# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 2012

OR

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

to

For the transition period from

Commission file number 001-33497

# Amicus Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware

(State or Other Jurisdiction of Incorporation or Organization)

**71-0869350** (I.R.S. Employer Identification Number)

Accelerated filer o

Smaller Reporting Company x

1 Cedar Brook Drive, Cranbury, NJ 08512

(Address of Principal Executive Offices and Zip Code)

Registrant's Telephone Number, Including Area Code: (609) 662-2000

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller-reporting company. See definition of "large accelerated filer," accelerated filer" and "smaller-reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o

Non-accelerated filer o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): Yes o No x

The number of shares outstanding of the registrant's common stock, \$.01 par value per share, as of October 26, 2012 was 49,449,489 shares.

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# AMICUS THERAPEUTICS, INC

Form 10-Q for the Quarterly Period Ended September 30, 2012

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Item 1. Financial Statements (unaudited)

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We have filed applications to register certain trademarks in the United States and abroad, including AMICUS<sup>TM</sup> and AMICUS THERAPEUTICS<sup>TM</sup> (and design).

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# SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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, included in this quarterly report on Form 10-Q regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this quarterly report on Form 10-Q include, among other things, statements about:

- the progress and results of our clinical trials of our drug candidates, including migalastat HCl;
- the continuation of our collaboration with GlaxoSmithKline PLC and GSK's achievement of milestone payments thereunder;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our product candidates including those testing the use of pharmacological chaperones co-administered with ERT and for the treatment of diseases of neurodegeneration;
- the costs, timing and outcome of regulatory review of our product candidates;
- · the number and development requirements of other product candidates that we pursue;
- the costs of commercialization activities, including product marketing, sales and distribution;
- $\cdot$   $\;$  the emergence of competing technologies and other adverse market developments;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property related claims;
- the extent to which we acquire or invest in businesses, products and technologies; and
- our ability to establish collaborations and obtain milestone, royalty or other payments from any such collaborators.

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 forwardlooking statements we make. We have included important factors in the cautionary statements discussed under the heading "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2012 that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, collaborations or investments we may make. You should read this quarterly report on Form 10-Q in conjunction with the documents that we reference herein. We do not assume any obligation to update any forward-looking statements.

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PART I. FINANCIAL INFORMATION

## Item 1. Financial Statements (unaudited)

## Amicus Therapeutics, Inc. (a development stage company) Consolidated Balance Sheets *(Unaudited)* (in thousands, except share and per share amounts)

	De	ecember 31, 2011	Se	ptember 30, 2012
Assets:				
Current assets:				
Cash and cash equivalents	\$	25,668	\$	24,273
Investments in marketable securities		30,034		81,942
Receivable due from GSK		5,043		3,184
Prepaid expenses and other current assets		5,903		3,077
Total current assets		66,648		112,476
Property and equipment, less accumulated depreciation and amortization of \$9,507 and \$8,080 at December				
31, 2011 and September 30, 2012, respectively		2,438		5,293
Other non-current assets		709		442
Total Assets	\$	69,795	\$	118,211
Liabilities and Stockholders' Equity				
Current liabilities:				
Accounts payable and accrued expenses	\$	9,708	\$	9,428
Current portion of deferred reimbursements		8,504		
Current portion of secured loan		1,044		502
Total current liabilities		19,256		9,930
		-		
Deferred reimbursements, less current portion		18,999		27,235
Warrant liability		1,948		3,889
Secured loan, less current portion		—		398
Commitments and contingencies				
Stockholders' equity:				
Common stock, \$.01 par value, 125,000,000 shares authorized, 34,654,206 shares issued and outstanding at December 31, 2011, 125,000,000 shares authorized, 49,360,659 shares issued and outstanding at				
September 30, 2012		407		554
Additional paid-in capital		299,285		385,042
Accumulated other comprehensive income		4		37
Deficit accumulated during the development stage		(270,104)		(308,874)
Total stockholders' equity		29,592		76,759
Total Liabilities and Stockholders' Equity	\$	69,795	\$	118,211

See accompanying notes to consolidated financial statements

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Amicus Therapeutics, Inc. (a development stage company) Consolidated Statements of Operations *(Unaudited)* (in thousands, except share and per share amounts)

								riod from bruary 4, 2002
	Three Months			Nine N		(inception)		
	 Ended Sep	tember	30,	 Ended Sep	30,	to Se	ptember 30,	
	 2011		2012	 2011		2012		2012
Revenue:								
Research revenue	\$ 4,138	\$		\$ 10,824	\$	11,591	\$	57,493

