)(i) |
| Finance Working Group | 2.1(a) |
| Financial Exhibit | 2.9(b) |
| FTE | Exhibit E |
| FTE Costs | Exhibit E |
| | |

| DEFINITION | SECTION |
|--|--------------|
| FTE Rate | Exhibit E |
| [**] | 15.12 |
| Initial Enforcement Party | 10.3(b) |
| Invalidity Claim | 10.4(b) |
| JCC | 2.1(a) |
| JDC | 2.1(a) |
| Joint Inventions | 10.1(c) |
| Joint Patents | 10.1(c) |
| JPC | 2.1(a) |
| JPC Designee | 2.8(e) |
| JSC | 2.1(a) |
| Manufacturing Costs | Exhibit E |
| Manufacturing Scale-Up Costs | Exhibit E |
| Marketing Activities | 6.3(a) |
| Marketing Expenses | Exhibit E |
| Marketing Management Expenses | Exhibit E |
| Medical Education Expenses | Exhibit E |
| Net Sales | Exhibit E |
| Non-Additional Development Party | 3.3(c) |
| Non-Breaching Party | 14.2(b)(i) |
| Objecting Party | 6.1(b) |
| Other Commercialization Costs | Exhibit E |
| Out-of-Pocket Costs | Exhibit E |
| Patent and Trademark Prosecution and Enforcement Costs | Exhibit E |
| Patent Prosecution Expenses | 10.2(e) |
| Payments | 9.9(a) |
| Pharmacovigilance Agreement | 5.3 |
| Phase IV Trial Expenses | Exhibit E |
| Product Liabilities | Exhibit E |
| Product Trademarks | 6.4(a) |
| Proposing Party | 6.1(b) |
| Prosecuting Party | 10.2(f)(i) |
| Recall Expenses | Exhibit E |
| Receiving Party | 11.1 |
| Reconciliation Procedures | 2.9(b) |
| Redacted Version | 11.3(b)(i) |
| Regulatory Interactions | 5.1(b) |
| Regulatory Expenses | Exhibit E |
| Regulatory Maintenance Costs | Exhibit E |
| Requesting Party | 11.3(b)(iii) |
| Royalty Term | 9.5(b) |
| Selling Expenses | Exhibit E |
| Step-In Enforcement Party | 10.3(d) |
| Term | 14.1 |
| Third Party Activity | 15.4(b) |
| | |

| DEFINITION | SECTION |
|---------------------------------------|------------|
| Third Party Contractors | 8.2(a)(ii) |
| Third Party Infringement | 10.3(a) |
| Third Party Infringement Action | 10.4(a) |
| Third Party Patent Costs | Exhibit E |
| Third Party Products Liability Action | 13.4(a) |
| ROW Territory Loss | Exhibit E |
| ROW Territory Profit | Exhibit E |
| ROW Territory Profit or Loss | Exhibit E |

Article II Governance; Collaboration

Section 2.1 General.

- (a) Governance Committees. The Parties hereby establish (i) a Joint Steering Committee ("JSC") to oversee and coordinate the overall conduct of all further activities concerning the Collaboration after the Effective Date; (ii) a Joint Development Committee ("JDC") to oversee and coordinate Development (including Manufacturing of clinical supply) of the Licensed Product(s); (iii) a Joint Commercialization Committee ("JCC") to oversee the Commercialization (including Manufacturing of commercial supply) of the Licensed Products; (iv) the Joint Patent Committee ("JPC") to coordinate the Prosecution of Agios Patent Rights, Agios Collaboration Patent Rights, Celgene Patent Rights and Celgene Collaboration Patent Rights (the JSC, the JDC, the JCC and JPC shall each be referred to as a "Committee"); and (v) a joint Finance Working Group ("Finance Working Group") to coordinate financial aspects of the Collaboration and to act as a resource for all financial matters for each Committee as needed. Each Committee may from time to time establish subcommittees or project teams to handle matters within the scope of its authority. 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.
- (b) <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):
- (i) All activities regarding Development, Manufacturing and Commercialization of a Compound or Licensed Product containing AGI-23088 shall cease under the 2010 Agreement and all future such activities shall be conducted solely under this Agreement and the AGI-23088 US Agreement.
- (ii) 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 8.8 of the 2010 Agreement.
- (iii) Neither AGI-23088 nor any other Compound or Licensed Product is or can be (A) included as an "Agreement Compound" or in any of the classes of compounds comprising "Agreement Compounds", (B) part of the "Compound List," (C) included in any of the "Picks", or (D) part of an "Agios Reverted Program," or "Celgene Reverted Program".

- (iv) 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 the Licensed Products.
- (v) 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. Each meeting of a Committee or working group under this Agreement shall be conducted separately from any meeting of a "Committee" or working group under the 2010 Agreement.
- (vi) All "Confidential Information" disclosed under the 2010 Agreement that solely relates to AGI-23088, Compound or any Licensed Product 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, AGI-23088, Compound or any Licensed Product 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 the 2010 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.

Section 2.2 Joint Steering Committee.

- (a) <u>Establishment</u>. The initial members of the JSC for each Party will be determined by each Party, respectively, within [**] days after the Effective Date, and the Parties will complete <u>Exhibit H</u> to reflect such appointments. The Parties intend that the JSC shall have the responsibility for general oversight over the Collaboration for the ROW Territory and for coordinating with the JSC from the AGI-23088 US Territory Agreement on such matters.
 - (b) <u>Duties</u>. The JSC shall:
- (i) oversee and coordinate the conduct of the Collaboration for the ROW Territory and related matters within the responsibilities of the Committees hereunder;
- (ii) by Mutual Consent provide strategic guidance, and coordinate efforts between the Parties, with respect to any Publications and by Mutual Consent approve requests for Publication, from either Party, according to Section 11.4 hereof;
 - (iii) serve as a forum for dispute resolution in accordance with Section 2.8 with respect to matters that are not resolved at the JDC or JCC;

(iv) approve the initial Development Plan (as provided in Section 1.32) and any changes thereto proposed by the JDC, in all cases by Mutual Consent; and

(v) perform such other duties as are specifically assigned to the JSC under this Agreement.

Section 2.3 Joint Development Committee.

(a) <u>Establishment</u>. The initial members of the JDC for each Party will be determined by each Party, respectively, within [**] days after the Effective Date, and the Parties will complete <u>Exhibit H</u> to reflect such appointments. The Parties intend that the JDC shall have the responsibility for overseeing the Development of Licensed Products under the Collaboration for the ROW Territory and for coordinating with the JDC from the AGI-23088 US Territory Agreement on such matters.

(b) Duties. The JDC shall:

- (i) review and recommend to the JSC approval of the initial Development Plan (as provided in Section 1.32) and any proposed updates or amendments to the Development Plan (and applicable Development Budget) as needed;
- (ii) oversee, review, coordinate and provide strategic guidance to the Parties on the Development of the Licensed Products in the ROW Territory, including assigning activities to be performed by each Party, subject to the provisions of Section 3.1;
- (iii) in conjunction with any committees under the AGI-23088 US Agreement responsible for Development of the Licensed Products, review and coordinate such committees' activities with respect to the Development of the Licensed Products with the Parties activities under this Agreement;
- (iv) subject to and within the parameters of each Development Plan (A) 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 (B) oversee and approve the overall strategy and positioning of all material submissions and filings with the applicable Regulatory Authorities;
 - (v) manage the Development of any Companion Diagnostics, including the Development of any biomarkers;
- (vi) oversee, review and coordinate the studies required for the preparation of the CMC section of an IND for filing with Regulatory Authorities for the Licensed Products, including studies relating to analytical methods and purity analysis, and (in conjunction with the JCC) formulation and Manufacturing development studies, together with associated regulatory activities;
 - (vii) oversee, review and coordinate Manufacturing of Licensed Product for Development purposes;

- (viii) review and approve the content of any IND for a Licensed Product;
- (ix) develop and approve a publication plan for any Publications made prior to the First Commercial Sale of a Licensed Product in the ROW Territory;
- (x) in conjunction with the JCC, oversee and coordinate the Parties' activities with respect to the Manufacture of pre-clinical and clinical supply of the Licensed Products; and
 - (xi) perform such other duties as are specifically assigned to the JDC under this Agreement.
- Section 2.4 <u>Joint Commercialization Committee</u>. Upon initiation of the [**] Study with respect to a Licensed Product or within [**] days 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 Licensed Products under the Collaboration for the ROW Territory and for coordinating with the JCC from the AGI-23088 US Territory Agreement on such matters.

(a) Duties. The JCC shall:

- (i) oversee, review and coordinate the Commercialization of the Licensed Products by the Parties in the ROW Territory;
- (ii) in conjunction with any committees under the AGI-23088 US Agreement responsible for Commercialization of the Licensed Products, review and coordinate such committees' activities with respect to the Commercialization of the Licensed Products with the Parties activities under this Agreement;
 - (iii) develop and oversee a pricing and branding strategy for the Licensed Products;
 - (iv) set overall strategic objectives and plans related to Commercialization of the Licensed Products in the ROW Territory;
- (v) review and approve the annual Commercialization Plan for the Licensed Products, and any updates or amendments thereto, and propose revisions to the Commercialization Plan as needed;
 - (vi) review and approve all sales, promotional and communication materials for the Licensed Products;
- (vii) develop and approve a publication plan for any Publications made after the First Commercial Sale of a Licensed Product in the ROW Territory;
 - (viii) provide a forum for the Parties to share information with respect to the Commercialization of the Licensed Products;

- (ix) review and provide strategic guidance on all Marketing Activities with respect to the Licensed Products worldwide;
- (x) subject to and within the parameters of the Commercialization Plan, oversee the implementation of such plan;
- (xi) confirm that both Parties' have approved all promotional materials in accordance with the Parties' internal copy review procedures;
- (xii) oversee, review and coordinate Manufacturing of commercial supply of the Licensed Products; and
- (xiii) perform such other duties as are specifically assigned to the JCC under this Agreement.

Section 2.5 Joint Patent Committee.

(a) <u>Establishment</u>. The initial members of the JPC for each Party will be determined by each Party, respectively, within [**] days after the Effective Date, and the Parties will complete <u>Exhibit H</u> to reflect such appointments. The Parties intend that the JPC shall have the responsibility for sharing information and coordinating Patent Prosecution matters involving Agios Patent Rights, Celgene Patent Rights, and Collaboration Patent Rights for the ROW Territory and for coordinating with the JPC from the AGI-23088 US Territory Agreement on such matters.

(b) <u>Duties</u>. The JPC shall:

- (i) discuss the current status of all Agios Patent Rights, Celgene Patent Rights and Collaboration Patent Rights in the ROW Territory;
- (ii) discuss filing and claiming strategies involving Agios Patent Rights, Celgene Patent Rights and Collaboration Patent Rights in the ROW Territory for all those existing as of the Effective Date as well as any new applications for the foregoing to be filed after the Effective Date;
- (iii) in conjunction with the JPC from the AGI-23088 US Territory Agreement, coordinate the timing and conduct of the Parties' respective activities assigned to each of them under this Agreement with respect to Prosecution;
- (iv) in conjunction with the JPC from the AGI-23088 US Territory Agreement, coordinate the Parties' respective activities in preparation for potential litigation involving the assertion of the Agios Patent Rights, Agios Collaboration Patent Rights, Celgene Patent Rights and Celgene Collaboration Patent Rights in the ROW Territory under Section 10.3(c); and
 - (v) perform such other duties as are specifically assigned to the JPC under this Agreement.

Section 2.6 <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, JDC and JCC 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.

Section 2.7 General Committee Membership and Procedures.

(a) Committee Membership. Each Committee shall each be composed of three (3) representatives from Celgene, on the one hand, and (3) representatives from Agios, on the other hand, 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 and Commercialization of the Licensed 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. [**] shall appoint an initial chairperson from among its members for the JDC, and [**] shall appoint an initial chairperson for each Committee shall alternate each Calendar Year between a representative of Agios and a representative of Celgene. The initial chairperson for each Committee is indicated on Exhibit H. Within fifteen (15) Business Days 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 Consent, such minutes within fifteen (15) Business Days following circulation.

(b) Committee Meetings.

(i) The JSC, JPC and JDC shall hold an initial meeting within [**] days of the Effective Date or as otherwise agreed by the Parties. Thereafter, each Committee shall meet at least once every Calendar Quarter, unless the respective Committee members otherwise agree. All Committee meetings shall be conducted in person, unless otherwise determined by the applicable Committee by Mutual Consent.

(ii) 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 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 XI; 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.

Section 2.8 Decision Making.

- (a) Committee Voting. All decisions of a Committee 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 [**] Business Days 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 [**] Business Days 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) Referrals from the JSC to Executive Officers. 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 [**] Business Days 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 [**] Business Days after the matter is referred to them, then, subject to Section 2.8(c):
- (i) if the unresolved matter relates to the Development of the Licensed Products, including Agios Clinical-Scale Manufacturing Responsibilities and Celgene Manufacturing Responsibilities during Development and Regulatory Interactions in a geography until Regulatory Approval for such geography, neither Party shall have final decision-making rights with respect to such matter and neither Party may take action with respect to the unresolved matter unless and until resolved by Mutual Consent;
- (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, provided that 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, subject to Section 6.3(f), Celgene shall have the right to decide the unresolved matter for the ROW Territory except for the matters specified in subsection (ii)(A) above, <u>provided that</u> Celgene shall give due consideration to any comments or preferences expressed by Agios with respect to such matter.

- (e) <u>JPC</u>. If the JPC is unable to decide, by unanimous vote, on any matter within [**] Business Days after the matter is first raised with the JPC, then the matter will be referred to the Vice President of Intellectual Property, Chief Patent Counsel of Celgene and the Vice President of Legal of Agios (each, a "<u>JPC Designee</u>") for resolution. If such matter is not resolved by such JPC Designees of the Parties within [**] Business Days after the matter was referred to them, then the JPC Designees shall submit such matter for attempted resolution by agreement of the Executive Officers. If the Executive Officers are unable to resolve any matter referred to them by the JPC Designees within [**] Business Days after the matter is referred to them, then, subject to Section 2.8(f), a Party may exercise its rights to decide the matter as provided in Article X. 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 Patent Rights 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. Notwithstanding the foregoing, neither Party shall have the right to finally resolve a dispute pursuant to Section 2.8(d)(ii) or (iii) or 2.8(e):
 - (i) in a manner that excuses such Party from any of its obligations specifically enumerated under this Agreement;
 - (ii) in a manner that negates any consent rights or other rights specifically allocated to the other Party under this Agreement;
 - (iii) to resolve any dispute involving the breach or alleged breach of this Agreement;
 - (iv) to resolve any dispute regarding whether a milestone event set forth in Section 9.3 has been achieved;
- (v) to resolve a matter if the provisions of this Agreement specify that mutual agreement of the Parties or a Mutual Consent is required for such matter; or
 - (vi) in a manner that would require the other Party to perform any act that is inconsistent with any Law.

Section 2.9 Finance Working Group.

(a) <u>Establishment</u>. Within [**] days after the Effective Date, the Parties shall establish the Finance Working Group. The Finance Working Group shall include individuals from each Party with reasonable expertise in the areas of accounting, cost allocation, budgeting financial reporting and tax. Membership and governance of the Finance Working Group shall be as set forth in Section 2.7 as if the Finance Working Group were a Committee for the limited purpose of such Section. The Parties intend that the Finance Working Group shall have the responsibility for the matters set forth in subsection (b) of this Section 2.9 with respect to the ROW Territory and for coordinating with the Finance Working Group from the AGI-23088 US Territory Agreement on such matters.

- (b) <u>Duties</u>. The purpose of the Finance Working Group is to provide financial information as requested to the JDC and JSC with respect to the Development of the Licensed Products, to the JCC and JSC with respect to the Commercialization of the Licensed Products, and to the JSC with respect to the preparation and approval of ROW Territory Profit or Loss statements in accordance with the provisions of Section 9.4 and <u>Exhibit E</u> to this Agreement (the "<u>Financial Exhibit"</u>). The Finance Working Group will also develop procedures for quarterly reporting of actual results and review and discussion of potential discrepancies, quarterly reconciliation, reasonable forecasting and for each Party's review of the applicable books and records of the other Party, as well as other finance, tax and accounting matters, to the extent not set forth in the provisions below or in the Financial Exhibit (the "<u>Reconciliation Procedures</u>"). Such procedures must be established in a manner that provides the ability to comply with financial reporting requirements of each Party. The Finance Working Group shall be responsible for:
- (i) coordinating and conducting the accounting, reporting, reconciliation and other related activities set forth in this Agreement and the Financial Exhibit;
- (ii) advising and providing support to the JSC and the other Committees with respect to financial, accounting, tax, budgeting, reporting and other issues that may arise in connection with the various plans and corresponding budgets for activities thereunder;
 - (iii) reviewing relevant FTE Costs and Out-of-Pocket Costs incurred by the Parties and their Affiliates hereunder;
 - (iv) recommending for approval by the JSC any changes to reporting procedures;
- (v) coordinating or performing the budgeting, consolidation, completion and review of Development Cost and ROW Territory Profit or Loss statements in accordance with the Reconciliation Procedures and the Financial Exhibit, including budgeting and calculation of expenses not covered in the Development Budget or the Commercialization Budget;
- (vi) establishing the overall FTE Rate to be applied to each FTE devoted to Commercialization on a country-by-country basis at least [**] months prior to commencement of Commercialization activities (including pre-launch activities) and annually thereafter in connection with updates to the Commercialization Plan; such overall FTE Rate for a country to be set in consideration of the wages and salaries, employee benefits, bonus, automobile allowance, meal expenses, travel/housing for meetings, dues, subscriptions, meetings and purchased services (including training, recruitment, communications, repairs and maintenance, and contractors), and other incidental expenses incurred by each such FTE in the ordinary course of employment and other things as may be determined by the JCC;
- (vii) performing and reviewing calculations for the reconciliation of payments, and controlling and performing such other accounting functions as provided in the Financial Exhibit;

- (viii) coordinating audits pursuant to Section 9.8 by Audit Teams, and discussing and attempting to resolve discrepancies or issues arising from such audits;
- (ix) performing such other functions as are specifically designated to the Finance Working Group in this Agreement or the Financial Exhibit, or as the Parties otherwise agree are appropriate to further the purposes of this Agreement;
- (x) working with the JSC, JDC and JCC to assist in financial, accounting, tax, budgeting and planning matters if and as requested by the respective Committee, and providing periodic updates to the JSC, JDC (if requested) and JCC on financial matters relating to this Agreement, and performing such other financial matters as are delegated to it under this Agreement or by the JSC, JDC and JCC; and
 - (xi) making such decisions and determinations as are assigned to it under this Agreement.
- Section 2.10 <u>Scope of Governance</u>. Notwithstanding the creation of each of the Committees and the Finance Working Group, each Party shall retain the rights, powers and discretion granted to it under this Agreement, and neither any Committee nor the Finance Working Group 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, and (except with respect to Section 2.9(b)(vi)) that the Finance Working Group has no decision making authority whatsoever.
- Section 2.11 Agios Participation. Notwithstanding anything in this Article II to the contrary, at any time, Agios shall have the right, but not the obligation, to participate in, and may elect not to appoint members to, any given Committee, the Finance Working Group, subcommittee or project team. If Agios elects not to participate in, or does not appoint members to, any Committee, 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, including decisions requiring Mutual Consent; provided that Celgene's sole discretion all decisions of such Committee, subcommittee, or project team, including decisions requiring Mutual Consent; provided that Celgene shall not unilaterally discharge the roles of such Committee, subcommittee or project team, as applicable, as permitted under this Article II unless Agios has not appointed any members within [**] days 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; provided that such Committee, subcommittee or project team shall not thereafter repeal prior decisions made by Celgene when Celgene was unilaterally discharging such role.