Collaboration and milestone revenue		1,660				4,980		6,820		64,382
Total revenue	\$	5,798	\$		\$	15,804	\$	18,411	\$	121,875
	ψ	5,750	Ψ		ψ	15,004	Ψ	10,411	Ψ	121,075
Operating Expenses:										
Research and development	\$	13,711	\$	11,499	\$	36,455	\$	39,226	\$	304,846
General and administrative	ψ	4,841	Ψ	4,995	Ψ	15,963	Ψ	14,909	Ψ	128,158
Restructuring charges		4,041		4,555		15,505		14,505		1,522
Impairment of leasehold improvements										1,030
Depreciation and amortization		380		422		1,243		1,284		11,347
In-process research and development		500		422		1,245		1,204		418
Total operating expenses		18,932		16,916		53,661		55,419		447,321
Loss from operations										
Other income (expenses):		(13,134)		(16,916)		(37,857)		(37,008)		(325,446)
Interest income		31		92		136		235		14 200
				-						14,308
Interest expense		(32)		(19)		(121)		(77)		(2,410)
Change in fair value of warrant liability		3,376		553		2,022		(1,941)		(1,041)
Other income		(0 == 0)		(16.200)		70		21		252
Loss before tax benefit		(9,759)		(16,290)		(35,750)		(38,770)		(314,337)
Benefit from income taxes										5,463
Net loss		(9,759)		(16,290)		(35,750)		(38,770)		(308,874)
Deemed dividend		—		—		—		—		(19,424)
Preferred stock accretion										(802)
Net loss attributable to common stockholders	\$	(9,759)	\$	(16,290)	\$	(35,750)	\$	(38,770)	\$	(329,100)
Net loss attributable to common stockholders per										
common shares — basic and diluted	\$	(0.28)	\$	(0.34)	\$	(1.03)	\$	(0.88)		
Weighted-average common shares outstanding —										
basic and diluted		34,979,702		48,513,647		34,544,768		44,255,885		
	_		_				_			

See accompanying notes to consolidated financial statements

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# Amicus Therapeutics, Inc. (a development stage company) Consolidated Statements of Comprehensive Loss *(Unaudited)* (in thousands, except share and per share amounts)

	Three Months           Ended September 30,           2011         2012				_	Nine M Ended Sep 2011	Period from February 4, 2002 (inception) to September 30, 2012		
Net loss	\$	(9,759)	\$	(16,290)	\$	(35,750)	\$ (38,770)	\$	(308,874)
Other comprehensive income/(loss):									
Unrealized (loss) gain on available-for-sale securities		(11)		20	<u> </u>	3	 33		37
Other comprehensive income/(loss), before income taxes		(11)		20		3	33		37
Provision for income taxes related to other comprehensive income/(loss) items (Note 1)							 		
Other comprehensive income/(loss)	\$	(11)	\$	20	\$	3	\$ 33	\$	37
Comprehensive loss	\$	(9,770)	\$	(16,270)	\$	(35,747)	\$ (38,737)	\$	(308,837)

Note 1 — Taxes have not been accrued on unrealized gain on securities as the Company is in a loss position for all periods presented.

See accompanying notes to consolidated financial statements

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

		Nine M Ended Sep 2011		<u>30,</u> 2012	Fe	Period from bruary 4, 2002 (inception) to September 30, 2012
Operating activities		2011		2012		2012
Net loss	\$	(35,750)	\$	(38,770)	\$	(308,874)
Adjustments to reconcile net loss to net cash used in operating activities:						
Non-cash interest expense						525
Depreciation and amortization		1,243		1,284		11,347
Amortization of non-cash compensation						522
Stock-based compensation - employees		7,243		4,743		40,480
Stock-based compensation - non-employees		_		_		853
Stock-based license payments		_		_		1,220
Change in fair value of warrant liability		(2,022)		1,941		1,041
Loss on disposal of asset		—		28		388
Impairment of leasehold improvements						1,030
Non-cash charge for in-process research and development		_		_		418
Debt instrument convertible beneficial conversion feature						135
Changes in operating assets and liabilities:						
Receivable due from GSK		(4,630)		1,859		(3,184)
Prepaid expenses and other current assets		(447)		2,826		(3,077)
Other non-current assets				267		(463)
Accounts payable and accrued expenses		(192)		(280)		9,428
Deferred reimbursements		(2,346)		(268)		27,235
Net cash used in operating activities		(36,901)		(26,370)		(220,976)
Investing activities		(00,001)		(20,070)		(==0,070)
Sale and redemption of marketable securities		78,255		47,445		719,535
Purchases of marketable securities		(47,097)		(99,320)		(801,558)
Purchases of property and equipment		(398)		(4,167)		(18,056)
Net cash provided by/(used in) investing activities		30,760		(56,042)		(100,079)
Financing activities		50,700		(50,042)		(100,075)
Proceeds from the issuance of preferred stock, net of issuance costs						143,022
Proceeds from the issuance of common stock and warrants, net of issuance costs				80,195		193,441
Proceeds from the issuance of convertible notes						5,000
Payments of capital lease obligations		(40)				(5,587)
Payments of secured loan agreement		(940)		(1,139)		(3,853)
Proceeds from exercise of stock options		359		966		2,677
Proceeds from exercise of stock options Proceeds from exercise of warrants (common and preferred)						2,077
Proceeds from capital asset financing arrangement						5,611
Proceeds from secured loan agreement		_		995		4,753
Net cash (used in) /provided by financing activities		(621)		81,017		345,328
Net (decrease) increase in cash and cash equivalents						
		(6,762)		(1,395)		24,273
Cash and cash equivalents at beginning of period Cash and cash equivalents at end of period	<u>۴</u>	29,572	¢	25,668	¢	24.272
	\$	22,810	\$	24,273	\$	24,273
Supplemental disclosures of cash flow information	<i>.</i>	101	<i>•</i>		<b>.</b>	0.404
Cash paid during the period for interest	\$	121	\$	72	\$	2,104
Non-cash activities						
Conversion of notes payable to preferred stock	\$	_	\$	_	\$	5,000
Conversion of preferred stock to common stock	\$		\$		\$	148,951
Accretion of redeemable convertible preferred stock	\$	_	\$	_	\$	802
Beneficial conversion feature related to the issuance of Series C redeemable convertible preferred stock	\$	_	\$	_	\$	19,424