Section 2.12 Agios Opt-Out.

- (a) [Not used].
- (b) Effects of Agios Opt-Out Notice or Date. Without it being a breach of Article VII of this Agreement, 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;
- (ii) effective as of the Agios Opt-Out Date, all decisions relating to Development, Manufacturing or Commercialization that require decision by a Committee or that are subject to Mutual Consent shall be made solely by Celgene and all decisions for which Agios was provided with final decision-making authority under Section 2.8 or Article 10 shall be made solely by Celgene; provided that Celgene shall exercise any such decision-making authority in a manner consistent with a commitment of Commercially Reasonable Efforts to the Development and Commercialization of the Licensed Products in the ROW Territory; provided, further, that if Celgene or its Affiliate propose(s) to take or take(s) any action not contemplated by the Development Plan in effect on the Agios Opt-Out Date, and that Agios reasonably determines is reasonably likely to have a material adverse impact on the Commercialization of any of the "Licensed Products," as such term is defined in the 2010 Agreement, then Agios shall provide written notice to such effect to Celgene specifying in reasonable detail which actions by Celgene or its Affiliates would have such an effect, and what such effect would be. The Parties shall not proceed with, or shall cease as quickly as reasonably possible, as applicable, such action without the written consent of Agios. If Celgene does not concur with Agios' determination, Celgene may present the issue to the Executive Officers for resolution pursuant to Section 15.1(a) and, if agreement is not reached, may seek resolution of such matter in accordance with Section 15.1(b);
- (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 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 Sections 5.4, 13.3 and 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 and cease to incur any further Development Costs or Commercialization Expenses except as approved by Celgene or as provided in Sections 5.4, 13.3 and 13.4;
- (vii) within [**] days 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 Sections 9.2 and 9.4;

- (viii) within [**] days 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, and Agios shall provide to Celgene an update to such summary within [**] days after the Agios Opt-Out Date;
- (ix) 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 Agios' sole expense, including those activities referenced in Section 14.3(b)(viii), all of which must be completed 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 Celgene requests that any contracts or agreements that extend beyond the Agios Opt-Out Date be terminated, Agios and Celgene shall share all costs associated with such termination, and, (B) if Celgene requests that any such contract or agreement remain in effect, Celgene shall be responsible for all Development Costs and Commercialization Expenses under such contract or agreement following the Agios Opt-Out Date or, if Celgene requests assignment of such contract or agreement prior to the Agios Opt-Out Date, following such assignment (whichever is earlier);
- (x) 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;
- (xi) in the event Agios is utilizing a Third Party manufacture 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;
- (xii) 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 or Agios USA within Agios Intellectual Property that is both 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 shall be completed before the Agios Opt-Out Date;
- (xiii) 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 ROW Territory Profit or Loss under Section 9.4;

(xiv) as quickly as reasonably possible but in no event later than the Agios Opt-Out Date, Agios shall transition to Celgene Agios' initial Prosecution and enforcement responsibilities with respect to Agios Patent Rights, Agios Collaboration Patent Rights, Joint Inventions and Joint Patents, and provide reasonable assistance to Celgene and cooperation in connection therewith, including execution of such documents as may be necessary to effect such transition, provided that Agios shall retain step-in rights under Section 10.2(b) as well as comparable step-in rights on Prosecution matters relating to Agios Patent Rights and Agios Collaboration Patent Rights that are not Joint Patents but not under Section 10.3; and

(xv) The AGI-23088 US Agreement will be affected in a corresponding manner as provided therein.

Article III Development

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

- (a) <u>Development Plan and Changes</u>. Once the Development Plan has been mutually agreed, the Parties shall undertake the Development of Licensed Products on a worldwide basis in accordance with the Development Plan, including the [**] budget of Development Costs ("<u>Development Budget</u>"). The JDC may propose changes to the Development Plan to the JSC. The Development Plan may be amended from time to time only by Mutual Consent of the JSC.
- (b) <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, <u>provided that</u> if Agios so desires, the Development Plan shall specify that Agios shall be responsible for conducting all Phase I Studies of the Licensed Product in the Territory. For purposes of clarity, except as provided in Section 3.3, neither Party shall undertake any Development activities relating to the Licensed Products that are not specifically allocated to such Party in the Development Plan.
- (c) <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 Development Activities 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 all other Major Markets and such other countries as the JSC deems appropriate.
- (d) Coordination and Reports. 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 [**] 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 [**]), 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; provided that, 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 in accordance with Section 9.2.
- Section 3.3 <u>Additional Development Activities</u>. Subject to Section 2.12, each Party shall be permitted (i) to undertake Development activities (including Clinical Trials) not contemplated by the Development Plan (for example, a Clinical Trial for an Indication not included in such plans) or (ii) to repeat any Clinical Trial previously conducted under the Development Plan that failed to meet its primary endpoints (collectively, "<u>Additional Development Activities</u>"); <u>provided that</u> such Party complies with the provisions of this Section 3.3.
- (a) Additional Development Proposals. If a Party desires to undertake Additional Development Activities, such Party shall submit to the JDC a proposal for the addition of such Additional Development Activities to the Development Plan (an "Additional Development Proposal"). Each Additional Development Proposal for Additional Development Activities shall include a general description of the Development activities including, as applicable, study design, clinical study endpoints, clinical methodology and monitoring requirements, and the funding budget. If the JDC approves an Additional Development Proposal, such Additional Development Proposal shall, within [**] days, be submitted to the JSC for review and approval.

(b) Inclusion of Additional Development Activities in the GDP. If the JSC approves an Additional Development Proposal, the Development Plan shall be deemed to be amended to include the Additional Development Activities and associated budget upon approval of such Additional Development Proposal by the JSC. For the sake of clarity, all Development Costs incurred by the Parties and their Affiliates in performing such Additional Development Activities shall be shared by the Parties in accordance with Section 9.2.

(c) Independent Performance of Additional Development Activities. If the JDC does not approve an Additional Development Proposal within [**] days after its submission to the JDC, or the JSC does not approve an Additional Development Proposal within [**] days after its submission to the JSC, then the Party that submitted the Additional Development Proposal (the "Additional Development Party") may, upon notice to the other Party, conduct the relevant Additional Development Activities in accordance with the Additional Development Proposal at its own expense; provided, however, that, if the other Party (the "Non-Additional Development Party") determines reasonably and in good faith that any of the proposed Additional Development Activities is reasonably likely to adversely affect the Development, Manufacturing or Commercialization of any of the Licensed Products or "Licensed Products" as such term is defined in the 2010 Agreement, then the Additional Development Party shall not undertake such Additional Development Activities unless and until the JDC or JSC determines that such Additional Development Activities should be permitted. Additional Development Activities undertaken by the Additional Development Party shall be subject to the oversight of the JDC and, except as expressly set forth in this Section 3.3(c), subject to all terms and conditions of this Agreement relating to Development of Licensed Products (including the license grants in Article VIII). For clarity, a Licensed Product that is the subject of Additional Development Activities shall continue to be a "Licensed Product" for all purposes of this Agreement. The Additional Development Party shall provide informal reports of its progress with regard to the Additional Development Activities at each meeting of the JDC and shall provide formal written reports of the results and budgeted costs of the Additional Development Activities to the JDC at least [**] during the first [**] months in which any Clinical Trial within the Additional Development Activities is being performed, and otherwise in the same manner and frequency as the Parties provide reports to the JDC with respect to activities covered by the Development Plan. If, at any time after the commencement of an Additional Development Activity, the Non-Additional Development Party determines reasonably and in good faith that any Additional Development Activity is reasonably likely to adversely affect the Development or Commercialization of the Licensed Products or "Licensed Products" as such term is defined in the 2010 Agreement, the Non-Additional Development Party shall so notify the Additional Development Party and such Additional Development Activity shall be promptly discontinued (subject to such ethical obligations to continue support of patients already enrolled in Clinical Trials, as the Additional Development Party may in good faith determine) unless and until the JDC or JSC determines that such Additional Development Activities should be permitted to continue.

(d) <u>Costs of Additional Development Activities</u>. The Additional Development Party shall bear all costs associated with the Additional Development Activities it

undertakes and such costs shall not be taken into account as Development Costs for purposes of Section 9.2. If the JSC determines, by Mutual Consent, to include Data generated from such Additional Development Activities (excluding only safety Data) for label expansion purposes in a submission for Regulatory Approval for a Licensed Product or for other specific commercial purposes, the Non-Additional Development Party shall reimburse the Additional Development Party an amount equal to [**] percent ([**]%) of the costs incurred by the Additional Development Party for the Additional Development Activities (to the extent not previously reimbursed pursuant to Section 3.3(e)). Such costs will be determined using the same manner of calculating Development Costs under the Development Plan.

- (e) Opt-In for Additional Development Activities. In the event that the Non-Additional Development Party elects, in its discretion and upon written notice to the Additional Development Party (an "Additional Development Opt-In Notice"), on a Clinical Trial-by-Clinical Trial basis, to opt in with respect to a given Clinical Trial within the Additional Development Activities, then:
- (i) such Clinical Trial shall be deemed to be included in the Development Plan from and after the date on which such Additional Development Opt-In Notice is received by the Additional Development Party (the "Additional Development Opt-In Date");
- (ii) the then-current plan and budget of the Additional Development Party with respect to such Clinical Trial shall be deemed to be included within and part of the Development Plan from the Additional Development Opt-In Date, and shall control with respect to such Clinical Trial unless and until an amendment to the Development Plan providing for a different or modified plan and budget is approved by the JSC;
- (iii) the Out-of-Pocket Costs and FTE Costs associated with such Clinical Trial incurred after the Additional Development Opt-In Date shall be treated as Development Costs and shared by the Parties in accordance with Section 9.2; and
- (iv) the Non-Additional Development Party shall reimburse the Additional Development Party an amount equal to [**] percent ([**]%) of the costs incurred prior to the Additional Development Opt-In Date by the Additional Development Party and its Affiliates for such Clinical Trial (to the extent not previously reimbursed pursuant to Section 3.3(d)). Such costs will be determined using the same manner of calculating Development Costs under the Development Plan.

Section 3.4 Companion Diagnostics.

(a) <u>Development of Companion Diagnostic</u>. The Parties may mutually agree to Develop and/or Commercialize a Companion Diagnostic for use with the Licensed Products; <u>provided that</u>, 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 Patent Rights, Celgene Patent Rights and Collaboration Patent Rights, and each of the licenses granted to a Party under Section 8.1 or 8.2; and (ii) all costs and profits with respect to such Development or Commercialization of the Companion Diagnostic shall be shared equally by the Parties 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 Sections 9.3 through 9.5 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 14.3, 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 Patent Rights necessary for the Development, Manufacture and/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 Patent Rights otherwise associated with such Licensed Products are transferred.
- (c) No Other Diagnostics. 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 and/or Commercialize any biomarker or diagnostic product for use with the Licensed Products, other than a Companion Diagnostic pursuant to this Section 3.4.

Section 3.5 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 [**] years (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 [**]-year 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[**] copies of all Agios Know-How and Agios 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[**] copies of all Celgene Know-How and Celgene 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) Agios Responsibilities. Agios shall be responsible for Manufacturing, or having Manufactured by its designee, (i) all pre-clinical supply of Licensed Products, (ii) all supply of Licensed Products for Phase I Studies, (iii) all active pharmaceutical ingredients for all Phase II Studies and Phase III Studies (collectively, items (i), (ii) and (iii), the "Agios Clinical-Scale Manufacturing Responsibilities"), and (iv) all active pharmaceutical ingredients for Commercialization of Licensed Products (the "Agios Commercial-Scale Manufacturing Responsibilities"). Agios shall fulfill a substantial portion of the Agios Commercial-Scale Manufacturing Responsibilities from within, and ship all such Licensed Products and active pharmaceutical ingredients to Celgene from, Agios' or its designee's manufacturing facility located in Switzerland or another country mutually agreed in writing by the Parties such that the Licensed Products are treated as manufactured in Switzerland or such other country 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 Celgene disagrees that the fulfillment of the Agios Manufacturing Responsibilities is such that the Licensed Products are so treated, Agios shall deliver to Celgene an opinion of an independent nationally recognized law or accounting firm that the Licensed Products should be so treated.

(b) Agios Commercial-Scale Manufacturing Responsibilities. 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 upon which Celgene and Agios are Affiliates, and (ii) a Change of Control of Celgene, Agios shall notify Celgene at least [**] months 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 Section 4.1(a).

- (c) Celgene Responsibilities. Celgene shall be responsible for Manufacturing, or having Manufactured by its designee, all supply of Licensed Products not included within Agios Clinical-Scale Manufacturing Responsibilities and Agios Commercial-Scale Manufacturing Responsibilities, including drug product manufacturing and processing, filling, packaging, labeling, shipping and storage of Licensed Products for all Clinical Trials (other than Phase I Studies) and for Commercialization of Licensed Products (collectively, the "Celgene Manufacturing Responsibilities"). Celgene shall fulfill a substantial portion of the Celgene Manufacturing Responsibilities from within Celgene's or its designee's manufacturing facility located in Switzerland or another country mutually agreed in writing by the Parties such that the Licensed Products are treated as manufactured in Switzerland or such other country 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 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 if Agios disagrees that the fulfillment of the Celgene Manufacturing Responsibilities is such that the Licensed Products are so treated, Celgene shall deliver to Agios an opinion of an independent nationally recognized law or accounting firm that the Licensed Products should be so treated.
- (d) <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.
- Section 4.2 <u>Third Party Manufacturers</u>. If either Party uses any Third Party to fulfill its Manufacturing obligations or rights under Section 4.1 with respect to 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 2.8.
- 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 or Agios USA 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, if deemed necessary by the JDC or JCC, as applicable, the establishment of an alternative supply source. Such Party 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 and/or Commercialize, as applicable, such Licensed Products as contemplated under the applicable Development Plan and/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) <u>Lead Responsibility</u>. Agios shall have the initial lead responsibility for all Regulatory Interactions with Regulatory Authorities in the ROW Territory with respect to each Licensed Product unless and until there is a transfer thereof to Celgene as provided in Section 5.1(c). Celgene shall have lead responsibility for all Regulatory Interactions with Regulatory Authorities in the ROW Territory for the applicable Licensed Product after any such transfer to the extent set forth in Section 5.1(c). The JDC may propose to the JSC a different allocation for the roles of each Party for all Regulatory Interactions in the ROW Territory but such roles may only be changed by Mutual Consent of the JSC.
- (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 in the ROW Territory with respect to the Licensed Products and (ii) interfacing, corresponding and meeting with the Regulatory Authorities in the ROW Territory with respect to the Licensed Products.
- (c) <u>Transfer of Regulatory Responsibility in ROW Territory</u>. At any time after either an Agios Opt-Out Notice or the date that is [**] days prior to the expected commencement of a Phase III Study for a Licensed Product, Celgene may notify Agios that Celgene desires to take over lead responsibility for the Regulatory Interactions in the ROW Territory for such Licensed Product. Upon and after such notice from Celgene:
- (i) Agios shall (1) at Celgene's option, either close or inactivate Agios' IND(s) for such Licensed Product, or transfer such IND(s) to Celgene, and (2) with Celgene input, complete all relevant activities related to such IND as required for Celgene to assume regulatory ownership, as applicable, all within [**] days 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.

If Celgene does not provide notice to Agios in accordance with this Section 5.1(c) that Celgene desires to take over lead responsibility for the Regulatory Interactions in the ROW Territory associated with a Licensed Product, Agios shall retain lead responsibility for all Regulatory Interactions in the ROW Territory with respect to such 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 (*i.e.*, initially the ROW Territory if the responsible Party is Agios, or the ROW Territory if the responsible Party is Celgene), and respond within a reasonable time frame to all reasonable inquiries by the other Party with respect thereto.
- Section 5.3 <u>Global Safety Database; Pharmacovigilance Agreement</u>. The Parties will use Commercially Reasonable Efforts to negotiate a pharmacovigilance agreement (the "<u>Pharmacovigilance Agreement</u>") to govern cooperation among the Parties together with Celgene USA and Agios USA 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 together with Celgene USA and Agios USA no later than the completion of the first Phase I Study of a Licensed Product.

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

ROW 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 ROW 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 [**] hours advise the other Party thereof by telephone or facsimile. The JSC shall decide whether to conduct a recall, market withdrawal or similar action in any portion of the ROW 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 Parties, 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 ROW Territory shall be taken into account in determining ROW Territory Profit or Loss as, and to the extent, provided in the Financial Exhibit. 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 ROW Territory shall be bome 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 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 ROW Territory shall be bome fifty per cent (50%) by each of the Parties 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 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 [**] days of receipt of invoice.

Article VI Commercialization

Section 6.1 Commercialization Responsibilities for Licensed Products.

- (a) <u>Responsibility</u>. Subject to oversight by the JCC and to Sections 2.8, 2.12 and 6.3(f), each Party shall have the responsibility for the Commercialization of Licensed Products in the ROW Territory as specified in the Commercialization Plan.
- (b) Effects on Licensed Product and "Licensed Products" Under 2010 Agreement. If (i) either Party or its Affiliate (the "Proposing Party") proposes to take or take(s) any Commercialization action (or make any business decision) that is not contemplated by the Commercialization Plan in effect at such time, that the other Party (the "Objecting Party") reasonably determines is reasonably likely to have a material adverse impact on the Commercialization of any of the "Licensed Products," as such term is defined in the 2010 Agreement or (ii) Celgene or its Affiliate proposes to take any such action that Agios or its

Affiliate reasonably determines is reasonably likely to have an adverse impact on Commercialization of the "Licensed Products," as such term is defined in the AGI-23088 US Agreement, in the ROW Territory, such Objecting Party (and its Affiliate, if applicable) shall provide written notice to such effect to the Proposing Party specifying in reasonable detail which actions by such Proposing Party or its Affiliates would have such an effect, and what such effect would be. The Parties shall use good faith efforts to discuss the pertinent actions and resolve the matter. If the Proposing Party concurs with the Objecting Party's determination, the Proposing Party and its Affiliates shall not proceed with, or shall cease as quickly as reasonably possible, as applicable, such action without the written consent of the Objecting Party If the Proposing Party does not concur with the Objecting Party's determination, the Objecting Party may present the issue to the Executive Officers for resolution pursuant to Section 15.1(a) and, if agreement is not reached, may seek resolution of such matter in accordance with Section 15.1(b). If the Objecting Party does present the issue to the Executive Officers for resolution, then Proposing Party and its Affiliates shall not proceed with, or shall cease as quickly as reasonably possible, as applicable, such action until the dispute is resolved by agreement of the Executive Officers or in accordance with Section 15.1(b).

(c) <u>Sales</u>. Celgene will book all sales of the Licensed Products in the ROW 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 Commercialization Plan.