See accompanying notes to consolidated financial statements

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## Note 1. Description of Business and Significant Accounting Policies

## Corporate Information, Status of Operations and Management Plans

Amicus Therapeutics, Inc. (the Company) was incorporated on February 4, 2002 in Delaware and is a biopharmaceutical company focused on the discovery, development and commercialization of orally-administered, small molecule drugs known as pharmacological chaperones, a novel, first-in-class approach to treating a broad range of diseases including lysosomal storage diseases and diseases of neurodegeneration. The Company's activities since inception have consisted principally of raising capital, establishing facilities and performing research and development. Accordingly, the Company is considered to be in the development stage.

On July 17, 2012, the Company entered into an Amended and Restated License and Expanded Collaboration Agreement (the "Expanded Collaboration Agreement") with an affiliate of GlaxoSmithKline PLC (GSK) pursuant to which the Company and GSK will continue to develop and commercialize

migalastat HCI, currently in Phase 3 development for the treatment of Fabry disease. The Expanded Collaboration Agreement amends and replaces in its entirety the License and Collaboration Agreement entered into between the Company and GSK on October 28, 2010 (the "Original Collaboration Agreement") for the development and commercialization of migalastat HCl. Under the terms of the Expanded Collaboration Agreement, the Company and GSK will co-develop all formulations of migalastat HCl for Fabry disease, including the development of migalastat HCl co-formulated with an investigational enzyme replacement therapy (ERT) for Fabry disease (the "Co-formulated Product") in collaboration with another GSK collaborator JCR Pharmaceutical Co., Ltd. The Company will commercialize all migalastat HCl products for Fabry disease in the United States while GSK will commercialize all such products in the rest of the world.

GSK is eligible to receive U.S. regulatory approval milestones totaling \$20 million for migalastat HCl monotherapy and migalastat HCl for coadministration with ERT, and additional regulatory approval and product launch milestone payments totaling up to \$35 million within seven years following the launch of the Co-formulated Product. The Company will also be responsible for certain pass-through milestone payments and single-digit royalties on the net U.S. sales of the Co-formulated Product that GSK must pay to a third party. In addition, the Company is no longer eligible to receive any milestones or royalties it would have been eligible to receive under the Original Collaboration Agreement other than a \$3.5 million clinical development milestone achieved in the second quarter of 2012 and paid by GSK to Amicus in the third quarter of 2012.

The Company and GSK will continue to jointly fund development costs for all formulations of migalastat HCl in accordance with agreed upon development plans pursuant to which the Company and GSK will fund 25% and 75% of such costs, respectively, for the monotherapy and co-administration development of migalastat HCl for the remainder of 2012 and 40% and 60%, respectively, thereafter. Effective upon entry into the Expanded Collaboration Agreement, costs for the development of the Co-formulated Product are also split 40% and 60% between Amicus and GSK, respectively.

Additionally, simultaneous with entry into the Expanded Collaboration Agreement, the Company and GSK entered into a Stock Purchase Agreement (the "SPA") pursuant to which GSK purchased approximately 2.9 million shares of Amicus common stock at a price of \$6.30 per share. The total value of this equity investment to the Company is approximately \$18.6 million and increases GSK's ownership position in the Company to 19.9%. GSK purchased approximately 6.9 million shares for an aggregate investment of approximately \$31 million in connection with entry into the Original Collaboration Agreement in 2010.