(a) Initial Commercialization Plan.

- (i) Subject to Sections 2.8 and 2.12, Commercialization of Products shall be governed by a Commercialization Plan (the "Commercialization Plan") that describes the Commercialization activities (including pre-launch and launch activities, if applicable) to be undertaken with respect to the Licensed Products in the ROW Territory, which shall include an [**] budget of Commercialization Expenses ("Commercialization Budget") and anticipated timelines for performance.
- (ii) Commencing no later than [**] months prior to the anticipated commercial launch of the first Licensed Product in the ROW Territory and thereafter at least [**] days prior to the start of each Calendar Year, Agios shall prepare the initial Commercialization Plan for each Licensed Product, with input and guidance from the JDC, JCC and the Finance Working Group. Such Commercialization Plan shall describe Commercialization activities to be undertaken by the Parties in the ROW Territory.
- (b) <u>JCC Approval</u>; <u>Amendments</u>. The JCC shall approve the first Commercialization Plan for each Licensed Product no later than [**] prior to the anticipated commercial launch of each such Licensed Product in the ROW Territory. Thereafter, the JCC shall review the Commercialization Plan not less frequently than [**] and shall propose updates to the Commercialization Plan for [**]. Either Party may also develop and submit to the JCC for review from time to time other proposed amendments to the applicable Commercialization Plan. The initial Commercialization Plan, and any amendments and updates to the Commercialization Plan, shall be effective upon the approval of the JCC (subject to resolution of any dispute involving such approval as provided in Section 2.8).

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 ROW Territory (*e.g.*, sales force (and the number of physicians to be called on and call frequency), field-based medical affairs, advertising, and field-based market access resources) (collectively, "<u>Marketing Activities</u>"), and the Commercialization Plan for each Licensed Product in the ROW Territory shall set forth such Marketing Activities for each Indication which is marketed in the ROW Territory.
- (b) Allocation of Activities. The Commercialization Plan will allocate to each Party its portion of the total Marketing Activities for each Licensed Product in the ROW Territory; provided that, unless otherwise agreed to by the Parties, Agios will be allocated thirty-three percent (33%) of the Marketing Activities in the Major European Countries, wherein such percentage refers to the total number of FTEs devoted to an activity when applicable, and Celgene will be allocated the balance of all Marketing Activities throughout the Major European Countries and other parts of the ROW Territory. The Commercialization Plan will attempt to provide that Marketing Activities are distributed geographically within the Major European Countries in a manner reasonably consistent with the distribution of the population in the Major European Countries 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 customer base and call volume measured against the customer base, geographic scope of activities, and the competitive market for the Licensed Product.
- (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 ROW Territory for each Licensed Product. Each Party, in its sole discretion, shall create a field management structure for its sales effort. Each Party shall use Commercially Reasonable Efforts to have hired, no later than [**] months before the applicable PDUFA date, the full sales force planned to be available for the launch of the Licensed Products in the ROW Territory and to have the sales force trained within [**] months of hiring. 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 but avoiding sales representatives detailing the same persons). 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; <u>provided that</u> the Commercialization Plan shall identify the portion of the detailing effort to be undertaken by each Party in the ROW Territory no later than [**] months before the planned date of the NDA submission in the ROW Territory.

- (d) <u>Training Materials and Sessions</u>. 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 ROW Territory. The JCC will develop a sales training program directed towards the Licensed Products use in the ROW Territory. 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. 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 ROW Territory. As requested by Agios, Celgene shall make its management, marketing, training and other personnel reasonably available to participate in Agios' national and regional sales meetings and Licensed Product training events for the ROW Territory.
- (e) Other Obligations. Subject to Section 2.12, in conducting the Marketing Activities in the ROW Territory, the Parties will comply with all applicable Laws, applicable industry professional standards and compliance policies of Celgene, and, subject to Section 6.3(f), Agios, 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 or otherwise approved by the JCC.
- (f) <u>Termination of Marketing Activities</u>. Agios shall have the right to terminate its Marketing Activities obligations in the ROW Territory with respect to any Licensed Product by providing at least [**] months' 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 [**]-month (or, if applicable, shorter) notice period, Agios' obligations to perform Marketing Activities under this Section 6.3 in the ROW Territory shall terminate, and Celgene's obligation under the first sentence of Section 6.3(e) to comply with Agios compliance policies, shall terminate (but, for clarity, Celgene's other obligations under such first sentence shall not terminate). Further, if Agios exercises this right with respect to the ROW Territory, then Celgene shall have final decision-making authority over all matters regarding Commercialization with respect to the ROW Territory.

Section 6.4 Trademarks.

(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 ROW 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 ROW Territory hereunder, to the extent permitted by Law.

- (b) Ownership. Celgene shall own all Product Trademarks for any Licensed Product in the ROW Territory.
- (c) Agios Acknowledgement and License. In connection with all packaging, literature, labels and other printed matters used in the ROW Territory, to the extent permitted by Law, the Parties shall include an expression to the effect that the Licensed Products were developed under license from Agios, together with the Agios logo. Agios hereby grants Celgene a license to use Agios' name and logo to comply with such obligation for the ROW Territory as reasonably required for Celgene to exercise its rights and perform its obligations under this Agreement in the ROW Territory.

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 Diligence Obligations.

- (a) In addition to the diligence obligations set forth in Section 7.1, the Parties shall use Commercially Reasonable Efforts to Develop and achieve Regulatory Approval for the Licensed Products in each of the Major Markets and, following such Regulatory Approval, to Commercialize such Licensed Products in each of the Major Markets.
- (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 14.2(b)(i). Notwithstanding the foregoing, the Parties acknowledge that it might be commercially reasonable, under certain circumstances, for the Party having lead responsibility for Marketing Activities in any portion of the Major Markets to determine not to launch a Licensed Product in [**] Major Markets, 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 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 License Grants. Subject to the terms and conditions of this Agreement:

- (a) <u>Licenses Granted to Celgene</u>. Agios hereby grants to Celgene a non-transferable (except as set forth in Section 15.4), right and license in the Field, with the right to grant sublicenses as set forth in Sections 8.2(a) and 8.2(b), under Agios' rights in Agios Intellectual Property and Agios Collaboration Intellectual Property, to Develop, Manufacture and/or Commercialize Licensed Products in the ROW Territory. Such license is a Sole license until the Agios Opt-Out Date; upon and after the Agios Opt-Out Date, such license automatically converts to an exclusive license (including exclusive of Agios and its Affiliates).
- (b) <u>Licenses Granted to Agios</u>. Celgene hereby grants to Agios a Sole, non-transferable (except as set forth in Section 15.4), right and license in the Field, with the right to grant sublicenses as set forth in Sections 8.2(a) and 8.2(b), under Celgene's rights in Celgene Intellectual Property and Celgene Collaboration Intellectual Property, to Develop, Manufacture and/or Commercialize Licensed Products in the ROW Territory.
 - Section 8.2 Sublicense Rights. 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 engaging Third Parties as contract research organizations, contract manufacturers, contract sales forces, consultants, academic researchers and the like ("<u>Third Party Contractors</u>") in connection with Development, Manufacturing or Commercialization activities on behalf of such Party or its Affiliates with respect to the Collaboration under this Agreement, subject to the following:
- (A) unless otherwise agreed by the JSC by Mutual Consent, 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 agreed by the JSC by Mutual Consent, each Party will obligate such Third Party to agree in writing to [**] 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 in the ROW Territory; and such Party shall structure such [**] 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 to research either or both of the Targets, each Party will only be required to obligate such academic collaborator to agree in writing to grant [**] to, and a right to negotiate for [**] to, any such inventions, which must be sublicensable 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 agreed by the JSC by Mutual Consent, each Party will require any such Third Party to grant to the other Party access to [**] 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 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 Sublicense Requirements. Any sublicense granted by a Party pursuant to this Agreement shall be subject to the following:
 - (a) each sublicense granted hereunder by a Party 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; provided that such Party shall remain responsible for the activities of its Affiliate;
- (c) a Party's or its Affiliates' Third Party sublicensees 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 sublicensees to comply with all relevant restrictions, limitations and obligations in this Agreement;

(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 [**] days after the execution of such sublicense agreement; provided that any such copy may be 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

(f) except as otherwise provided in the sublicense agreement, if this Agreement terminates for any reason, any Third Party sublicensee of a Party shall, from the effective date of such termination, automatically become a direct licensee of the other Party with respect to the rights licensed to such Party hereunder and sublicensed to the sublicensee by such Party; provided, however, that such sublicensee is not in breach of its sublicense agreement and continues to perform thereunder.

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 Existing Third Party Agreement.

- (a) <u>Acknowledgement</u>. Except as provided in Section 8.5(b), the Parties acknowledge that Agios or Agios USA is responsible for the fulfillment of all of their respective obligations under the Existing Third Party Agreement and will fulfill the same, including any provisions necessary to maintain in effect any rights sublicensed to Celgene hereunder and the exclusive nature of such rights, subject to Celgene's compliance with its obligations hereunder. In the event of any conflict between the terms of this Agreement and the Existing Third Party Agreement, the Parties will discuss in good faith how to address the conflict; <u>provided that</u>, if the Parties are unable to agree on how to address the conflict, the terms of this Agreement shall govern.
- (b) Incorporation of Certain Provisions. Celgene acknowledges and agrees that it shall be bound by the following provisions of the Existing Third Party Agreement, as a sublicensee of the rights licensed to Agios USA thereunder but only to the extent applicable to the rights sublicensed to Celgene hereunder: Sections 1.3 (as described in Section 8.7(b) hereof), 2.1, 2.3, 5.2, 5.3, 5.4, 5.5, 6.2, 7.1, 8.1 (with respect to information of the licensors under the [**] Agreement or with respect to the licensors' obligation to keep information of either Party confidential), 10.1 and 10.4 of the [**] Agreement. Furthermore, Celgene acknowledges that Agios USA is required to share certain reports and copies of sublicense agreements provided by Celgene to Agios hereunder with the licensors under the 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(b) (ii)(B) hereunder; provided that any such copies of sublicense agreements must be redacted to the extent permitted under such Existing Third Party Agreement.

(c) Covenants Regarding the Existing Third Party Agreement. Agios agrees that during the Term:

- (i) The rights granted to Celgene hereunder with respect to the Existing Third Party Agreement are passed through Agios to Celgene to the fullest extent possible as if granted directly from Agios USA, and Agios shall not modify or amend or terminate any such rights licensed from Agios USA to Agios under the Existing Third Party Agreement in any way without Celgene USA's prior written consent;
- (ii) As between the Parties, Agios shall be solely responsible for, and shall make, all royalty payments, milestone payments, yearly fees, sublicensee fees, Prosecution fees (as defined under the AGI-23088 US Agreement), and all other payments owed to the licensors under and pursuant to the Existing Third Party Agreement;
- (iii) Agios shall not exercise or fail to exercise any of Agios' rights, or fail to perform any of Agios' obligations, under the Existing Third Party Agreement or its sublicense thereunder with Agios USA, in each case that relate to Celgene's rights under the this Agreement without the prior written consent of Celgene, including rights with respect to including improvements within the licenses granted under the 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 the Existing Third Party Agreement;
- (iv) Agios shall promptly furnish Celgene with copies of all reports and other communications that Agios USA furnishes to the licensors under the 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 USA receives from the licensors under the Existing Third Party Agreement that relate to the subject of this Agreement (including notices relating to improvements under the Existing Third Party Agreement);
- (vi) Agios shall furnish Celgene with copies of all notices received by Agios USA relating to any alleged breach or default by Agios USA or any of its sublicensees (of any tier) under the Existing Third Party Agreement within [**] Business Days after Agios USA's receipt thereof; in addition, if Agios USA should at any time breach the Existing Third Party Agreement or become unable to timely perform its obligations thereunder, Agios shall immediately notify Celgene;
- (vii) If Agios USA cannot or chooses not to cure or otherwise resolve any alleged breach or default under the Existing Third Party Agreement, (A) Agios shall so notify Celgene within [**] Business Days of such decision, which shall not be less than [**] Business Days prior to the expiration of the cure period under the Existing Third Party

Agreement; provided that Agios shall use Commercially Reasonable Efforts to cure any such breach or default (to the extent within Agios' control); 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 the Existing Third Party Agreement in accordance with the terms and conditions of the Existing Third Party Agreement or otherwise resolve such breach directly with the licensors under the Existing Third Party Agreement; and (C) if Celgene pays any such licensor any amounts owed by Agios under the Existing Third Party Agreement, Celgene may deduct 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 the licensors under the 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 the 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 licensors under such Existing Third Party Agreement and Agios shall use Commercially Reasonable Efforts to assist Celgene in exercising such rights; <u>provided that</u> Celgene 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 the licensors under the Existing Third Party Agreement for a direct license. In the event of any such direct license following any termination of the Existing Third Party Agreement without Celgene's consent, Celgene shall be entitled to deduct from any payments owed to Agios hereunder [**] percent ([**]%) of 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 the Existing Third Party Agreement.
- (e) <u>Termination of Existing Third Party Agreement</u>. The Parties agree that termination, without Celgene's prior written consent, of the Existing Third Party Agreement with respect to any Patent Right 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 the Existing Third Party Agreement, Celgene agrees to use Commercially Reasonable Efforts to assist Agios in curing such breach of the Existing Third Party Agreement, and (ii) if Celgene's breach of this Agreement results in a termination of the Existing Third Party Agreement, such termination of the Existing Third Party Agreement shall not be deemed a material breach by Agios of this Agreement or a material breach by Agios USA of the AGI-23088 US Agreement.

Section 8.6 Exclusivity.

(a) <u>Agios Exclusivity Obligations</u>. During the Term, Agios and, subject to Sections 15.4(b) and 15.4(c), its Affiliates shall not, directly or indirectly, Develop, Manufacture or Commercialize any therapeutic modality (including any small molecule or biologic) in any field or application that [**], except for the following:

(i) Licensed Products pursuant to the Collaboration under this Agreement (including those activities specifically permitted upon and after termination);

- (ii) Collaboration Compounds, Development Candidates, Licensed Compounds, Independent Compounds and products that contain any of the foregoing pursuant to the 2010 Agreement (as such terms are defined in the 2010 Agreement); and
- (iii) Agios Reverted Compounds (other than Agios Reverted Compounds that [**]) and Agios Reverted Products that contain any such Agios Reverted Compound, in each case pursuant to the 2010 Agreement (as such terms are defined in the 2010 Agreement).
- (b) <u>Celgene Exclusivity Obligations</u>. During the Term, Celgene and, subject to Sections 15.4(b) and 15.4(c), its Affiliates shall not, directly or indirectly, Develop, Manufacture or Commercialize any therapeutic modality (including any small molecule or biologic) in any field or applications that [**], except for the following:
 - (i) Licensed Products pursuant to this Agreement (including those activities specifically permitted upon and after termination); and
- (ii) Collaboration Compounds, Development Candidates, Licensed Compounds, Independent Compounds, Celgene Reverted Compounds and products that contain any of the foregoing in each case pursuant to the 2010 Agreement (as such terms are defined in the 2010 Agreement).
- (c) Exception. A Party shall not be deemed to be, directly or indirectly, Developing, Manufacturing or Commercializing in violation of the provisions of Section 8.6(a) or 8.6(b) as a result of conducting a research program or discovery effort (or 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 [**], as applicable, that are subject to the prohibitions of Section 8.6(a) or 8.6(b).
- (d) <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 2010 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) the [**]; (ii) the [**]; (iii) [**]; (iv) [**]; or (vi) [**].

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 Collaboration Intellectual Property and any other Patent Rights or Know-How of Agios and its Affiliates, are hereby retained by Agios and its Affiliates. Except

as expressly provided in Sections 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 Patent Rights 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 the rights retained by the licensors under the [**] Agreement pursuant to Sections 1.3 and 2.3 of the [**] 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. 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>Initial Payment</u>. In consideration of Agios' discovery of AG-23088 and the rights and licenses granted hereunder, Celgene shall make an initial, non-refundable payment to Agios of [**] Dollars (US \$[**]) within [**] days following the Effective Date.

Section 9.2 Development Costs.

(a) Sharing of Development Costs. Subject to Section 2.12:

(i) The Development Costs to be shared by the Parties under this Agreement and the parties to the AGI-23088 US Agreement are those (A) Development Costs that are incurred after the IND Acceptance Date and (B) Manufacturing Costs associated with clinical supply of Licensed Products (even if incurred before the Effective Date), and, in either case, that are within [**] percent ([**]%) of the approved Development Budget under the Development Plan. Any Development Costs in excess of [**] percent ([**]%) of the approved

Development Budget 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. The Parties have determined the reasonably anticipated benefits share for purposes of Section 482 of the Code between the US Territory and ROW Territory to be derived from the Development activities and as a result each Party agrees to have it and its Affiliates allocate [**] percent ([**]%) of the Development Costs to the US Territory under the AGI-23088 US Agreement and the remainder of their portion of the Development Costs to the ROW Territory under this Agreement. Each Party shall be responsible for fifty percent (50%) of the Development Costs allocated to this Agreement.

(ii) Within [**] days following the beginning of the [**], each Party shall prepare and deliver to the Finance Working Group a [**] report detailing its and its Affiliates' Development Costs incurred during the first [**], estimated to be incurred during the [**], and actually incurred in the [**] 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 [**] days after the other Party's receipt of such request. The Parties, with the assistance of the Finance Working Group, shall conduct a reconciliation of Development Costs for the subject [**] within [**] days 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 [**]. Such reconciliation shall balance the actual amount of Development Costs incurred during the [**] (to correct for any differences between the estimates and actual amount of such costs) together with the amounts incurred during the first [**] and those estimated to be incurred during the [**]. The paying Party shall pay all amounts payable under any such invoice within [**] days after its receipt of such invoice.

(b) Annual Cost Cap. In the event of an Excess Amount, as calculated under Section 9.2(b) of the AGI-23088 US Agreement, for any Calendar Year, then any such amounts for such Calendar Year shall be bome initially by Celgene and Celgene USA, and not by Agios or Agios USA, and the reimbursement calculations set forth in Section 9.2(a) for such Calendar Year shall be adjusted accordingly with [**] percent ([**]%) of the Excess Amount being applied under the AGI-23088 US Agreement and [**] percent ([**]%) of the Excess Amounts being applied to this Agreement (and the reimbursement calculations in Section 9.2(a) of the AGI-23088 US Agreement also being adjusted accordingly. Celgene may recoup the [**] percent ([**]%) of the Excess Amounts due under this Agreement, together with interest thereon calculated at the rate set forth in Section 9.11, calculated on the number of days from the date on which Agios' payment of such Excess Amounts would otherwise be due to Celgene if this Section 9.2(b) did not apply until the date reimbursed to Celgene, from any milestone payments owed under Section 9.3 and Agios' share of ROW Territory Profits (if any) and Agios USA's share of US Territory Profits (if any) and Agios USA's share of US Territory Profits (if any) and Agios USA's share of US Territory Profits (if any) and Agios USA's share of US Territory Profits (if any) and Agios USA's share of US Territory Profits (if any) and Agios USA's share of US Territory Profits (if any) and Agios USA's share of US Territory Profits (if any) and Agios USA's share of US Territory Profits (if any) and Agios USA's share of US Territory Profits (if any) (as defined in the AGI-23088 US Agreement), and shall not otherwise be owed from Agios to Celgene; provided, however, that in the event that the

Development and Commercialization of all Licensed Products are permanently discontinued by Mutual Consent or this Agreement is terminated for any reason, then all Excess Amounts due under this Agreement shall be paid by Agios to Celgene in equal annual installments over the next [**]. Agios may in its discretion elect to pre-pay any portion of outstanding Excess Amounts or associated interest upon written notice to Celgene.