For further information, see "- Note 7. Collaborative Agreements."

The Company had an accumulated deficit of approximately \$308.9 million at September 30, 2012 and anticipates incurring losses through the year 2012 and beyond. The Company has not yet generated commercial sales revenue and has been able to fund its operating losses to date through the sale of its redeemable convertible preferred stock, issuance of convertible notes, net proceeds from our initial public offering (IPO) and subsequent stock offerings, payments from partners during the terms of collaboration agreements and other financing arrangements. In March 2010, the Company sold 4.95 million shares of its common stock and warrants to purchase 1.85 million shares of common stock in a registered direct offering to a select group of institutional investors for net

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proceeds of \$17.1 million. In October 2010, the Company sold 6.87 million shares of its common stock as part of the Original Collaboration Agreement with GSK for proceeds of \$31 million and 2.9 million shares of its common stock in connection with the Expanded Collaboration Agreement. In March 2012, the Company sold 11.5 million shares of its common stock in a stock offering for net proceeds of \$62.0 million. The Company believes that its existing cash and cash equivalents and short-term investments will be sufficient to cover its cash flow requirements for 2013.

#### **Basis of Presentation**

The Company has prepared the accompanying unaudited consolidated financial statements in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10-01 of Regulations S-X. Accordingly, they do not include all of the information and disclosures required by generally accepted accounting principles for complete financial statements. In the opinion of management, the accompanying unaudited financial statements reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly the Company's interim financial information.

The accompanying unaudited consolidated financial statements and related notes should be read in conjunction with the Company's financial statements and related notes as contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2011. For a complete description of the Company's accounting policies, please refer to the Annual Report on Form 10-K for the fiscal year ended December 31, 2011.

## **Revenue Recognition**

The Company recognizes revenue when amounts are realized or realizable and earned. Revenue is considered realizable and earned when the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the price is fixed or determinable; and (4) collection of the amounts due are reasonably assured.

In multiple element arrangements, revenue is allocated to each separate unit of accounting and each deliverable in an arrangement is evaluated to determine whether it represents separate units of accounting. A deliverable constitutes a separate unit of accounting when it has standalone value and there is no general right of return for the delivered elements. In instances when the aforementioned criteria are not met, the deliverable is combined with the undelivered elements and the allocation of the arrangement consideration and revenue recognition is determined for the combined unit as a single unit of accounting. Allocation of the consideration is determined at arrangement inception on the basis of each unit's relative selling price. In instances where there is determined to be a single unit of accounting, the total consideration is applied as revenue for the single unit of accounting and is recognized over the period of inception through the date where the last deliverable within the single unit of accounting is expected to be delivered.

The Company's current revenue recognition policies provide that, when a collaboration arrangement contains multiple deliverables, such as license and research and development services, the Company allocates revenue to each separate unit of accounting based on a selling price hierarchy. The selling price hierarchy for a deliverable is based on (i) its vendor specific objective evidence (VSOE) if available, (ii) third party evidence (TPE) if VSOE is not available, or (iii) estimated selling price (BESP) if neither VSOE nor TPE is available. The Company would establish the VSOE of selling price using the price charged for a deliverable when sold separately. The TPE of selling price would be established by evaluating largely similar and interchangeable competitor products

or services in standalone sales to similarly situated customers. The best estimate of selling price would be established considering internal factors such as an internal pricing analysis or an income approach using a discounted cash flow model.

The Company also considers the impact of potential future payments it makes in its role as a vendor to its customers and evaluates if these potential future payments could be a reduction of revenue from that customer. If the potential future payments to the customer are:

A payment for an identifiable benefit, and

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- The identifiable benefit is separable from the existing relationship between the Company and its customer, and
- The identifiable benefit can be obtained from a party other than the customer, and
- · The Company can reasonably estimate the fair value of the identifiable benefit,

then the payments are accounted for separate from the revenue received from that customer. If, however, all these criteria are not satisfied, then the payments are treated as a reduction of revenue from that customer.

If the Company determines that any potential future payments to its customers are to be considered as a reduction of revenue, it must evaluate if the total amount of revenue to be received under the arrangement is fixed and determinable. If the total amount of revenue is not fixed and determinable due to the uncertain nature of the potential future payments to the customer, then any customer payments cannot be recognized as revenue until the total arrangement consideration becomes fixed and determinable.

The reimbursements for research and development costs under collaboration agreements that meet the criteria for revenue recognition are included in Research Revenue and the costs associated with these reimbursable amounts are included in research and development expenses.

In order to determine the revenue recognition for contingent milestones, the Company evaluates the contingent milestones using the criteria as provided by the Financial Accounting Standards Boards (FASB) guidance on the milestone method of revenue recognition at the inception of a collaboration agreement. The criteria requires that (i) the Company determines if the milestone is commensurate with either its performance to achieve the milestone or the enhancement of value resulting from the Company's activities to achieve the milestone, (ii) the milestone be related to past performance, and (iii) the milestone be reasonable relative to all deliverable and payment terms of the collaboration arrangement. If these criteria are met then the contingent milestones can be considered as substantive milestones and will be recognized as revenue in the period that the milestone is achieved.

## Fair Value Measurements

The Company records certain asset and liability balances under the fair value measurements as defined by the FASB guidance. Current FASB fair value guidance emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Therefore, a fair value measurement should be determined based on the assumptions that market participants would use in pricing the asset or liability. As a basis for considering market participant assumptions in fair value measurements, current FASB guidance establishes a fair value hierarchy that distinguishes between market participant assumptions based on market data obtained from sources independent of the reporting entity (observable inputs that are classified within Levels 1 and 2 of the hierarchy) and the reporting entity's own assumptions that market participants assumptions would use in pricing assets or liabilities (unobservable inputs classified within Level 3 of the hierarchy).

Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access at measurement date. Level 2 inputs are inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs may include quoted prices for similar assets and liabilities in active markets, as well as inputs that are observable for the asset or liability (other than quoted prices), such as interest rates, foreign exchange rates, and yield curves that are observable at commonly quoted intervals. Level 3 inputs are unobservable inputs for the asset or liability, which is typically based on an entity's own assumptions, as there is little, if any, related market activity. In instances where the determination of the fair value measurement is based on inputs from different levels of the fair value hierarchy, the level in the fair value hierarchy within which the entire fair value measurement falls is based on the lowest level input that is significant to the fair value measurement in its entirety. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment, and considers factors specific to the asset or liability.

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#### New Accounting Standards

In June 2011, the FASB amended its guidance on the presentation of comprehensive income in financial statements to improve the comparability, consistency and transparency of financial reporting and to increase the prominence of items that are recorded in other comprehensive income. The new accounting guidance requires entities to report components of comprehensive income in either (1) a continuous statement of comprehensive income or (2) two separate but consecutive statements. The provisions of this guidance are effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. Other than a change in presentation, the implementation of this accounting pronouncement did not have a material impact on our financial statements.

In May 2011, the FASB amended the FASB Accounting Standards Codification to converge the fair value measurement guidance in U.S. GAAP and International Financial Reporting Standards. Some of the amendments clarify the application of existing fair value measurement requirements, while other amendments change particular principles in fair value measurement guidance. In addition, the amendments require additional fair value disclosures. The amendments are effective for fiscal year 2012 and should be applied prospectively. The Company is currently evaluating the impact, if any, that the provisions of the amendments will have on its consolidated results of operations or financial position.

## Note 2. Cash, Cash Equivalents and Available-for-Sale Investments

As of September 30, 2012, the Company held \$24.3 million in cash and cash equivalents and \$81.9 million of available-for-sale investment securities which are reported at fair value on the Company's balance sheet. Unrealized holding gains and losses are reported within accumulated other comprehensive income/ (loss) as a separate component of stockholders' equity. If a decline in the fair value of a marketable security below the Company's cost basis is determined to be other than temporary, such marketable security is written down to its estimated fair value as a new cost basis and the amount of the writedown is included in earnings as an impairment charge. To date, only temporary impairment adjustments have been recorded.

Consistent with the Company's investment policy, the Company does not use derivative financial instruments in its investment portfolio. The Company regularly invests excess operating cash in deposits with major financial institutions, money market funds, notes issued by the U.S. government, as well as fixed income investments and U.S. bond funds both of which can be readily purchased and sold using established markets. The Company believes that the market risk arising from its holdings of these financial instruments is mitigated as many of these securities are either government backed or of the highest credit rating.