Section 9.3 <u>Milestone Payments</u>. Celgene shall pay Agios the following amounts after the first achievement by or on behalf of the Parties or their respective Affiliates or sublicensees of the corresponding milestone events set forth below with respect to the first Licensed Product to achieve such milestone events.

| Milestones | Amount |
|--|----------|
| (1) Filing of first NDA in a Major Market, whether such NDA is filed in the ROW Territory pursuant to this Agreement or in the US Territory pursuant to the AGI-23088 US Agreement | US\$[**] |
| (2) First Regulatory Approval in any Major Market, whether such Regulatory Approval is obtained in the ROW Territory pursuant to this Agreement or in the US Territory pursuant to the AGI-23088 US Agreement | US\$[**] |
| (3) Second Regulatory Approval in any Major Market, but only if received in a different country or region, as applicable, than the first Regulatory Approval, whether such Regulatory Approval is obtained in the ROW Territory pursuant to this Agreement or in the US Territory pursuant to the AGI-23088 US Agreement | US\$[**] |

- (a) For purposes of determining the occurrence of milestones under item (1) in the table above, [**] shall be deemed to have occurred [**] days following [**]; provided that, if such [**]. For purposes of determining the occurrence of milestones under items (2) and (3) in the table above, the [**]. For purposes of clarity, no milestone amount shall be payable to Agios under item (3) if [**] for purposes of item (3).
- (b) Each milestone payment under this Section 9.3 shall be made within [**] days 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 [**] days following Celgene's receipt of written notice of the achievement of such milestone).
- (c) For clarity, (i) 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 and (ii) the milestone payments set forth in the table above shall be in addition to any milestones payable pursuant to the AGI-23088 US Agreement.

Section 9.4 ROW Territory Profit or Loss. Subject to Section 2.12:

(a) <u>Profit or Loss</u>. The Parties shall share in ROW Territory Profit or Loss as follows: Agios shall bear (and be entitled to) fifty percent (50%), and Celgene shall bear (and be entitled to) fifty percent (50%). Each Party may include Commercialization Expenses in the ROW Territory Profit or Loss incurred by such Party that are within [**] percent ([**]%) of the approved Commercialization Budget under the Commercialization Plan. Any Commercialization Expenses in excess of [**] percent ([**]%) of the approved Commercialization Budget under the Commercialization Plan shall be borne solely by the Party incurring such costs and not included in ROW Territory Profit or Loss unless such Party has received the other Party's written approval to share such excess costs.

(b) [**] Reconciliation and Payments. Unless the Parties otherwise agree, the Reconciliation Procedures shall provide that:

(i) Within [**] days following the end of [**], each Party shall prepare and deliver to the Finance Working Group a [**] report detailing its Net Sales made and Commercialization Expenses incurred, and other amounts necessary to calculate ROW Territory Profit or Loss, during such [**], with respect to which the Parties share ROW Territory 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 [**] days after the other Party's receipt of such request. The Parties, with the assistance of the Finance Working Group, shall conduct a reconciliation of ROW Territory Profit or Loss for the full [**] within [**] days 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 of the ROW Territory Profit or Loss identified in such reconciliation for such [**]. The paying Party shall pay all amounts payable under any such invoice within [**] days after its receipt of such invoice.

Section 9.5 Royalty Payments Following Agios Opt-Out. In the event of an Agios Opt-Out Date:

(a) Royalty Rate. Celgene shall pay to Agios royalties on Annual Net Sales of Licensed Products in the ROW Territory (i) at the royalty rate of [**] percent ([**]%), if acceptance for review of the first NDA for a Licensed Product occurred prior to the Agios Opt-Out Date, or (ii) at the following rates, if acceptance for review of the first NDA for a Licensed Product did not occur prior to the Agios Opt-Out Date:

| Annual Net Sales of Licensed Products | Royalty Rate |
|--|--------------|
| On the tranche of Annual Net Sales in the ROW Territory occurring until aggregate, worldwide Annual Net Sales reaches US\$[**] | [**]% |
| On the tranche of Annual Net Sales in the ROW Territory occurring so long as aggregate, worldwide Annual Net Sales is equal to or greater than US\$[**] and less than US\$[**] | [**]% |
| On the tranche of Annual Net Sales in the ROW Territory occurring upon and after aggregate, worldwide Annual Net Sales equals US\$[**] | [**]% |

- (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 of the ROW Territory with respect to which royalty payments are due, until the latest of:
- (i) the last to expire of any Valid Claim of Agios Patent Rights or Agios Collaboration Patent Rights (including Joint Patents), in each case Covering such Licensed Product in such country of the ROW Territory;
 - (ii) [**] years following the date of First Commercial Sale in such country of the ROW Territory; and
 - (iii) the expiration of Regulatory Exclusivity for such Licensed Product in such country of the ROW Territory;

(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 of the ROW Territory continues solely due to Section 9.5(b)(ii) above (i.e., the Licensed Product is not Covered by a Valid Claim of Agios Patent Rights or Agios Collaboration Patent Rights 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 of the ROW Territory, 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 of the ROW Territory, 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.
- (c) <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 9.5, 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 from and after the Agios Opt-Out Date (i) with respect to any license obtained prior to the Agios Opt-Out Date pursuant to Section 9.6(b)(i), and (ii) with respect to any other license obtained pursuant to Section 9.6(b) but only

to the extent that the Patent Rights and/or Know-How licensed under such other license are necessary (A) to use the Targets to which the applicable Licensed Product is directed or (B) to the Development, Manufacture or Commercialization of such Licensed Product in a country(ies) in the ROW Territory, from royalty payments otherwise due and payable by Celgene to Agios under this Section 9.5 with respect to such Licensed Product in such country(ies), on a Licensed Product-by-Licensed Product and country-by-country basis; provided, however, that in no event shall the aggregate deductions permitted by this Section 9.5(c) reduce the royalties payable by Celgene to Agios with respect to any such Licensed Product in such country(ies) for any Calendar Quarter to less than [**] percent ([**]%) of the royalties otherwise due in the absence of any deduction pursuant to this Section 9.5(c); provided further 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) <u>Royalty Reports</u>: <u>Payments</u>. Within [**] calendar days after the end of any [**] 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, licensees and sublicensees, as applicable, in the ROW Territory, 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.

Section 9.6 Third Party Payments.

- (a) Existing Third Party Agreement. Except as otherwise provided in Section 14.3(b)(vii), [**] shall be [**] responsible for [**] amounts payable under the Existing Third Party Agreement with respect to the Licensed Products.
- (b) Additional Agreements. If Celgene at any time or Agios before an Agios Opt-Out Notice believes that a license under Third Party Patent Rights or Third Party Know-How could be [**] to Develop, Manufacture or Commercialize the Licensed Products in the ROW Territory, then such Party shall notify the (A) JDC if such notice is provided during Development or Manufacturing of Licensed Products for Development or (B) 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 2.8; provided that, if the JSC cannot agree on which Party should obtain such license, then until an Agios Opt-Out Notice, Agios shall have the first right to obtain such license for the ROW Territory and if Agios does not promptly exercise such right then Celgene shall have the right to do so, and after an Agios Opt-Out Notice, Celgene shall have the sole right to obtain such license.

(ii) The costs of each such license 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 in the ROW Territory and/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 Patent Rights and Third Party Know-How licensed pursuant to this Section 9.6 shall be deemed "Collaboration Intellectual Property" of the Party obtaining such license.

(iv) (1) The Party designated to pursue the license 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 license shall reasonably consider all comments and suggestions reasonably recommended by the other Party; and (3) the Party seeking the license 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 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 Financial Records. 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 [**] years 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, ROW Territory Profit or Loss and, if applicable, Annual Net Sales.

Section 9.8 Audits.

(a) <u>Audit Team</u>. 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 "<u>Audit Team</u>") 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 only [**], (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 [**] Calendar Years 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 [**] proposed dates of the audit not less than [**] days 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>Audit Report</u>. The audit report and basis for any determination by an Audit Team shall be made available first for review and comment by the Auditee, and the Auditee shall have the right, at its expense, to request a further determination by such Audit Team as to matters which the Auditee disputes (to be completed no more than [**] days after the first determination is provided to such Auditee and to be limited to the disputed matters). Such Audit Team shall not disclose to the Audit Rights Holder any information relating to the business of the Auditee except that which should properly have been contained in any report required hereunder or otherwise required to be disclosed to the Audit Rights Holder to the extent necessary to verify the payments required to be made pursuant to the terms of this Agreement.
- (e) Payments. 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 [**] days 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 [**] days after receiving appropriate invoices and other support for such audit-related costs.
- (f) <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</u> Rights Holder."

Section 9.9 Tax Matters.

(a) Withholding Taxes. The milestones and other amounts payable by a Party to the other Party pursuant to this Agreement ("Payments") shall not be reduced on account of any taxes unless required by Law. The receiving Party alone shall be responsible for paying any and all taxes (other than withholding taxes required by Law to be deducted and paid on the receiving Party's behalf by the paying Party) levied on account of, or measured in whole or in part by reference to, any Payments it receives. The Parties will cooperate in good faith to obtain the benefit of any relevant tax treaties to minimize as far as reasonably possible any taxes which may be levied on any Payments. The paying Party shall deduct or withhold from the Payments any taxes that it is required by Law to deduct or withhold. If the receiving Party is entitled under any applicable tax treaty or any Law to a reduction of the rate of, or the elimination of, applicable withholding tax, it may deliver to the paying Party or the appropriate governmental authority (with the assistance of the paying Party to the extent that this is reasonably required and is expressly requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve the paying Party of its obligation to withhold tax, and the paying Party shall apply the reduced rate of withholding tax, or dispense with withholding tax, as the case may be; provided that the paying Party has received evidence of the receiving Party's delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) at least [**] days prior to the time that the Payment is due. If, in accordance with the foregoing, the paying Party withholds any amount, it shall make timely payment to the proper taxing authority of the withheld amount, and send to the receiving Party proof of such payment within [**] days following that latter payment.

(b) Limited Gross-Up Obligation. Notwithstanding the foregoing, if the rights and obligations of a Party making payments hereunder are assigned to an Affiliate or Third Party outside of the United States or Switzerland pursuant to Section 15.4, and if such Affiliate or Third Party shall be required by Law to withhold any additional taxes from or in respect of any sum payable under this Agreement as a result of such assignment, then any such sum payable under this Agreement shall be increased to take into account the additional taxes withheld as may be necessary so that, after making all required withholdings, the receiving Party receives an amount equal to the sum it would have received had no such assignment been made; provided, however, that, if the rights and obligations of the paying Party hereunder are assigned to an Affiliate or Third Party outside of the United States or Switzerland pursuant to Section 15.4 and if at the time of such assignment such Affiliate or Third Party is not required by Law to withhold any additional taxes as a result of such assignment, the paying Party shall not be required to increase any such sum payable under this Agreement in the event of a change in Law. In addition, if the rights and obligations of the receiving Party hereunder are assigned to an Affiliate or Third Party pursuant to Section 15.4, the paying Party shall not have an obligation to pay an additional sum pursuant to this Section 9.9(b) to the extent that the additional sum would not have been due pursuant to this Section 15.4.

Section 9.10 Currency Exchange.

- (a) <u>Currency Conversion</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 made using the average of the buying and selling exchange rate for conversion of the applicable foreign currency into United States Dollars, quoted for current transactions reported in <u>The Wall Street Journal</u> (U.S., Eastern Edition) (or similarly recognized source for currency exchange rates agreed by the Parties) for the last [**] Business Days of the Calendar Quarter to which such payment pertains.
- (b) <u>Restrictions on Payments</u>. Where Payments are due in a country where, for reasons of currency, tax or other regulations, transfer of foreign currency out of such country is prohibited, the paying Party has the right to place Payments due to the other Party in a bank account in such country in the name of and under the sole control of such other Party; <u>provided</u>, <u>however</u>, <u>that</u> the bank selected be reasonably acceptable to such other Party and that the paying Party inform such other Party of the location, account number, amount and currency of money deposited therein. After such other Party has been so notified, those monies shall be considered as Payments duly paid to such Party and will be completely controlled by such Party.
- (c) <u>Prohibitions on Payments</u>. When in any country in the ROW 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 [**] month LIBOR plus [**] percent ([**]%), as reported by <u>The Wall Street Journal</u>, 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) Non-Collaboration Know-How. 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 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 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 ("<u>Joint Inventions</u>" and, any Patent Rights 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 [**] written reports disclosing to the other Party all 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(d).
- (e) Inventorship. 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 [**] to resolve such dispute. The decision of such [**] 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 (and/or its Parent, as designated by such requesting Party) the ownership rights set forth in this Article X.
- Section 10.2 <u>Prosecution of Patent Rights</u>. Subject to the terms and conditions of the Existing Third Party Agreement to the extent such agreement applies to the Agios Patent Rights or Agios Collaboration Patent Rights in the ROW Territory, the following provisions shall apply with respect to the Agios Patent Rights, Celgene Patent Rights and Collaboration Patent Rights in the ROW Territory:
- (a) Agios Patent Rights. Subject to the provisions of Section 10.2(h) and coordination with the JPC, Agios shall have the initial right and option to Prosecute the Agios Patent Rights and Agios Collaboration Patent Rights (excluding Joint Patents) in the ROW Territory with respect to which Celgene does not have the initial right to Prosecute pursuant to Section 10.2(b). In the event that Agios declines to Prosecute such Patent Rights, it shall give Celgene reasonable notice to this effect, sufficiently in advance to permit Celgene to undertake such Prosecution in such country without a loss of rights, and thereafter Celgene may, upon written notice to Agios, Prosecute such Patent Rights in Agios' name subject to coordination with the JPC.

- (b) Agios Patent Rights Prosecuted by Celgene. Subject to coordination with the JPC, Celgene shall have the initial right and option to Prosecute the Core Patent Rights within any of the Agios Patent Rights or Agios Collaboration Patent Rights in the ROW Territory that specifically Cover a Compound or a Licensed Product ("Celgene Controlled Agios Patent Rights"). Certain of the Agios Patent Rights and Agios Collaboration Patent Rights may from time to time Cover some Celgene Controlled Agios Patent Rights and other Agios Patent Rights or Agios Collaboration Patent Rights in the same application. Each Party will cooperate reasonably with any requests of the other Party from time to time to attempt to isolate Celgene Controlled Agios Patent Rights, on the one hand, from applications containing other Agios Patent Rights and Agios Collaboration Patent Rights, on the other hand. In the event that Celgene declines to Prosecute such Patent Rights, Celgene shall give Agios reasonable notice to this effect, sufficiently in advance to permit Agios to undertake such Prosecution in such country without a loss of rights, and thereafter Agios may, upon written notice to Celgene, Prosecute such Patent Rights in Agios' name subject to coordination with the JPC.
- (c) <u>Celgene Patent Rights</u>. Celgene shall have the sole right and option to Prosecute the Celgene Patent Rights in the ROW Territory and, subject to coordination with the JPC, the initial right and option to Prosecute the Celgene Collaboration Patent Rights (excluding Joint Patents) in the ROW Territory. In the event Celgene declines to Prosecute any such Celgene Collaboration Patent Right, Celgene shall give Agios reasonable notice to this effect, sufficiently in advance to permit Agios to undertake such Prosecution for such Celgene Collaboration Patent Right in such country without a loss of rights, and thereafter Agios may, upon written notice to Celgene, Prosecute such Patent Rights in Celgene's name.
- (d) <u>Joint Patents</u>. The JPC shall determine which Party shall have the initial right and option to Prosecute Joint Patents in the ROW Territory; <u>provided that</u> (i) if the JPC cannot make such determination by unanimous vote, then (x) Celgene shall have such initial right and option with respect to such Joint Patents that (A) are Core Patent Rights and that specifically Cover a Compound or Licensed Product or (B) claim or embody an improvement to technology claimed or embodied in Celgene Intellectual Property, and (y) Agios shall have such initial right and option with respect to all other such Joint Patents; and (ii) in the event that the Party with the initial right to Prosecute Joint Patents declines the option to Prosecute any such Joint Patents in any country, such Party shall give the other Party reasonable notice to this effect, sufficiently in advance to permit such other Party to undertake such Prosecution in such country without a loss of rights, and thereafter such other Party may, upon written notice to the first Party, Prosecute such Joint Patent in both Parties' names, with expenses shared as provided in Section 10.2(e).
- (e) <u>Costs and Expenses</u>. The Parties shall jointly bear all costs and expenses in Prosecuting Agios Patent Rights, Agios Collaboration Patent Rights, Celgene Collaboration Patent Rights and Joint Patents (collectively, "<u>Patent Prosecution Expenses</u>") in the ROW Territory as either Development Costs (to the extent incurred for any country of the ROW Territory prior to the First Commercial Sale of the Licensed Product in the country to which the

Patent Rights relate) or Commercialization Expenses (if incurred after First Commercial Sale of the Licensed Product in the ROW Territory); <u>provided</u>, <u>however</u>, <u>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.