Cash and available for sale securities consisted of the following as of December 31, 2011 and September 30, 2012 (in thousands):

	As of December 31, 2011								
	Cost		Unrealized Gain		Unrealized Loss		Fair Value		
Cash balances	\$ 25,668	\$	_	\$	_	\$	25,668		
U.S. government agency securities	2,000		_		_		2,000		
Corporate debt securities	13,943				(8)		13,935		
Commercial paper	13,737		12		—		13,749		
Certificate of deposit	350				—		350		
	\$ 55,698	\$	12	\$	(8)	\$	55,702		
Included in cash and cash equivalents	\$ 25,668	\$	—	\$	—	\$	25,668		
Included in marketable securities	30,030		12		(8)		30,034		
Total cash and available for sale securities	\$ 55,698	\$	12	\$	(8)	\$	55,702		

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	As of September 30, 2012								
	 Cost		ealized Gain		realized Loss		Fair Value		
Cash balances	\$ 24,273	\$		\$		\$	24,273		
Corporate debt securities	49,773		11		(7)		49,777		
Commercial paper	29,211		30				29,241		
Certificate of deposit	2,921		3				2,924		
	\$ 106,178	\$	44	\$	(7)	\$	106,215		
Included in cash and cash equivalents	\$ 24,273	\$	—	\$	—	\$	24,273		
Included in marketable securities	81,905		44		(7)		81,942		
Total cash and available for sale securities	\$ 106,178	\$	44	\$	(7)	\$	106,215		

Unrealized gains and losses are reported as a component of accumulated other comprehensive income/(loss) in stockholders' equity. For the year ended December 31, 2011, unrealized holding gains included in accumulated other comprehensive income was \$4 thousand. For the nine months ended September 30, 2012, unrealized holding gains included in accumulated other comprehensive income was \$33 thousand.

For the year ended December 31, 2011 and the nine months ended September 30, 2012, there were no realized gains or losses. The cost of securities sold is based on the specific identification method.

Unrealized loss positions in the available for sale securities as of December 31, 2011 and September 30, 2012 reflect temporary impairments that have not been recognized and have been in a loss position for less than twelve months. The fair value of these available for sale securities in unrealized loss positions was \$13.2 million and \$15.3 million as of December 31, 2011 and September 30, 2012, respectively.

#### Note 3. Basic and Diluted Net Loss Attributable to Common Stockholders per Common Share

The Company calculates net loss per share as a measurement of the Company's performance while giving effect to all dilutive potential common shares that were outstanding during the reporting period. The Company has a net loss for all periods presented; accordingly, the inclusion of common stock options and warrants would be anti-dilutive. Therefore, the weighted average shares used to calculate both basic and diluted earnings per share are the same.

The following table provides a reconciliation of the numerator and denominator used in computing basic and diluted net loss attributable to common stockholders per common share:

	Three Mon Septem		Nine Mon Septem		
(In thousands, except per share amounts)	 2011	2012	2011	_	2012
Statement of Operations					
Net loss attributable to common stockholders	\$ (9,759)	\$ (16,290)	\$ (35,750)	\$	(38,770)
Net loss attributable to common stockholders per common share					
— basic and diluted	\$ (0.28)	\$ (0.34)	\$ (1.03)	\$	(0.88)

Dilutive common stock equivalents would include the dilutive effect of common stock options and warrants for common stock equivalents. Potentially dilutive common stock equivalents totaled approximately 8.5 million and 10.4 million for the nine months ended September 30, 2011 and 2012, respectively.

Potentially dilutive common stock equivalents were excluded from the diluted earnings per share denominator for all periods because of their anti-dilutive effect.

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# Note 4. Stockholders' Equity

# Common Stock and Warrants

On July 17, 2012, Amicus and GSK entered into the SPA pursuant to which GSK purchased 2.9 million unregistered shares of Amicus common stock at a price of \$6.30 per share. The total purchase price for these shares was \$18.6 million and increases GSK's ownership position in the Company to 19.9%. The Company received all proceeds from the sale of such shares on July 26, 2012.

In March 2012, the Company sold 11.5 million shares of its common stock at a public offering price of \$5.70 through a Registration Statement on Form S-3 that was declared effective by the SEC on May 27, 2009. The aggregate offering proceeds were \$65.6 million.

In October 2010, GSK purchased approximately 6.9 million shares of the Company's common stock at \$4.56 per share in connection with the Original Collaboration Agreement. The total value of this equity investment was approximately \$31 million.

In March 2010, the Company sold 4.9 million shares of its common stock and warrants to purchase 1.9 million shares of common stock in a registered direct offering to a selected group of institutional investors through a Registration Statement on Form S-3 that was declared effective by the SEC on May 27, 2009. The shares of common stock and warrants were sold in units consisting of one share of common stock and one warrant to purchase 0.375 shares of common stock at a price of \$3.74 per unit. The warrants have a term of four years and are exercisable any time on or after the six month anniversary of the date they were issued, at an exercise price of \$4.43 per share. The aggregate offering proceeds were \$18.5 million.

## **Stock Option Plans**

During the three and nine months ended September 30, 2012, the Company recorded compensation expense of approximately \$1.6 million and \$4.7 million, respectively. The stock-based compensation expense had no impact on the Company's cash flows from operations and financing activities. As of September 30, 2012, the total unrecognized compensation cost related to non-vested stock options granted was \$11.6 million and is expected to be recognized over a weighted average period of 2.7 years.

The fair value of the options granted is estimated on the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions:

	Three N Ended Sept	,	Nine M Ended Sept		
	2011	2012	2011	2012	
Expected stock price volatility	78.4%	 76.2%	78.8%	77	7.5%
Risk free interest rate	1.3%	0.9%	2.0%	0	).8%
Expected life of options (years)	6.25	6.25	6.25	6.2	25
Expected annual dividend per share	\$ 0.00	\$ 0.00 \$	0.00	\$ 0.0	00
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A summary of option activities related to the Company's stock options for the nine months ended September 30, 2012 is as follows:

	Number of Shares (in thousands)	 Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	 Aggregate Intrinsic Value (in millions)
Balance at December 31, 2011	6,653.5	\$ 6.87		
Options granted	2,801.1	\$ 5.34		
Options exercised	(256.9)	\$ 3.76		
Options forfeited	(692.8)	\$ 7.79		
Balance at September 30, 2012	8,504.9	\$ 6.39	7.6 years	\$ 3.7
Vested and unvested expected to vest, September 30, 2012	7,967.8	\$ 6.46	7.5 years	\$ 3.5
Exercisable at September 30, 2012	4,211.0	\$ 7.48	6.2 years	\$ 1.7

## Note 5. Short-Term Borrowings and Long-Term Debt

In May 2009, the Company entered into a loan and security agreement with Silicon Valley Bank (SVB) that provides for up to \$4 million of equipment financing through October 2012 (the "2009 Loan Agreement"). Borrowings under the agreement are collateralized by equipment purchased with the proceeds of the loan and bear interest at a fixed rate of approximately 9%. The 2009 Loan Agreement contained customary terms and conditions, including a financial covenant whereby the Company must maintain a minimum amount of liquidity measured at the end of each month where unrestricted cash, cash equivalents, and marketable securities, is greater than \$20 million plus outstanding debt due to SVB.

In addition, the Company committed to a second loan and security agreement with SVB in August 2011 (the "2011 Loan Agreement") in order to finance certain capital expenditures made by the Company in connection with its move in March 2012 to new office and laboratory space in Cranbury, New Jersey.

The 2011 Loan Agreement provides for up to \$3 million of equipment financing through January 2014. Borrowings under the 2011 Loan Agreement are collateralized by equipment purchased with the proceeds of the loan and bear interest at a variable rate of SVB prime + 2.5%. The current SVB prime rate is 4.0%. In February 2012, the Company borrowed approximately \$1.0 million from the 2011 Loan Agreement which will be repaid over the following 2.5 years. The 2011 Loan Agreement contains the same financial covenants as the 2009 Loan Agreement. The Company has at all times been in compliance with these covenants during the term of both agreements.

At September 30, 2012, the total amount due under the 2009 Loan Agreement and the 2011 Loan Agreement was \$0.9 million. The carrying amount of the Company's borrowings approximates fair value at September 30, 2012.

## Note 6. Assets and Liabilities Measured at Fair Value

The Company's financial assets and liabilities are measured at fair value and classified within the fair value hierarchy which is defined as follows:

Level 1 — Quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

Level 2 — Inputs other than quoted prices in active markets that are observable for the asset or liability, either directly or indirectly.

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Level 3 — Inputs that are unobservable for the asset or liability.

#### Cash, Money Market Funds and Marketable Securities

The Company classifies its cash and money market funds within the fair value hierarchy as Level 1 as these assets are valued using quoted prices in active market for identical assets at the measurement date. The Company considers its investments in marketable securities as available for sale and classifies these assets within the fair value hierarchy as Level 2 primarily utilizing broker quotes in a non-active market for valuation of these securities. No changes in valuation techniques or inputs occurred during the three months ended September 30, 2012. No transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy occurred during the nine months ended September 30, 2012.

#### Secured Debt

As disclosed in Note 5, the Company has loan and security agreements with Silicon Valley Bank. The carrying amount of the Company's borrowings approximates fair value at September 30, 2012. The Company's secured debt is classified as Level 2 and the fair value is estimated using quoted prices for similar liabilities in active markets, as well as inputs that are observable for the liability (other than quoted prices), such as interest rates that are observable at commonly quoted intervals.