(f) 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 Patent Rights, Collaboration Patent Rights and Joint Patents in the ROW Territory, including the scope and priority of the claims to be pursued within such Patent Rights and to maximize the value of such Patent Rights, together with their counterparts in the US Territory, 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 2.8(e), and if such attempt fails, then as follows: Prosecution matters involving (A) Agios Patent Rights (other than Celgene Controlled Agios Patent Rights therein) may be resolved by Agios; (B) Agios Collaboration Patent Rights (other than Celgene Controlled Agios Patent Rights and Joint Patents therein) may be resolved by Agios; (C) Celgene Controlled Agios Patent Rights and Celgene; (D) all Core Patent Rights within the Joint Patents may be resolved by Celgene; and (E) all other Joint Patents may be resolved only by Mutual Consent. The Party conducting Prosecution (the "Prosecuting Party") with respect to each such Patent Right shall follow such strategy in connection with all Prosecution of such Patent Rights 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 2.8(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), (b), (c), and (d). Each Party agrees to cooperate with the other with respect to the Prosecution of such Patent Rights 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 Patent Rights that such other Party is entitled, and has elected, to Prosecute, as provided for in Sections 10.2(a), 10.2(b), 10.2(c), and 10.2(d) and (y) giving consideration to the proper scope of Patent Rights. The Prosecuting Party shall:

(A) regularly provide the JPC in advance with reasonable information relating to the Prosecuting Party's Prosecution of Patent Rights 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 at least [**] days prior to any filing or response deadlines, or within [**] Business Days of the Prosecuting Party's receipt of any official correspondence if such correspondence only allows for [**] days or less to respond; provided that, if the foregoing time periods are not practicable under the circumstances, the Prosecuting Party shall provide such copies as far in advance as is practicable but with sufficient time for the non-Prosecuting party to provide meaningful input;

- (B) 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 ROW 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 Patent Rights or Collaboration Patent Rights (including the Joint Patents), as applicable.
- (iii) The JPC shall determine the countries in which Agios Patent Rights and Collaboration Patent Rights (including Joint Patents) shall be Prosecuted, with the understanding that the countries set forth on Exhibit F of this Agreement shall generally form the basis for the overall Prosecution strategy for such Patent Rights 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(f). Further, Agios shall consult with the JPC well in advance of [**] and [**] deadlines as to additional countries (if any) in which the JPC or Celgene desires that the Agios Patent Rights and Collaboration Patent Rights be Prosecuted.
- (iv) The Prosecuting Party agrees not to abandon the subject matter of a claim in an Agios Patent Right, Collaboration Patent Right or Joint 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; provided that, prior to such abandonment or narrowing, if feasible, the Parties will co-operate to file divisional or continuation applications to separate such claim.
- (g) Third Party Rights. Agios covenants and agrees that it shall not grant any Third Party any right to control the Prosecution of the Agios Patent Rights or Agios Collaboration Patent Rights or to approve or consult with respect to any Patent Rights licensed to Celgene hereunder, in any case, that is more favorable to the Third Party than the rights granted to Celgene hereunder or that otherwise conflicts with Celgene's rights hereunder.
- (h) Existing Third Party Agreement. Each Party acknowledges that, pursuant to the Existing Third Party Agreement, the applicable licensors thereunder Prosecute the Agios Patent Rights 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 licensors under the Existing Third Party Agreement or their patent counsel relating to the Agios Patent Rights covered by such agreements. To the extent that Agios is permitted to proceed with Prosecution or provide comments or suggestions to patent documents under the Existing Third Party Agreement, then the Agios Patent Rights under such Existing Third Party Agreement shall be treated in the same manner as other Agios Patent Rights under this Section 10.2, and Agios shall exercise all such rights with respect to such Agios Patents Rights 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 Patent Rights and Collaboration Patent Rights</u>. Subject to the terms and conditions of the Existing Third Party Agreement to the extent such agreement applies to the Agios Patent Rights or Agios Collaboration Patent Rights in the ROW Territory, the following provisions shall apply with respect to the Agios Patent Rights, Agios Collaboration Patent Rights, Celgene Collaboration Patent Rights, Agios Know-How, Agios Collaboration Know-How, and Celgene Collaboration Know-How in the ROW Territory:

- (a) Notice. Each Party shall immediately provide the other Party with written notice reasonably detailing any (i) known or alleged infringement of any Agios Patent Rights or Collaboration Patent Rights, or known or alleged misappropriation of any Agios Know-How or 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) First Right to Initiate Infringement Actions. Until an Agios Opt-Out Notice, Agios shall have the initial right throughout the ROW Territory, but not the obligation, to initiate a suit or take other appropriate action in the ROW Territory that Agios believes is reasonably required to protect the Agios Intellectual Property or Agios Collaboration Intellectual Property against the infringement, including Third Party Infringement, unauthorized use or misappropriation by a Third Party that relates to a Licensed Product ("Competitive Infringement"). Celgene shall have the sole right throughout the ROW Territory, but not the obligation, to initiate a suit or take other appropriate action in the ROW Territory that Celgene believes is reasonably required to protect the Celgene Collaboration Patent Rights from Competitive Infringement. Upon and after an Agios Opt-Out Notice, Celgene also shall have the initial right throughout the ROW Territory, but not the obligation, to initiate a suit or take other appropriate action in the ROW Territory that Celgene believes is reasonably required to protect the Agios Patent Rights and Agios Collaboration Patent Rights from Competitive Infringement. The Party having such initial or sole right under the preceding three sentences ("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 ROW Territory, subject to coordination with the JPC, the Initial Enforcement Party shall use reasonable efforts to prepare for the possibility of suit for Competitive Infringement starting [**] years 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.

(d) Step-in Rights. If Agios, as the Initial Enforcement Party, fails to initiate a suit or take such other appropriate action under Section 10.3(b) above within [**] days after becoming aware of the Competitive Infringement, then Celgene may, in its discretion, provide Agios with written notice of Celgene's intent to initiate a suit or take other appropriate action to combat such Competitive Infringement. If Celgene, as the Initial Enforcement Party for the Agios Patent Rights and Agios Collaboration Patent Rights after the Agios Opt-Out Notice, fails to initiate a suit or take such other appropriate action under Section 10.3(b) above within [**] days after becoming aware of the Competitive Infringement, then Agios may, in its discretion, provide Celgene with written notice of Agios' intent to initiate a suit or take other appropriate action to combat such Competitive Infringement. If the Party with such step-in rights under either of the two preceding sentences ("Step-In Enforcement Party") provides such notice and the Initial Enforcement Party fails to initiate a suit or take such other appropriate action within [**] days after receipt of such notice from the Step-In Enforcement Party, then 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 or Agios Collaboration Intellectual Property from Competitive Infringement. The Step-In Enforcement Party shall give the Initial Enforcement Party advance notice of the Step-In Enforcement Party's intent to file any such suit or take any such action and the reasons therefor and shall provide the Initial 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. For the avoidance of any doubt, this Section 10.3(d) shall not be applicable to any of the Celgene Collaboration Patent Rights, so Agios shall not have any right to be the Step-In Enforcement Party for Celgene Collaboration Patent Rights without the written agreement of Celgene.

(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 and/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 of the ROW Territory prior to the First Commercial Sale of a Licensed Product in the country) or Commercialization Expenses (if incurred after the First Commercial Sale of a Licensed Product in the ROW Territory). 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 ROW Territory 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) Existing Third Party Agreement. In the event that (i) a Patent Right covered by the 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 Patent Rights 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 licensors' consent under the 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.

Section 10.4 Claimed Infringement; Claimed Invalidity.

- (a) Infringement of Third Party Rights. 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, in the ROW Territory, 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 ("Third Party Infringement Action"), 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 ROW Territory 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; <u>provided that</u>, in the event of an Agios Opt-Out Notice or the failure of the Parties to so mutually agree, Celgene 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 ROW Territory 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 ROW Territory 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 and the AGI-23088 US Agreement, in each case (A) (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 (if approved by the non-controlling Party) shall be deemed Patent and Trademark Enforcement Costs that are factored into the calculation of ROW Territory 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 Right or Agios Collaboration Patent Right (including Joint 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 the Existing Third Party Agreement to the extent such agreement applies to such Agios Patent Right or Agios Collaboration Patent Right, 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 Right or Agios Collaboration Patent Right before any such right 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 Patent Rights, Agios Collaboration Patent Rights and Celgene Collaboration Patent Rights that Cover Licensed Products. If the JPC is unable to agree upon which of such Patent Rights should be extended, and the matter remains unresolved after the procedure described in Section 2.8(e), then the Initial Enforcement Party shall have the right to resolve the dispute, subject in each case to the terms and conditions of the Existing Third Party Agreement to the extent such agreement applies to such Agios Patent Right or Agios Collaboration Patent Right.

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>CREATE Act Application</u>. It is agreed and acknowledged that this Agreement establishes a qualifying collaboration within the scope of the U.S. CREATE Act and, accordingly, shall be deemed to constitute a "Joint Research Agreement" for all purposes under the CREATE Act. Neither Party shall invoke the provisions of the CREATE Act, or file this Agreement, in connection with the prosecution of any patent application claiming, in whole or in part, any CREATE Act 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 CREATE Act invention (a "<u>CREATE Act Patent</u>"), 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 "<u>Earlier Patent</u>"), then, if the Parties agree, the Parties shall coordinate the filing of such terminal disclaimer in good faith, and, to the extent required under the CREATE Act, both Parties shall agree, in such terminal disclaimer, that they shall not separately enforce the CREATE Act Patent independently from the Earlier Patent. To this end, to the extent required under the CREATE Act, following the filing of such terminal disclaimer, the Parties shall, in good faith, coordinate all enforcement actions with respect to the CREATE Act Patent.

Section 10.8 Challenges to Patent Rights.

(a) <u>Certain Consequences of Celgene Challenges</u>. Without limiting Celgene's obligations pursuant to Section 8.5(b), if Celgene or any of its Affiliates or any of its sublicensees under the licenses granted to Celgene in this Agreement (i) initiates or requests an interference or opposition proceeding with respect to any Agios Patent Right or Agios Collaboration Patent Right that Covers a Target or Licensed Product, (ii) makes, files or maintains any claim, demand, lawsuit, or cause of action to challenge the validity or enforceability of any Agios Patent Right or Agios Collaboration Patent Right that Covers a Target or Licensed Product, or (iii) funds or otherwise provides material assistance to any other Person with respect to any of the foregoing (any of the actions described in the foregoing clauses (i), (ii) and (iii), a "<u>Challenge</u>"), and if the outcome of such Challenge is that any claim

of an Agios Patent Right or Agios Collaboration Patent Right that Covers a Target or Licensed Product and that is subject to such Challenge remains valid and enforceable, then (A) Celgene shall [**] Agios in connection with such Challenge (which amounts shall not be deemed to constitute Development Costs or Commercialization Expenses), and (B) thereafter, if the Agios Opt-Out Date has not occurred before such outcome, then Agios' share of ROW Territory Profit or Loss hereunder with respect to any Licensed Product Covered by any remaining such valid and enforceable claim of a Challenged Agios Patent Right or Agios Collaboration Patent Right shall [**], notwithstanding Section 9.4(a), and if the Agios Opt-Out Date has occurred before such outcome, then all royalty amounts payable by Celgene to Agios hereunder with respect to any Licensed Product Covered by any remaining such valid and enforceable claim of a Challenged Agios Patent Right or Agios Collaboration Patent Right shall [**] of the otherwise applicable royalty amounts payable under Section 9.5(a).

- (b) No Use of Confidential Information. Without limiting Celgene's obligations pursuant to Section 10.8(a), Celgene shall not, and shall ensure that its Affiliates and its sublicensees under the licenses granted to Celgene in this Agreement do not, use or disclose any Confidential Information of Agios or any nonpublic information regarding the Prosecution or enforcement of any Agios Patent Rights or Agios Collaboration Patent Rights to which Celgene or any of its Affiliates or sublicensees are or become privy as a consequence of the rights granted to Celgene pursuant to this Article X, in initiating, requesting, making, filing or maintaining, or in funding or otherwise assisting any other Person with respect to, any Challenge.
- (c) <u>Certain Consequences of Agios Challenges</u>. The provisions of Sections 10.8(a) and 10.8(b) shall apply with respect to Celgene Patent Rights and Celgene Collaboration Patent Rights licensed to Agios pursuant to Section 8.1, in each case, substituting "Celgene" for "Agios" and vice versa with respect to all obligations and definitions, and otherwise *mutatis mutandis*.

Section 10.9 <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 10.4, all recoveries with respect to any such action, by settlement or otherwise, shall be [**] by Celgene.

Article XI Confidentiality

Section 11.1 <u>Confidential Information</u>. All Confidential Information of a Party ("<u>Disclosing Party</u>") shall not be used by the other Party (the "<u>Receiving Party</u>") except in performing its obligations or exercising rights explicitly granted under this Agreement and shall be maintained in confidence by the Receiving Party and shall not otherwise be disclosed by the Receiving Party to any Third Party, without the prior written consent of the Disclosing Party with respect to such Confidential Information, 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; 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 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 and have an obligation to treat such information and materials as confidential;
- (b) to patent offices in order to seek or obtain Patent Rights 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 Patent Rights or Regulatory Approvals; or
- (c) if such disclosure is required by judicial order or applicable Law or to defend or prosecute litigation or arbitration; provided that, 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) <u>Public Announcements</u>. 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 [**] Business Days 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 <u>Exhibit G</u> 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 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) Permitted Disclosures. 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), 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 Securities and Exchange Commission, 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) Either Party may disclose the existence and terms of this Agreement in confidence:

(A) to (1) its attorneys, professional accountants, and auditors, and (2) bankers or other financial advisors in connection with a public offering, other strategic transaction, or corporate valuation for internal purposes; <u>provided that</u> any such disclosure to such professional accountants, auditors, bankers or other financial advisors is under an agreement to keep the terms of confidentiality and non-use no less rigorous than the terms contained in this Agreement and to use such information solely for the applicable purpose permitted pursuant to this Section 11.3(b)(ii)(A);

(B) to the licensors under the Existing Third Party Agreement; provided that such disclosure is under the confidentiality and non-use provisions of such agreement;

(C) to potential acquirers (and their respective attorneys and professional advisors), in connection with a potential merger, acquisition or reorganization; provided that (1) the Party making the disclosure has a bona fide offer from such Third Party for such a transaction, and (2) such disclosure is under an agreement to keep the terms of confidentiality and non-use no less rigorous than the terms contained in this Agreement and to use such information solely for the purpose permitted pursuant to this Section 11.3(b)(ii)(C);

(D) to existing investors, lenders or permitted assignees of such Party (and their respective attorneys and professional advisors); provided that such disclosure is under an agreement to keep the terms of confidentiality and non-use no less rigorous than the terms contained in this Agreement; and

(E) to potential investors, lenders or permitted assignees of such Party, or to potential licensees or sublicensees of such Party (and their respective attorneys and professional advisors); provided that (1) such disclosure shall not be made prior to [**] Business Days prior to the good faith anticipated closing date for the investment, loan, assignment or license, as applicable, and shall be made only if such Party reasonably concludes that such transaction with such disclosee is likely to be consummated; (2) the disclosure shall be limited to the Redacted Version plus such additional terms and conditions reasonably requested by the disclosing Party and consented to by the other Party (for purposes of clarity, the disclosing Party shall not be obligated to disclose the identity of the disclosee in order to request such consent); and (3) such disclosure is under an agreement to keep the terms of confidentiality and non-use no less rigorous than the terms contained in this Agreement.

(iii) The Parties acknowledge the importance of supporting each other's efforts to publicly disclose results and significant developments regarding the Licensed Products and other activities in connection with this Agreement that may include information that is not otherwise permitted to be disclosed under this ARTICLE XI, and that may be beyond what is required by applicable Law, and each Party may make such disclosures from time to time. Such disclosures may include achievement of milestones, significant events in the development and regulatory process, commercialization activities and the like. Except for the initial press release described in Section 11.3(a), whenever a Party (the "Requesting Party") elects to make any such public disclosure, 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 [**] Business Days 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 [**] Business Days 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 o

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 by Mutual Consent 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, by Mutual Consent, shall then have [**] days prior to submission for any Publication ([**] days 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 Patent Rights or Know-How belonging (whether through ownership or license, including under this Agreement) in whole or in part to the non-publishing Party.
- (b) <u>Removal of Confidential Information</u>. 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 the 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 by Mutual Consent delegate its responsibilities under this Section 11.4 to one or more representatives of Agios and Celgene.

Section 11.5 Term. All obligations under this Article XI shall expire [**] years following termination or expiration of this Agreement.

Section 11.6 Return of Confidential Information.

- (a) Obligations to Return or Destroy. 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 Mutual Representations. Agios and Celgene each represents, warrants and covenants to the other Party, as of the Effective Date, that:
 - (a) Authority. It has full corporate right, power and authority to enter into this Agreement and to perform its obligations under this Agreement.
- (b) <u>Consents</u>. Except as provided in Section 15.17, 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 have been or shall be obtained by the Effective Date.
- (c) No Conflicts. 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 Effective Date and (ii) do not and will not conflict with, violate, breach or constitute a default under any contractual obligations of such Party or any of its Affiliates existing as of the Effective Date. It has not used, and during the Term will not knowingly use, any Know-How 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 the other Party hereunder. It has not granted, and during the Term it will not grant, any right or license, to any Third Party relating to any of the intellectual property rights it Controls, that conflicts with the rights or licenses granted or to be granted to the other Party hereunder.
 - (d) Enforceability. This Agreement is a legal and valid obligation binding upon it and is enforceable in accordance with its terms.
- (e) Employee Obligations. 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, non-competition or non-solicitation.
 - Section 12.2 Additional Agios Representations. Agios represents, warrants and covenants to Celgene, as of the Effective Date, as follows:
- (a) Agios possesses sufficient rights to enable Agios to grant all rights and licenses it purports to grant to Celgene with respect to the Agios Intellectual Property under this Agreement.
- (b) The Agios Patent Rights existing as of the Effective Date constitute all of the Patent Rights Controlled by Agios or Agios USA as of such date that are necessary or useful for the Development, Manufacture or Commercialization of the Licensed Products.

- (c) There is no pending litigation, and Agios has not received any written notice of any claims or litigation, seeking to invalidate or otherwise challenge the Agios Patent Rights or Agios' rights therein.
- (d) There is no pending litigation, and Agios has not received any written notice of any claims or litigation, that alleges that Agios' activities with respect to IDH1 or IDH2 have infringed or misappropriated any intellectual property rights of any Third Party.
- (e) [**] practice of the Agios Intellectual Property as contemplated under this Agreement does not (i) infringe any claims of any Patent Rights of any Third Party, or (ii) misappropriate any Know-How of any Third Party.
- (f) None of (i) the Agios Patent Rights owned by Agios or both Controlled by and Prosecuted by Agios and (ii) [**], the Agios Patent Rights Controlled but not Prosecuted by Agios are subject to any pending re-examination, opposition, interference or litigation proceedings.
- (g) All of (i) the Agios Patent Rights owned by Agios or both Controlled by and Prosecuted by Agios and (ii) [**], the Agios Patent Rights Controlled but not Prosecuted by Agios have been filed and diligently Prosecuted in accordance with all applicable Laws in the Territory and have been maintained, with all applicable fees with respect thereto having been paid.
- (h) True and correct copies of the Existing Third Party Agreement have been provided to Celgene, and such agreement is in full force and effect and have not been modified or amended. Neither Agios nor, [**], any licensor under the Existing Third Party Agreement 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 Agreement.
- (i) [**] Agios Patent Rights Controlled by Agios pursuant to the Existing Third Party Agreement were not and are not subject to any restrictions or limitations except as set forth in the Existing Third Party Agreement.
- (j) Agios has not waived or allowed to lapse any of its rights under the Existing Third Party Agreement with respect to the Licensed Products, and no such rights have lapsed or otherwise expired or been terminated.
- (k) Agios has and, [**], the applicable licensor under the Existing Third Party Agreement has complied with any and all obligations under [**] to perfect rights to the applicable Patent Rights or Know-How licensed thereunder.
- (l) Agios has not employed and, to its knowledge, has not used a contractor or consultant that has employed, any individual or entity (i) debarred by the FDA (or subject to a similar sanction of another applicable Regulatory Authority), (ii) who is the subject of an FDA debarment investigation or proceeding (or similar proceeding of another applicable Regulatory Authority), or (iii) has been charged with or convicted under United States Law for conduct relating to the development or approval, or otherwise relating to the regulation of any Licensed Product under the Generic Drug Enforcement Act of 1992, in each case, in the conduct of its activities prior to the Effective Date.

Section 12.3 Additional Celgene Representations. Celgene represents, warrants and covenants to Agios, as of the Effective Date, as follows:

- (a) Celgene possesses sufficient rights to enable Celgene to grant all rights and licenses it purports to grant to Agios with respect to the Celgene Intellectual Property under this Agreement.
- (b) Celgene has not employed and, to its knowledge, has not used a contractor or consultant that has employed, any individual or entity (i) debarred by the FDA (or subject to a similar sanction of another applicable Regulatory Authority), (ii) who is the subject of an FDA debarment investigation or proceeding (or similar proceeding of another applicable Regulatory Authority), or (iii) has been charged with or convicted under United States Law for conduct relating to the development or approval, or otherwise relating to the regulation of any Licensed Product under the Generic Drug Enforcement Act of 1992, in each case, in the conduct of its activities prior to the Effective Date.
- Section 12.4 Employee Obligations. Agios and Celgene each covenants to the other Party that all of its and its Affiliates' employees, officers, consultants and advisors who have been, are or will be involved in the Collaboration have executed (or, prior to becoming involved in the Collaboration, will have executed agreements) or have existing obligations under Law requiring assignment to such Party of all intellectual property made during the course of and as the result of their association with such Party, and obligating the individual to maintain as confidential such Party's Confidential Information, to the extent required to support such Party's obligations under this Agreement.

Section 12.5 No Warranties. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH HEREIN, THE PARTIES MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY REPRESENTATIONS OR WARRANTIES AS TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NONINFRINGEMENT.

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; 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 [**] Business Days, notify Celgene in writing of the claim. Celgene shall have the right, exercisable by notice to Agios within [**] Business Days 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 (including the right to settle the claim solely for monetary consideration) 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.

Section 13.2 By Agios.

- (a) Agios Indemnification Obligation. 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 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; or
 - (ii) the gross negligence, willful misconduct or violation of Law of Agios or its Affiliates.
- (b) <u>Indemnification Procedures</u>. In the event of any such claim against the Celgene Indemnified Parties by any Third Party, Celgene shall promptly, and in any event within [**] Business Days, notify Agios in writing of the claim. Agios shall have the right, exercisable by notice to Celgene within [**] Business Days 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 (including the right to settle the claim solely for monetary consideration) with counsel selected by Agios and reasonably acceptable to Celgene; <u>provided that</u> 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 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.

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 shall be taken into account in determining ROW Territory Profit or Loss as, and to the extent, provided in the Financial Exhibit.
- (b) All such costs and expenses incurred after the Agios Opt-Out Date relating to Licensed Products in the ROW Territory shall be bome solely by Celgene if and only to the extent such Product Liabilities were caused by the occurrence after the Agios Opt-Out Date of the event, incident or circumstance that led to the Third Party Liability Action.
- (c) All such costs and expenses incurred after the Agios Opt-Out Date relating to Licensed Products in the ROW Territory shall be borne fifty per cent (50%) by each of the Parties to the extent such Product Liabilities were caused by the occurrence before the Agios Opt-Out Date of an event, incident or circumstance that is the subject of the Third Party Liability Action. If Agios is invoiced for its portion of such costs and expenses incurred after the Agios Opt-Out Date, payment is due within [**] days of receipt of invoice.

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 in the ROW Territory 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; provided that, in the event of an Agios Opt-Out Notice or the failure of the Parties to mutually agree otherwise, 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. Subject to Section 13.3, each Party shall be responsible for its own Out-of-Pocket Costs incurred in connection with any litigation or proceedings related to such Third Party Products Liability Action, including the fees and expenses of the counsel selected by the controlling Party. 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 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 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 the [**] 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 \$[**] per claim and annual aggregate. Celgene may elect to self-insure all or parts of the limits described above. Within [**] days 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 2.12(b) or 14.2, in full force and effect as long as the Parties continue to Develop and/or Commercialize Licensed Products in accordance with the terms and conditions of this Agreement, or, in the event of an Agios Opt-Out Date, until expiration of the Royalty Term for all Licensed Products.

Section 14.2 Termination.

(a) <u>Termination for Convenience</u>. Celgene shall have the right to terminate this Agreement in its entirety for convenience upon ninety (90) days' prior written notice to Agios; <u>provided that</u> Celgene shall not have the right to terminate this Agreement until twelve (12) months following the Effective Date.

(b) Termination for Material Breach or Insolvency.

- (i) If either Party (the "Non-Breaching Party") believes that the other Party (the "Breaching Party") is in material breach of this Agreement, then the Non-Breaching Party may deliver written notice of such breach to the Breaching Party. If the Breaching Party fails to cure such breach, or take such steps as would be considered reasonable to effectively cure such breach, within the [**] day period after delivery of such notice, the Non-Breaching Party may terminate this Agreement upon written notice to the Breaching Party. Notwithstanding the foregoing, if such breach is capable of being cured, but is not reasonably capable of being cured within the [**]-day cure period, if the Breaching Party (A) proposes within such [**]-day period a written plan to cure such breach within a defined time frame extending for a period not to exceed an additional [**] days, and (B) makes good faith efforts to cure such default and to implement such written cure plan, then the Non-Breaching Party may not terminate this Agreement until the earlier of such time as the Breaching Party is no longer diligently pursuing such cure in accordance with such plan or the end of such additional period.
- (ii) 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; provided, however, that, in the event of any involuntary bankruptcy or receivership proceeding such right to terminate shall only become effective if the Party consents to the involuntary bankruptcy or receivership or such proceeding is not dismissed within ninety (90) days after the filing thereof.
- (c) <u>Termination of AGI-23088 US Agreement</u>. This Agreement terminates automatically if the AGI-23088 US Agreement terminates for any reason. The AGI-23088 US Agreement terminates if this Agreement terminates for any reason.

Section 14.3 Effects Of Termination.

- (a) Effects of Celgene Termination for Convenience or Agios Termination for Celgene Breach or Insolvency. Upon termination of this Agreement by Celgene under Section 14.2(a), by Agios under Section 14.2(b), as a result of termination of the AGI-23088 US Agreement by Celgene USA under Section 14.2(a) for Celgene USA convenience therein, or as a result of termination of the AGI-23088 US Agreement by Agios USA under Section 14.2(b) for Celgene USA breach therein, the following shall apply:
- (i) all licenses granted by Agios to Celgene under Section 8.1(a) shall terminate, and all licenses granted by Celgene to Agios under Section 8.1(b) shall remain in effect and, from and after such termination, Agios shall pay Celgene royalties on Annual Net Sales of Licensed Products in the ROW Territory pursuant to Section 9.5 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;

(ii) each Party shall be released from its Development, Manufacture and Commercialization obligations (except as set forth in Section 14.3(a)(vii) and (viii) below with respect to Celgene's transfer of Manufacturing to Agios hereunder);

(iii) within [**] days 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 Sections 9.2 and 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 [**] days after the other Party's receipt of such request. The Parties, with the assistance of the Finance Working Group, shall conduct a final reconciliation of such costs and payments within [**] days 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 Sections 9.2 and 9.4, as applicable. The paying Party shall pay all amounts payable under any such invoice within [**] days after its receipt of such invoice; provided, however, that, Celgene shall remain responsible for its applicable share of the Developments Costs of any Clinical Trials or other Development activities committed and not cancelable by Agios with respect to the Licensed Products prior to the effective date of termination to the extent such Development Costs are within an approved Development Budget under an approved Development Plan in place prior to termination;

(iv) within [**] days 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 ROW Territory;

(vi) Celgene shall as soon as reasonably practicable transfer and assign to Agios all Regulatory Approvals of the Licensed Products in the ROW Territory, 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; and provided further that, if such Regulatory Approvals or Regulatory Documentation are necessary or useful for the Development, Manufacture and/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 ROW Territory;

(vii) Agios shall have the option, exercisable within [**] days following the effective date of such termination of this Agreement, to obtain Celgene's inventory of the Licensed Products at a price equal to one hundred five percent (105%) 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 [**]day 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 [**] months 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 one hundred five percent (105%) 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 [**] months 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 manufacture 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 or Celgene USA 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) 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, <u>provided</u>, <u>however</u>, <u>that</u> in the event of a termination under Section 14.2(a) by Celgene, if Agios or any of its Affiliates propose(s) to take or take(s) any action not contemplated by the Development Plan in effect at the time of such termination, and that

Celgene reasonably determines is reasonably likely to have a material adverse impact on the Commercialization of any of the "Licensed Products," as such term is defined in the 2010 Agreement, then Celgene shall provide written notice to such effect to Agios specifying in reasonable detail which actions by Agios or its Affiliates would have such an effect, and what such effect would be. The Parties shall use good faith efforts to discuss the pertinent actions and resolve the matter. If Agios concurs with Celgene's determination, Agios and its Affiliates shall not proceed with, or shall cease as quickly as reasonably possible, as applicable, such action without the written consent of Celgene. If Agios does not concur with Celgene's determination, Celgene may present the issue to the Executive Officers for resolution pursuant to Section 15.1(a) and, if agreement is not reached, may seek resolution of such matter in accordance with Section 15.1(b). If Celgene does present the issue to the Executive Officers for resolution, then Agios and its Affiliates shall not proceed with, or shall cease as quickly as reasonably possible, as applicable, such action until the dispute is resolved by agreement of the Executive Officers or in accordance with Section 15.1(b); and

- (x) 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 Rights and Collaboration Patent Rights then being Prosecuted or enforced by Celgene, including execution of such documents as may be necessary to effect such transition.
- (b) Effects of Celgene Termination for Agios Breach. Upon any termination of this Agreement by Celgene under Section 14.2(b) or as a result of termination of the AGI-23088 US Agreement by Celgene USA under Section 14.2(b) for Agios USA breach therein:
- (i) all future milestones payable by Celgene under Section 9.3 shall be reduced by fifty percent (50%) of the otherwise applicable payment amounts; <u>provided that</u>, if the termination of this Agreement is as a result of Agios' breach of Section 8.6, all future milestones payable by Celgene under Section 9.3 shall terminate;
- (ii) from and after such termination, if the Agios Opt-Out Date has not occurred before the effective date of termination, then Celgene shall pay Agios royalties on Annual Net Sales of Licensed Products in the ROW Territory pursuant to Section 9.5, with the Agios Opt-Out Date, as used therein, deemed to be the effective date of termination, and if the Agios Opt-Out Date has occurred before the effective date of termination, then Celgene shall continue to pay to Agios royalties on Annual Net Sales of Licensed Products in the ROW Territory but the applicable royalty rate(s) shall be reduced by fifty percent (50%) of the otherwise applicable rate(s);
 - (iii) all licenses granted by Celgene to Agios under Sections 8.1(b) with respect to the Licensed Products shall terminate;
- (iv) each Party shall be released from its Development, Manufacture and Commercialization obligations (except as set forth in clause (viii) 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 9.4; provided, however, that, Agios shall remain responsible for its applicable share of the Developments Costs of any Clinical Trials or other Development activities committed by the Parties with respect to the Licensed Products prior to the effective date of termination to the extent such Development Costs are within an approved Development Budget under an approved Development Plan in place prior to termination;

(vi) within [**] days 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) the license granted by Agios to Celgene in Section 8.1(a) shall immediately become an exclusive (even as to Agios) license for the entire ROW Territory, which license shall continue in full force in perpetuity; provided that Celgene shall be solely responsible for any payments owed by Agios to any Third Party licensors of Agios Intellectual Property or Agios Collaboration Intellectual Property 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;

(viii) the provisions of Section 14.3(a)(v), (vi), (vii) and (viii), shall apply, in each case, substituting "Agios" for "Celgene" and vice versa with respect to all obligations and definitions, and otherwise *mutatis mutandis*;

(ix) notwithstanding anything to the contrary in Section 8.6, Celgene shall have the right to pursue the Development, Manufacture and Commercialization of the Licensed Products, provided, however, that if Celgene or any of its Affiliates propose(s) to take or take(s) any action not contemplated by the Development Plan in effect at the time of such termination, and that Agios reasonably determines is reasonably likely to have a material adverse impact on the Commercialization of any of the "Licensed Products," as such term is defined in the 2010 Agreement, then Agios shall provide written notice to such effect to Celgene specifying in reasonable detail which actions by Celgene or its Affiliates would have such an effect, and what such effect would be. The Parties shall use good faith efforts to discuss the pertinent actions and resolve the matter. If Celgene concurs with Agios' determination, Celgene and its Affiliates shall not proceed with, or shall cease as quickly as reasonably possible, as applicable, such action without the written consent of Agios. If Celgene does not concur with Agios' determination, Celgene may present the issue to the Executive Officers for resolution pursuant to Section 15.1(a) and, if agreement is not reached, may seek resolution of such matter in accordance with Section 15.1(b). If Agios does present the issue to the Executive Officers for resolution, then Celgene and its Affiliates shall not proceed with, or shall cease as quickly as reasonably possible, as applicable, such action until the dispute is resolved by agreement of the Executive Officers or in accordance with Section 15.1(b); and

(x) 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 Rights and Agios Collaboration Patent Rights and all Joint Inventions and Joint Patents, including execution of such documents as may be necessary to effect such transition.

- (c) <u>Sell-Down</u>. Unless Agios exercises its option under Section 14.3(a)(vii), if Celgene, its Affiliates or sublicensees at termination of this Agreement possess Licensed Product, have started the manufacture thereof or have accepted orders therefor, Celgene, its Affiliates or sublicensees shall have the right, for up to [**] following the date of termination, to sell their inventories thereof, complete the manufacture thereof and Commercialize such fully-manufactured Licensed Product, in order to fulfill such accepted orders or distribute such fully-manufactured Licensed Product, subject to the obligation of Celgene to pay Agios any and all payments as provided in this Agreement.
- (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</u>, <u>however</u>, <u>that</u> Sections 2.1(b), 3.4(b), 8.3(f), 8.7, 8.8, 9.2(b), 9.5(b) (v), 9.7, 9.8, 9.9, 10.1, 12.5, 13.6 (for at least [**]) and this Section 14.3 and Articles IX (to the extent any amounts are due but unpaid), XI, XIII (other than Section 13.6 (Insurance)) and XV, 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 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.
- (f) <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.

Article XV Miscellaneous

Section 15.1 Dispute Resolution.

(a) 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 2.8), the Parties agree that any disputes arising with respect to the interpretation, enforcement, termination or invalidity of this Agreement (each, a "Dispute") 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(a) after in-person discussions between the Executive Officers within [**] Business Days after referring such dispute to the Executive Officers, either Party may, at its sole discretion, seek resolution of such matter in accordance with Section 15.1(b) or Section 15.2, as applicable.

- (b) If the Parties do not resolve a Dispute with respect to any Arbitrable Matter after referring such matter to the Executive Officers pursuant to Section 15.1(a), then either Party may request that such Dispute be resolved by binding arbitration in accordance with the expedited procedures applicable to the Commercial Arbitration Rules of the American Arbitration Association (the "AAA") and the provisions of this Section 15.1(b). Dispute resolution pursuant to this Section 15.1(b) shall apply only to the following Disputes if the Parties cannot agree by Mutual Consent ("Arbitrable Matters"): (x) whether an action proposed to taken by a Party or its Affiliate pursuant to Section 2.12(b)(ii), 6.1(b)(i), 14.3(a)(ix) or 14.3(b)(ix) is reasonably likely to have a material adverse impact on the Commercialization of any of the "Licensed Products," as such term is defined in the 2010 Agreement; or (y) whether an action proposed to be taken by Agios or its Affiliate pursuant to Section 6.1(b)(ii) is reasonably likely to have an adverse impact on Commercialization of any of the "Licensed Products," as such term is defined in the AGI-23088 US Agreement.
- (i) The Party desiring to initiate an arbitration proceeding with respect to an Arbitrable Matter will send a written notice to the other Party requesting the commencement of the arbitration proceeding and specifying the issue to be resolved. Within [**] days after the date such notice is sent, the Parties shall negotiate in good faith to appoint a mutually acceptable independent person, with scientific, technical, and regulatory experience with respect to the development of pharmaceutical products in the Field necessary to resolve such Dispute and with availability to comply with the time periods in this Section 15.1(b) (an "Expert"). If the Parties fail to choose an Expert within the foregoing time period, the AAA shall choose an Expert (with such experience and availability) on behalf of the Parties within [**] days after receipt of written request by a Party to the AAA. Disputes about arbitration procedure will be resolved by the Expert or, failing agreement, by the AAA in New York, New York. Unless otherwise agreed by the Parties, the arbitration proceedings will be conducted in New York, New York. The fees and costs of the Expert and the AAA, if applicable, shall be shared equally by the Parties.
- (ii) Within [**] days after selection of the Expert, each Party shall simultaneously deliver to the Expert and the other Party a written statement: (A) stating each of the issues that is the subject of the Arbitrable Matter dispute, (B) setting forth such Party's position on each issue in dispute, and (C) setting forth such Party's final position with respect to each such issue. With such statement, each Party may also submit supporting documentation, if any, for such Party's final position. Each Party shall have [**] days after the other Party's submission to submit to the Expert and the other Party a written response thereto, which may include any scientific and technical information in support thereof. The Expert shall have the right to meet with the Parties, either alone or together, as necessary to make a determination.
- (iii) In resolving the dispute, the Expert will have no authority to make a decision on any issue other than by selecting the final position of one of the Parties. An

arbitration decision with respect to the Arbitrable Matter will be rendered in writing the designation of the Expert, which decision will be final and binding on the Parties. For all purposes under this Agreement, any decision made pursuant to this Section 15.1(b) shall be deemed to be the decision of the Parties, by Mutual Consent.

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 15.7 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>Right to Assign</u>. Neither Party may assign this Agreement, in whole or in part, without the consent of the other Party, except that either Party may assign this Agreement without the consent of the other Party, (i) in whole or in part, to any non-U.S. Affiliate of such Party, (ii) in whole to a non-U.S. Person as part of a Change of Control of such Party, or (iii) in whole to a non-U.S. Person as part of a Change of Control of Agios USA or Celgene USA, as applicable; <u>provided that</u> the assigning Party provides the other Party with written notice of such assignment and such assignee agrees in writing to be bound by the terms and conditions of this Agreement. The terms of this Agreement shall be binding upon and shall 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 shall be null and void.
- (b) Acquisition of a Party. Each Party agrees that in the event that a Party (the "Acquired Party") is acquired by Change of Control (an "Acquisition") by a Third Party (the "Acquirer"), (i) the non-Acquired Party shall not obtain any rights or access under this Agreement to any Know-How or Patent Rights Controlled by such Acquirer which were not already within Agios Intellectual Property (if the Acquired Party is Agios) or Celgene Intellectual Property (if the Acquired Party is Celgene) immediately prior to the consummation of such Acquisition; and (ii) the provisions of Section 8.6 shall not apply to any activity otherwise prohibited therein if a Party's involvement in such prohibited activity results from the Acquirer's activities but only if (A) such Acquirer, prior to such acquisition or merger, was already engaged in such prohibited activity (the "Third Party Activity"), and (B) no Celgene Intellectual Property, Agios Intellectual Property, or Collaboration Intellectual Property is used in connection with such Third Party Activity.

(c) Acquisition by a Party. Each Party agrees that in the event that a Party acquires (whether by way of merger, acquisition, sale of all or substantially all of its business or assets to which this Agreement pertains, or otherwise) a Third Party (the "Acquired Third Party"), the provisions of Section 8.6 shall not apply to any activity otherwise prohibited therein if a Party's involvement in such prohibited activity results from such acquisition, but only if (i) such Acquired Third Party, prior to such acquisition, was already engaged in such prohibited activity (the "Acquired Party Activity"), and (ii) the Party acquiring such Acquired Third Party shall, within [**] days after the date of the consummation of such acquisition, notify the other Party of such acquisition and comply with the other provisions of this Section 15.4(c). Following consummation of such an acquisition, the acquiring Party shall, at its option, either (A) use good faith efforts to identify a Third Party purchaser to whom such Party will divest its interest in the Acquired Party Activity and to enter into a definitive agreement with such Third Party for such divestiture as soon as reasonably practicable under the circumstances, but such divestiture must be completed no later than [**] months after the closing of such Party's acquisition of the Acquired Party Activity, or (B) promptly discontinue such Acquired Party Activity; provided that notwithstanding which option is chosen, such divesture or discontinuation must be accomplished no later than [**] months after the closing of such Party's acquisition of the Acquired Party Activity, the acquiring Party shall not use any Celgene Intellectual Property, Agios Intellectual Property, or Collaboration Intellectual Property in connection with such Acquired Party Activities. So long as the acquiring Party divests of, or discontinues, the Acquired Party Activity in accordance with this Section 15.4(c), such acquisition shall not be deemed a violation of Section 8.6.

Section 15.5 <u>Certain Additional Matters Relating to Change of Control of a Party</u>. In the event that either Party is subject to a Change of Control, such Party shall notify the other Party at least [**] Business Days prior to the consummation of such Change of Control (or such lesser period of time as is practicable under the circumstances), and shall thereafter provide written notice to the other Party promptly following consummation of such Change of Control.

- (a) Agios Change of Control. Upon consummation of a Change of Control of Agios, the Collaboration shall continue in effect as provided in this Agreement except that:
 - (i) the license and sublicense granted to Agios under Section 8.1(b) shall terminate;
- (ii) all decisions relating to Development, Manufacturing and Commercialization that require decision by a Committee or that are subject to Mutual Consent shall be made solely by Celgene and all decisions for which Agios was provided with final decision-making authority under Section 2.8 shall be made solely by Celgene; <u>provided</u>, <u>however</u>, <u>that</u> Celgene shall not exercise such decision-making authority in any manner that diminishes Agios' rights with respect to Marketing Activities pursuant to Section 6.3;

- (iii) except as otherwise directed by Celgene and except with respect to Marketing Activities allocated to Agios pursuant to Section 6.3, Agios shall cease to conduct any further Development or Commercialization activities with respect to any Licensed Products and cease to incur any further Development Costs or Commercialization Expenses except as approved by Celgene or as provided in Sections 5.4, 13.3 and 13.4;
- (iv) 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;
- (v) 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 ROW Territory (other than Marketing Activities allocated to Agios pursuant to Section 6.3), at Agios' sole expense, including those activities referenced in Section 14.3(b)(viii); 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 Celgene requests that any contracts or agreements that extend beyond consummation of the Change of Control be terminated, Agios shall be responsible for all costs associated with such termination, and (B) if Celgene requests that any such contract or agreement remain in effect, Celgene shall be responsible for all Development Costs and Commercialization Expenses under such contract or agreement following consummation of the Change of Control;
- (vi) Celgene shall have the option to obtain Agios' inventory of the Licensed Products and their active pharmaceutical ingredients at a price equal to their Manufacturing Costs;
- (vii) in the event Agios is utilizing a Third Party manufacture 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;
- (viii) Agios shall 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 or Agios USA within Agios Intellectual Property that is both 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;
- (ix) notwithstanding anything to the contrary in Section 2.8 or otherwise herein, Celgene shall have the right to resolve all disputes within any Committee and final decision making authority on all unresolved matters throughout the ROW Territory;

(x) all of Agios' rights under Article X (other than Section 10.1) shall terminate, and Agios shall transition to Celgene all of Agios' Prosecution and enforcement responsibilities with respect to Agios Patents Rights, Agios Collaboration Patent Rights, Joint Inventions and Joint Patents, and provide reasonable assistance to Celgene and cooperation in connection therewith, including execution of such documents as may be necessary to effect such transition, and Agios' rights under Sections 10.2(a) and 10.2(d) on Prosecution matters all terminate notwithstanding anything to the contrary in Article X, provided that Agios shall retain step-in rights under Sections 10.2(b) and Section 10.3(d) as well as comparable step-in rights on Prosecution matters relating to Agios Patent Rights and Agios Collaboration Patent Rights; and

- (xi) the AGI-23088 US Agreement will be affected in a corresponding manner as provided therein.
- (b) <u>Celgene Change of Control</u>. Upon consummation of a Change of Control of Celgene before the Agios Opt-Out Notice, the Collaboration shall continue in effect as provided in this Agreement, except that:
 - (i) the license and sublicense granted to Celgene under Section 8.1(a) shall terminate;
- (ii) all decisions relating to Development, Manufacturing and Commercialization that require decision by a Committee or that are subject to Mutual Consent shall be made solely by Agios and all decisions relating to Commercialization for which Celgene was provided with final decision-making authority under Section 2.8 shall be made solely by Agios; provided, however, that Agios shall not exercise such decision-making authority in any manner that diminishes Celgene's rights with respect to Marketing Activities pursuant to Section 6.3;
- (iii) except as otherwise directed by Agios and except with respect to Marketing Activities allocated to Celgene pursuant to Section 6.3, Celgene shall cease to conduct any further Development or Commercialization activities with respect to any Licensed Products and cease to incur any further Development Costs or Commercialization Expenses except as approved by Agios or as provided in Sections 5.4, 13.3 and 13.4;
- (iv) Celgene shall provide to Agios a reasonably detailed summary of Development and Commercialization activities undertaken by Celgene under the Collaboration, including any Clinical Trials committed but not yet completed as of such date;
- (v) Celgene shall undertake, and coordinate with Agios with respect to, any wind-down or transitional activities reasonably necessary to transfer to Agios all Development, Manufacturing (including all Celgene Manufacturing Responsibilities) and Commercialization responsibility for the Licensed Products throughout the Territory (other than Marketing Activities allocated to Celgene pursuant to Section 6.3), at Celgene's sole expense, including those activities referenced in Section 14.3(b)(viii); 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 Agios requests that any contracts or agreements that extend beyond the consummation of the Change of Control be terminated, Celgene shall be responsible

for all costs associated with such termination, and (B) if Agios requests that any such contract or agreement remain in effect, Agios shall be responsible for all Development Costs and Commercialization Expenses under such contract or agreement following the consummation of the Change of Control;

- (vi) Agios shall have the option to obtain Celgene's inventory of the Licensed Products and their active pharmaceutical ingredients at a price equal to their Manufacturing Costs;
- (vii) in the event Celgene is utilizing a Third Party manufacture to Manufacture the Licensed Products or their active pharmaceutical ingredients, to the extent permitted by the terms of such contract, Celgene shall, if requested by Agios, promptly assign to Agios the manufacturing agreements with such Third Party with respect to such products and ingredients;
- (viii) 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 or Celgene USA within Celgene Intellectual Property that is both necessary to Manufacture the Licensed Products or their active pharmaceutical ingredients as Manufactured by or on behalf of Celgene and its Affiliates, 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 deemed Development Costs;
- (ix) notwithstanding anything to the contrary in Section 2.8 or otherwise herein, Agios shall have the right to resolve all disputes within any Committee and final decision making authority on all unresolved matters throughout the ROW Territory;
- (x) all of Celgene's rights under Article X (other than Section 10.1) with respect to the Agios Patent Rights, Agios Collaboration Intellectual Property, and Joint Patents shall terminate, and Celgene shall transition to Agios all of Celgene's Prosecution and enforcement responsibilities with respect to Agios Patents Rights, Agios Collaboration Patent Rights, Joint Inventions and Joint Patents, and provide reasonable assistance to Agios and cooperation in connection therewith, including execution of such documents as may be necessary to effect such transition, and Celgene's rights under Sections 10.2(b) and 10.2(d) on Prosecution matters all terminate notwithstanding anything to the contrary in Article X, provided that Celgene shall retain its step-in rights under Section 10.2(a) and 10.3(d) and shall be extended comparable step-in rights under Celgene-Controlled Agios Patent Rights as those Agios had under Section 10.2(b) and 10.2(d); and
 - (xi) the AGI-23088 US Agreement will be affected in a corresponding manner as provided therein.
- (c) <u>Definition</u>. For purposes of this Agreement, "<u>Change of Control</u>" of a Party means any of the following, in a single transaction or a series of related transactions: (i) the sale or disposition of all or substantially all of the assets of such Party to a Third Party, (ii) 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 fifty percent (50%) of the then-outstanding common shares or voting power of such Party, or (iii) the merger or consolidation of such Party with or into a Third Party, unless, following such merger or consolidation, the stockholders of such Party immediately prior to such merger or consolidation beneficially own directly or indirectly more than fifty percent (50%) of the then-outstanding common shares or voting power of the entity resulting from such merger or consolidation.

Section 15.6 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 15.7 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:

<u>To Agios</u>: <u>To Celgene</u>:

Agios International Sarl c/o BK-Services AG Baarerstrasse 8 6301 Zug Switzerland Attention: President Telephone:

Facsimile:

Celgene International II Sàrl rue des Nasieux 18 Couvet, CH 2108 Switzerland Attention: President Phone: +41 32 729 85 00 Fax: +41 32 729 85 08 With copies to: With a copy to:

WilmerHale LLP Celgene Corporation 60 State Street 86 Morris Avenue Boston, MA 02109 Summit, NJ 07901

Attention: Steven D. Singer, Esq. Attention: Legal Department Telephone: (617) 526-6000 Telephone: (908) 673-9000 Facsimile: (617) 526-5000 Facsimile: (908) 673-2162

Agios Pharmaceuticals, Inc.

38 Sidney Street

Cambridge, MA 02139

Celgene Corporation

86 Morris Avenue

Summit, NJ 07901

Attention: Legal Department Attention: George S. Golumbeski Telephone: (617) 649-8600 Telephone: (908) 673-9043 Facsimile: (617) 649-8618 Facsimile: (908) 673-2769

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

Section 15.8 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 15.9 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 15.10 Entire Agreement. This Agreement (including the Exhibits attached hereto) 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 solely with respect to AGI-23088. 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 15.11 <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 15.12 <u>Independent Contractors</u>; No <u>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 Sections 13.1 and 13.2, and (b) except that [**] are intended third party beneficiaries of certain provisions of this Agreement, as specifically referred to herein. Notwithstanding the provisions of this Section 15.12, the provisions of Section 15.16 shall control for U.S. federal income tax purposes, as applicable.

Section 15.13 <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; (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 15.14 <u>Performance by Affiliates</u>. To the extent that this Agreement imposes obligations on Affiliates of a Party, such Party agrees to cause its Affiliates to perform such obligations.

Section 15.15 <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.

Section 15.16 <u>Certain U.S. Federal Income Tax Treatment</u>. Pursuant to Section 15.12, 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; <u>provided however</u>, the Parties hereby acknowledge and agree that the Collaboration shall be treated as a partnership for U.S. 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 and

Celgene shall be treated as partners in such partnership (the "CA 23088 ROW 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 U.S. federal and state income tax purposes for such time. For so long as the tax partnership remains in existence, (a) Celgene shall control all tax matters with respect to the CA 23088 ROW Partnership (including the preparation of returns and making of elections) and shall be the "tax matters partner" of the CA 23088 ROW Partnership (as that term is defined in Section 6231(a)(7) of the Code), (b) Agios shall cooperate as reasonably requested by Celgene in furtherance of (a), (c) the CA 23088 ROW Partnership shall comply with the provisions of Subchapter K of the Code and the Treasury Regulations thereunder, including the requirements of Section 704 of the Code and the Treasury Regulations thereunder with respect to the maintenance of capital accounts and allocation of items, and (d) each payment made by Celgene in connection with this Agreement (including the initial payment pursuant to Section 9.1 and each milestone payment pursuant to Section 9.3) shall be reported for U.S. federal income tax purposes so as to maximize the amount deductible to Celgene in respect of any such payment (including as a result of the allocation of an amortization deduction) to the full extent permitted by the Code. Exhibit I of this Agreement sets for the Parties' intentions regarding allocations and other tax matters related to the tax partnership. Exhibit I shall be interpreted in a manner consistent with this Section 15.16.

Section 15.17 Agios Guarantee and Related Covenants.

(a) Agios Guarantee. To induce Celgene to enter into this Agreement, the Person indicated on the guarantor signature page of this Agreement as the "Agios Guarantor" hereby irrevocably, absolutely, and unconditionally guarantees, not as a primary obligor but only as surety to Celgene, on the terms and conditions set forth herein, the full and punctual payment, performance and discharge of the payment and other obligations of Agios when due under this Agreement (the "Agios Obligations"). In furtherance of the foregoing, the Agios Guarantor acknowledges that its liability under this Section 15.17 shall extend to the Agios Obligations and that Celgene may, in its sole discretion, bring and prosecute a separate action or actions against the Agios Guarantor for the full amount of the Agios Obligations, provided that Celgene may only do so in respect of any Agios Obligation if (i) Celgene has first provided written notice to Agios of Agios's failure to fulfill or otherwise satisfy such Agios Obligation in accordance with this Agreement (and, at such time, Agios has in fact failed to fulfill or otherwise satisfy such Agios Obligation within the time specified in this Agreement), and (ii) Agios has failed to fulfill or satisfy such Agios Obligation within [**] days after Agios's receipt of such written notice (the requirements in clauses (i) and (ii), collectively, the "Agios Non-Satisfaction Condition").

(b) Changes in Obligations; Certain Waivers.

(i) The Agios Guarantor agrees that Celgene and Agios may from time to time and at any time, without notice to or further consent of the Agios Guarantor, extend the time of payment of the Agios Obligations, and Celgene may also make any agreement with Agios or with any other Person interested in the transactions contemplated by this Agreement, for the payment, compromise, extension, discharge, renewal, or release thereof, in whole or in part, or for any modification of the terms thereof or of any agreement between Celgene, Agios or

any such other Person without in any way impairing or affecting the Agios Guarantor's obligations under this Section 15.17. The Agios Guarantor agrees that its obligations hereunder shall not be released or discharged, in whole or in part, or otherwise affected by (A) the existence of any claim, set-off or other right which the Agios Guarantor may have at any time against Agios, whether in connection with the Agios Obligations or otherwise; (B) any insolvency, bankruptcy, reorganization or other similar proceeding affecting Agios or any other Person interested in the transactions contemplated by this Agreement; (C) any change in the corporate existence, structure or ownership of Agios or any other Person interested in the transactions contemplated by this Agreement; (D) the addition, substitution or release of any Person to or from this Section 15.17, this Agreement, or any related agreement or document (provided that any such addition, substitution or release shall, in the case of this Agreement or any such agreement or document, be subject to the prior written consent of Agios to the extent required thereunder); (E) any change in the time, place or manner of payment of the Agios Obligations or any rescission, waiver, compromise, consolidation or other amendment or modification of any of the terms or provisions of this Agreement or any other agreement evidencing, securing or otherwise executed in connection with the Agios Obligations (provided that any such change, rescission, waiver, compromise, consolidation or other amendment or modification shall be subject to the prior written consent of Agios to the extent required under this Agreement or such other agreement); or (F) the failure of Celgene to assert any claim or demand or to enforce any right or remedy against Agios or any other Person interested in the transactions contemplated by this Agreement (but subject, however, to the fulfillment of the Agios Non-Satisfaction Condition). To the fullest extent permitted by Law, the Agios Guarantor hereby expressly waives any and all rights or defenses arising by reason of any Law which would otherwise require any election of remedies by Celgene. Subject to the fulfillment of the Agios Non-Satisfaction Condition, the Agios Guarantor waives (x) promptness, diligence, presentment, demand for payment, notice of non-performance and all other notices of any kind, and all defenses by virtue of any valuation, stay, moratorium or similar law now or hereafter in effect, and (y) any right to require Celgene to proceed against Agios or pursue any other remedy in Celgene's power whatsoever.

(ii) The Agios Guarantor hereby unconditionally and irrevocably agrees not to exercise any rights that it may now have or hereafter acquire against Agios or any other Person interested in the transactions contemplated by this Agreement that arise from the existence, payment, performance, or enforcement of the Agios Guarantor's obligations under or in respect of this Section 15.17 or any other agreement in connection therewith, including any right of subrogation, reimbursement, exoneration, contribution or indemnification and any right to participate in any claim or remedy of Celgene against Agios or such other Person, whether or not such claim, remedy or right arises in equity or under contract, statute or common law, including the right to take or receive from Agios or such other Person, directly or indirectly, in cash or other property or by set-off or in any other manner, payment or security on account of such claim, remedy or right.

(iii) The Agios Guarantor hereby covenants and agrees that it shall not institute, and shall cause its respective Affiliates not to institute, any proceedings asserting and shall not in any case assert that this Section 15.17 is illegal, invalid or unenforceable in accordance with its terms.

(c) Nature of Guarantee. The liability of the Agios Guarantor as surety hereunder shall not be affected or impaired by any circumstance or occurrence whatsoever, including the failure of the Agios Guarantor to receive any benefit from or as a result of its execution, delivery and performance of this Section 15.17. Celgene shall not be obligated to file any claim relating to the Agios Obligations in the event that Agios becomes subject to a reorganization, bankruptcy or similar proceeding, and the failure of Celgene to so file shall not affect the Agios Guarantor's obligations under this Section 15.17. In the event that any payment to Celgene in respect of the Agios Obligations is rescinded or must otherwise be returned for any reason whatsoever, the Agios Guarantor shall remain liable hereunder with respect to the Agios Obligations as if such payment had not been made (subject to the terms hereof). This Section 15.17 is an unconditional guarantee of payment, and not merely of collectability.

Section 15.18 Celgene Guarantee and Related Covenants.

(a) <u>Guarantee</u>. To induce Agios to enter into this Agreement, the Person indicated on the guarantor signature page of this Agreement as the "<u>Celgene Guarantor</u>" hereby irrevocably, absolutely, and unconditionally guarantees, not as a primary obligor but only as surety to Agios, on the terms and conditions set forth herein, the full and punctual payment, performance and discharge of the payment and other obligations of Celgene when due under this Agreement (the "<u>Celgene Obligations</u>"). In furtherance of the foregoing, the Celgene Guarantor acknowledges that its liability under this Section 15.18 shall extend to the Celgene Obligations and that Agios may, in its sole discretion, bring and prosecute a separate action or actions against the Celgene Guarantor for the full amount of the Celgene Obligations, provided that Agios may only do so in respect of any Celgene Obligation if (i) Agios has first provided written notice to Celgene of Celgene's failure to fulfill or otherwise satisfy such Celgene Obligation in accordance with this Agreement (and, at such time, Celgene has in fact failed to fulfill or otherwise satisfy such Celgene Obligation within the time specified in this Agreement), and (ii) Celgene has failed to fulfill or satisfy such Celgene Obligation within [**] days after Celgene's receipt of such written notice (the requirements in clauses (i) and (ii), collectively, the "<u>Celgene Non-Satisfaction Condition</u>").

(b) Changes in Obligations; Certain Waivers.

(i) The Celgene Guarantor agrees that Celgene and Agios may from time to time and at any time, without notice to or further consent of the Celgene Guarantor, extend the time of payment of the Celgene Obligations, and Agios may also make any agreement with Celgene or with any other Person interested in the transactions contemplated by this Agreement, for the payment, compromise, extension, discharge, renewal, or release thereof, in whole or in part, or for any modification of the terms thereof or of any agreement between Celgene, Agios or any such other Person without in any way impairing or affecting the Celgene Guarantor's obligations under this Section 15.18. The Celgene Guarantor agrees that its obligations hereunder shall not be released or discharged, in whole or in part, or otherwise affected by (A) the existence of any claim, set-off or other right which the Celgene Guarantor may have at any time against Celgene, whether in connection with the Celgene Obligations or otherwise; (B) any insolvency, bankruptcy, reorganization or other similar proceeding affecting Celgene or any other Person interested in the transactions contemplated by this Agreement; (C)

any change in the corporate existence, structure or ownership of Celgene or any other Person interested in the transactions contemplated by this Agreement; (D) the addition, substitution or release of any Person to or from this Section 15.18, this Agreement, or any related agreement or document (provided that any such addition, substitution or release shall, in the case of this Agreement or any such agreement or document, be subject to the prior written consent of Celgene to the extent required thereunder); (E) any change in the time, place or manner of payment of the Celgene Obligations or any rescission, waiver, compromise, consolidation or other amendment or modification of any of the terms or provisions of this Agreement or any other agreement evidencing, securing or otherwise executed in connection with the Celgene Obligations (provided that any such change, rescission, waiver, compromise, consolidation or other amendment or modification shall be subject to the prior written consent of Celgene to the extent required under this Agreement or such other agreement); or (F) the failure of Agios to assert any claim or demand or to enforce any right or remedy against Celgene or any other Person interested in the transactions contemplated by this Agreement (but subject, however, to the fulfillment of the Celgene Non-Satisfaction Condition). To the fullest extent permitted by Law, the Celgene Guarantor hereby expressly waives any and all rights or defenses arising by reason of any Law which would otherwise require any election of remedies by Agios. Subject to the fulfillment of the Celgene Non-Satisfaction Condition, the Celgene Guarantor waives (x) promptness, diligence, presentment, demand for payment, notice of non-performance and all other notices of any kind, and all defenses by virtue of any valuation, stay, moratorium or similar law now or hereafter in effect, and (y) any right to require Agios to proceed against Celgene or pursue any other remedy in Agios's power whatsoever.

(ii) The Agios Guarantor hereby unconditionally and irrevocably agrees not to exercise any rights that it may now have or hereafter acquire against Agios or any other Person interested in the transactions contemplated by this Agreement that arise from the existence, payment, performance, or enforcement of the Agios Guarantor's obligations under or in respect of this Section 15.18 or any other agreement in connection therewith, including any right of subrogation, reimbursement, exoneration, contribution or indemnification and any right to participate in any claim or remedy of Celgene against Agios or such other Person, whether or not such claim, remedy or right arises in equity or under contract, statute or common law, including the right to take or receive from Agios or such other Person, directly or indirectly, in cash or other property or by set-off or in any other manner, payment or security on account of such claim, remedy or right.

(iii) The Celgene Guarantor hereby covenants and agrees that it shall not institute, and shall cause its respective Affiliates not to institute, any proceedings asserting and shall not in any case assert that this Section 15.18 is illegal, invalid or unenforceable in accordance with its terms.

(c) <u>Nature of Guarantee</u>. The liability of the Celgene Guarantor as surety hereunder shall not be affected or impaired by any circumstance or occurrence whatsoever, including the failure of the Celgene Guarantor to receive any benefit from or as a result of its execution, delivery and performance of this Section 15.18. Agios shall not be obligated to file any claim relating to the Celgene Obligations in the event that Celgene becomes subject to a reorganization, bankruptcy or similar proceeding, and the failure of Agios to so file shall not affect the Celgene Guarantor's obligations under this Section 15.18. In the event that any

payment to Agios in respect of the Celgene Obligations is rescinded or must otherwise be returned for any reason whatsoever, the Celgene Guarantor shall remain liable hereunder with respect to the Celgene Obligations as if such payment had not been made (subject to the terms hereof). This Section 15.18 is an unconditional guarantee of payment, and not merely of collectability.

[Remainder of page intentionally left blank]

 $IN\ WITNESS\ WHEREOF, the\ Parties\ have\ executed\ this\ Collaboration\ and\ License\ Agreement\ as\ of\ the\ Effective\ Date.$

AGIOS INTERNATIONAL SARL

By: /s/ David Schenkein

Name: David Schenkein

Title: CEO / Managing Director

CELGENE INTERNATIONAL II SARL

 By:
 /s/ Tuomo Patsi

 Name:
 Tuomo Patsi

 Title:
 President, EMEA

By: /s/ Michael J. Morrissey
Name: Michael J. Morrissey
Title: Managing Director

Guarantors Signature Page

IN WITNESS WHEREOF, the Parties have executed this Collaboration and License Agreement as of the Effective Date as guarantors for purposes of Sections 15.17 and 15.18.

AGIOS PHARMACEUTICALS, INC., as Agios Guarantor

By: /s/ David Schenkein

Name: David Schenkein

Title: CEO

CELGENE SWITZERLAND SA, as Celgene Guarantor

Signed in Switzerland:

By: /s/ Jurg Oehen
Name: Jurg Oehen

Title: Director

Exhibit A

AGI-23088 (Also known as AG-881)

[**]

A-1

Exhibit B

Agios Patent Rights and Agios Collaboration Patent Rights (as of the Effective Date)

| AGIOS DOCKET NO. | APPLICATION NO. | FILING DATE | PUBLICATION NO. | PATENT NO. |
|------------------|-----------------|-------------|-----------------|------------|
| [**] | [**] | [**] | [**] | [**] |

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of two pages were omitted. [**]

Exhibit C

[Exhibit no longer used]

C-1

Exhibit D

Existing Third Party Agreement

[**]

Exhibit E

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.

"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 ROW 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 or the AGI-23088 US Agreement (as the term "Licensed Products" is defined therein), 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 or the AGI-23088 US 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 ROW Territory, and shall consist of the following expenses: (a) Distribution Costs; (b) Manufacturing Costs for commercial supply in the ROW Territory; (c) Marketing Expenses; (d) Other Commercialization Costs; (e) Patent and Trademark Prosecution and Enforcement Costs incurred in any country of the ROW Territory from and after the First Commercial Sale of a Licensed Product in the country; (f) Product Liabilities; (g) Recall Expenses; (h) Regulatory Maintenance Costs; (i) Selling Expenses; and (j) Third Party Patent Costs incurred in a country of the ROW Territory 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 ROW 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).

"<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 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;
- (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 Trial 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 ROW 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 a full-time equivalent person year (consisting of a total of [**] hours per year) of scientific, technical or commercialization work undertaken by a Party's employees.

"FTE Costs" means, for any period, the FTE Rate multiplied by the number of FTEs in such period.

"FTE Rate" means \$[**] per FTE for each FTE devoted to Development and the overall rate as established from time to time by the Finance Working Group pursuant to Section 2.9(b)(vi) for each FTE devoted to Commercialization. On January 1, 2016 and on January 1st of each subsequent Calendar Year, the foregoing rates shall be increased for the Calendar Year then commencing by the percentage increase, if any, in the Consumer Price Index ("CPI") as of December 31 of the then most recently completed Calendar Year with respect to the level of the CPI on December 31, 2014. 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 Vital Statistics (or its successor equivalent index).

"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:

(a) 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

(b) 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 ROW 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 and/or promotion of a Licensed Product in the Territory; provided, that, 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; provided, further, that 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 ROW Territory with respect to a Licensed Product in the ROW 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; and education grant programs.

"Net Sales" means, with respect to any Licensed Product, gross amounts invoiced by the Parties, their respective Affiliates or sublicensees to Third Parties (that are not sublicensees) for the sale or other commercial disposition of such Licensed Product anywhere within the ROW Territory, including sales to wholesale distributors, less deductions from such amounts calculated in accordance with the Accounting Standards so as to arrive at "net sales" under the Accounting Standards, and further reduced by write-offs of accounts receivables or increased for collection of accounts that were previously written off.

Net Sales, and any and all set-offs against gross amounts invoiced, shall be determined from books and records maintained in accordance with the Accounting Standards, consistently applied throughout the organization and across all products of the entity whose sales of any Product are giving rise to Net Sales. Sales or other commercial dispositions of Licensed Products between a Party and its Affiliates and its sublicensees, and Licensed Products provided to Third Parties without charge, in connection with research and development, clinical trials, compassionate use, humanitarian and charitable donations, or indigent programs or for use as samples shall be excluded from the computation of Net Sales, and no payments will be payable on such sales or such other commercial dispositions, except where such an Affiliate or sublicensee is an end user of the Licensed Product.

If a Licensed Product is sold or otherwise commercially disposed of for consideration other than cash or in a transaction that is not at arm's length between the buyer and the seller, then the gross amount to be included in the calculation of Net Sales shall be the amount that would have been invoiced had the transaction been conducted at arm's length and for cash. Such amount that would have been invoiced shall be determined, wherever possible, by reference to the average selling price of the relevant Product in arm's length transactions in the relevant country.

In the event of an Agios Opt-Out Date, then, notwithstanding the foregoing, in the event a Licensed Product is sold as a Combination Product following the Agios Opt-Out Date, then Net Sales shall be calculated by multiplying the Net Sales of the Combination Product by the fraction A/(A+B), where A is the gross invoice price of the Licensed Product if sold separately in a country and B is the gross invoice price of the other product(s) included in the Combination Product if sold separately in such country. If no such separate sales are made by the relevant Party, its Affiliates or sublicensees in a country, Net Sales of the Combination Product shall be calculated in a manner to be negotiated and agreed upon by the Parties, reasonably and in good faith, prior to any sale of such Combination Product, which shall be based upon the relative value of the active components of such Combination Product.

As used in this definition, "Combination Product" means any product that comprises a Licensed Product sold in conjunction with another active ingredient so as to be a combination product (whether packaged together or in the same therapeutic formulation). Pharmaceutical dosage form vehicles, adjuvants and excipients shall be deemed not to be "active ingredients."

"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 Sections 10.2(e), 10.3(e) and 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 Trial Expenses" means all Out-of-Pocket Costs incurred for the ROW Territory related to a Phase IV Study for any Licensed Product in the ROW Territory, including expenses arising from: (a) the activities related to the performance of the Phase IV Trial; (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, 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 Trial 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.

"Product Liabilities" 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 and/or Commercialization) in the ROW 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 and/or the voluntary or involuntary withdrawal of the Licensed Product.

"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 in the ROW Territory and 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 in the ROW Territory, and personnel engaged in the filing and maintenance of Regulatory Approvals.

"ROW Territory Profit or Loss" means the profits or losses resulting from the Commercialization of the Licensed Products in the ROW Territory and which shall be equal to (a) the sum of (i) Net Sales of Licensed Products, plus (ii) Additional Revenue, less (b) Commercialization Expenses for such Licensed Products, less (c) to the extent approved by the JSC (with any disputes resolved pursuant to Section 2.8(e)), income taxes incurred by any sales or distribution Affiliate of Celgene directly attributable to the sale or other commercial disposition of Licensed Product in any jurisdiction within the ROW Territory, less (d) non-refundable, non-creditable value added and similar taxes incurred by either Party in connection with the activities undertaken pursuant to this Agreement. As used herein, "ROW Territory Profit" refers to a Calendar Quarter or Calendar Year in which a profit exists, and "ROW Territory Loss" refers to a Calendar Quarter or Calendar Year in which a loss exists.

"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 ROW 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 in the ROW Territory, and (b) Out-of-Pocket Costs and FTE Costs directly attributable to selling the Licensed Products in the ROW Territory, 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(b) of this Agreement.

Exhibit F

Countries for Filing Agios Patent Rights and Collaboration Patent Rights

[**]

Exhibit G

Press Release

Agios Pharmaceuticals Selects Third Novel IDH Mutant Inhibitor, AG-881, for Clinical Development

- Brain-penetrant, pan-IDH mutant inhibitor broadens pipeline for treatment of patients with IDH mutant positive cancers
- New worldwide development and profit share collaboration for AG-881 entered into by Agios and Celgene
- Expect to initiate clinical development for AG-881 in second quarter 2015

CAMBRIDGE, Mass., April 28, 2015 — Agios Pharmaceuticals, Inc. (NASDAQ: AGIO), a leader in the fields of cancer metabolism and rare genetic disorders of metabolism, today announced that it plans to advance into clinical development AG-881, a small molecule that has shown in preclinical studies to fully penetrate the blood brain barrier and inhibit isocitrate dehydrogenase-1 (IDH1) and IDH2 mutant cancer cells, in collaboration with its cancer metabolism partner Celgene Corporation. The companies have entered into a new joint worldwide development and profit share collaboration for AG-881, and plan to initiate clinical development of AG-881 in the second quarter of 2015. AG-881 will be the third IDH mutant inhibitor discovered by Agios to enter clinical development.

"The addition of our third IDH mutant inhibitor to our growing pipeline is an exciting milestone for Agios and underscores our goals to lead the scientific understanding of cancer metabolism and help as many patients as possible with an IDH mutant positive cancer," said David Schenkein, M.D., chief executive officer of Agios. "AG-221 and AG-120 remain our lead medicines in clinical development and are advancing rapidly. We believe the addition of AG-881 given its unique profile provides added flexibility to our portfolio of IDH inhibitors. Based on our preclinical findings, it has the potential to support our ongoing development effort to provide treatment options to patients with glioma, and it represents a possible second-generation molecule for both AG-221 and AG-120 in IDH mutant tumors. We look forward to generating data for AG-881 to inform our future development plans."

Under the terms of the new AG-881 collaboration, Agios will receive an initial payment of \$10 million in the second quarter of 2015 and is eligible to receive regulatory milestone payments of up to \$70 million. Agios and Celgene will jointly collaborate on the worldwide development program for AG-881, sharing development costs 50/50 worldwide. The two companies have agreed to share any worldwide profits 50/50, with Celgene booking worldwide commercial sales. Agios would lead commercialization in the U.S. with both companies sharing equally in field-based commercial activities, and Celgene would lead commercialization ex-U.S. with Agios providing one third of field-based commercial activities in the major E.U. markets.

Summary of Agios and Celgene Collaboration on IDH Mutant Inhibitors

Agios and Celgene entered a global, strategic collaboration in April 2010 and, to date, three potential new distinct investigational medicines have emerged – the IDH2 mutant inhibitor, AG-221; the IDH1 mutant inhibitor, AG-120; and the pan-IDH mutant inhibitor, AG-881, which as described above is now part of a new collaboration between the companies. These three investigational medicines aim to improve the treatment outcomes for patients whose cancers carry these IDH mutations, including difficult to treat acute myelogenous leukemia and glioma, a type of aggressive brain tumor with poor prognosis. Each of these investigational medicines carries different financial terms and rights under the collaboration, including:

- AG-221: Celgene has worldwide development and commercialization rights for AG-221. Agios is eligible for up to \$120 million in milestone
 payments and royalties on any net sales.
- AG-120: Agios retains U.S. development and commercialization rights, while Celgene has development and commercialization rights outside the U.S. Agios is eligible to receive royalties on any net sales outside the U.S. and up to \$120 million in milestone payments. Celgene is eligible to receive royalties on any net sales in the U.S.
- AG-881: Joint worldwide development and 50/50 profit share agreement. Agios is eligible to receive regulatory milestone payments up to \$70 million.

About Agios Pharmaceuticals, Inc.

Agios Pharmaceuticals is focused on discovering and developing novel investigational medicines to treat cancer and rare genetic disorders of metabolism through scientific leadership in the field of cellular metabolism. In addition to an active research and discovery pipeline across both therapeutic areas, Agios has multiple first-in-class investigational medicines in clinical and/or preclinical development. All Agios programs focus on genetically identified patient populations, leveraging our knowledge of metabolism, biology and genomics. For more information, please visit the company's website at agios.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Such forward-looking statements include those regarding the potential benefits of, and plans relating to, the collaboration with Celgene; the potential benefits of AG-221, AG-120 and AG-881; and Agios' plans to generate data from AG-881 to inform its future development plans; and the benefit of Agios' strategic plans and focus. The words "anticipate," "believe," "estimate," "expect," "goal," "intend," "may," "plan," "possible," "potential," "predict," "project," "could," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from Agios' current expectations and beliefs. For example, there can be no guarantee that AG-881 or any other product candidate Agios is developing will successfully continue. There can be no guarantee that any positive development phases, or that development of any of Agios' product candidates will successfully continue. There can be no guarantee that any positive developments in Agios' business will result in stock price appreciation. Management's expectations and, therefore, any forward-looking statements in this press release could also be affected by risks and uncertainties relating to a number of

other important factors, including: Agios' results of clinical trials and preclinical studies, including subsequent analysis of existing data and new data received from ongoing and future studies; the content and timing of decisions made by the U.S. FDA and other regulatory authorities, investigational review boards at clinical trial sites and publication review bodies; Agios' ability to obtain and maintain requisite regulatory approvals and to enroll patients in its planned clinical trials; unplanned cash requirements and expenditures; competitive factors; Agios' ability to obtain, maintain and enforce patent and other intellectual property protection for any product candidates it is developing; Agios' ability to maintain key collaborations; and general economic and market conditions. These and other risks are described in greater detail under the caption "Risk Factors" included in Agios' Annual Report on Form 10-K for the year ended December 31, 2014, and other filings that Agios may make with the Securities and Exchange Commission in the future. Any forward-looking statements contained in this press release speak only as of the date hereof, and Agios expressly disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

###

Contact:

Agios Pharmaceuticals, Inc. Lora Pike, 617-649-8608 Senior Director, Investor Relations and Public Relations lora.pike@agios.com

Exhibit H

Initial JSC, JDC and JPC Appointments

Joint Steering Committee (JSC)

| Position | Initial Chairmanan | Celgene Appointee | Agios Appointee | | |
|----------|------------------------------|-----------------------------------|-----------------|--|--|
| | <u>Initial Chairperson</u> | [**] | [**] | | |
| | JSC Member | [**] | [**] | | |
| | JSC Member | [**] | [**] | | |
| | JSC Member | [**] | [**] | | |
| | | | | | |
| | | Joint Development Committee (JDC) | | | |
| Position | | Celgene Appointee | Agios Appointee | | |
| | Initial Chairperson | [**] | [**] | | |
| | JDC Member | [**] | [**] | | |
| | JDC Member | [**] | [**] | | |
| | JDC Member | [**] | [**] | | |
| | | | | | |
| | Joint Patent Committee (JPC) | | | | |
| Position | | Celgene Appointee | Agios Appointee | | |
| | Initial Chairperson | [**] | [**] | | |
| | JPC Member | [**] | [**] | | |
| | JPC Member | [**] | [**] | | |

H-1

Exhibit I

Partnership Tax Matters

(See attached.)

I-1

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 7, 2015

/s/ David P. Schenkein

David P. Schenkein 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 7, 2015

/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, 2015, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, David P. Schenkein, 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 7, 2015

/s/ David P. Schenkein

David P. Schenkein 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, 2015, 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 7, 2015

/s/ Glenn Goddard

Glenn Goddard Senior Vice President, Finance (principal financial and accounting officer)