#### Warrants

The Company allocated \$3.3 million of proceeds from its March 2010 registered direct offering to warrants issued in connection with the offering that was classified as a liability. The valuation of the warrants is determined using the Black-Scholes model. This model uses inputs such as the underlying price of the shares issued when the warrant is exercised, volatility, risk free interest rate and expected life of the instrument. The Company has determined that the warrant liability should be classified within Level 3 of the fair value hierarchy by evaluating each input for the Black-Scholes model against the fair value hierarchy criteria and using the lowest level of input as the basis for the fair value classification. There are six inputs: closing price of Amicus stock on the day of evaluation; the exercise price of the warrants; the remaining term of the warrants; the volatility of Amicus' stock over that term; annual rate of dividends; and the riskless rate of return. Of those inputs, the exercise price of not granting dividends. The closing price of Amicus stock would fall under Level 1 of the fair value hierarchy as it is a quoted price in an active market. The riskless rate of return is a Level 2 input, while the historical volatility is most appropriately classified within Level 3 of the fair value hierarchy. This liability is subject to fair value mark-to-market adjustment each period. As a result, the Company recognized the change in the fair value of the warrant liability as non-operating income of \$0.6 million and non-operating expense of \$1.9 million for the three and nine months ended September 30, 2012 was \$3.9 million. The weighted average assumptions used in the Black-Scholes valuation model for the warrants as of December 31, 2011 and September 30, 2012 are as follows:

	December	31, 2011	September 30, 20	)12
Expected stock price volatility		67.3%		76.0%
Risk free interest rate		0.28%		0.19%
Expected life of warrants (years)		2.17		1.42
Expected annual dividend per share	\$	0.00	\$	0.00
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A summary of the fair value of the Company's assets and liabilities aggregated by the level in the fair value hierarchy within which those measurements fall as of September 30, 2012, are identified in the following table (in thousands):

	Balance as of December 31, 2011							
	 Level 1		Level 2		Total			
Assets:								
Cash/Money market funds	\$ 25,668	\$		\$	25,668			
U.S. government agency securities			2,000		2,000			

Commercial paper				13,749		13,749		
Corporate debt securities				13,935		13,935		
Certificate of deposit				350		350		
	\$	25,668	\$	30,034	\$	55,702		
		<u> </u>		<u> </u>	<u> </u>	<u> </u>		
		Level 1		Level 2		Level 3		Total
Liabilities:							_	
Secured debt	\$	—	\$	1,044	\$		\$	1,044
Warrants liability		_		_		1,948		1,948
	\$		\$	1,044	\$	1,948	\$	2,992
				<u> </u>				<u> </u>
		Bal	ance as	of September 30, 20	)12			
		Level 1		Level 2		Total		
		Lever		Level -		Total		
Assets:	-			Lttt				
Cash/Money market funds	\$	24,273	\$		\$	24,273		
	\$		\$	49,777	\$			
Cash/Money market funds	\$		\$	_	\$	24,273		
Cash/Money market funds Corporate debt securities	\$		\$	49,777	\$	24,273 49,777		
Cash/Money market funds Corporate debt securities Commercial paper	\$	24,273 	\$	49,777 29,241 2,924	\$	24,273 49,777 29,241 2,924		
Cash/Money market funds Corporate debt securities Commercial paper	\$ \$			49,777 29,241		24,273 49,777 29,241		
Cash/Money market funds Corporate debt securities Commercial paper	\$ \$	24,273 		49,777 29,241 2,924		24,273 49,777 29,241 2,924		Total
Cash/Money market funds Corporate debt securities Commercial paper	\$	24,273 		49,777 29,241 2,924 81,942		24,273 49,777 29,241 2,924 106,215		Total
Cash/Money market funds Corporate debt securities Commercial paper Certificate of deposit	\$	24,273 		49,777 29,241 2,924 81,942		24,273 49,777 29,241 2,924 106,215	\$	Total 900
Cash/Money market funds Corporate debt securities Commercial paper Certificate of deposit Liabilities:	\$	24,273 	\$	49,777 29,241 2,924 81,942 Level 2	\$	24,273 49,777 29,241 2,924 106,215	\$	
Cash/Money market funds Corporate debt securities Commercial paper Certificate of deposit <i>Liabilities:</i> Secured debt	\$	24,273 	\$	49,777 29,241 2,924 81,942 Level 2	\$	24,273 49,777 29,241 2,924 106,215 Level 3	\$	900

The change in the fair value of the Level 3 liability was a decrease of \$0.6 million and \$3.4 million for the three months ended September 30, 2012, and 2011, respectively. The change in fair value for the Level 3 liability was an increase of \$1.9 million and a decrease of \$2.0 million for the nine months ended September 30, 2012 and 2011, respectively.

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### Note 7. Collaborative Agreements

### GSK Collaboration

On October 28, 2010, the Company entered into the Original Collaboration Agreement with Glaxo Group Limited, an affiliate of GSK, to develop and commercialize migalastat HCl. Under the terms of the Original Collaboration Agreement, GSK received an exclusive worldwide license to develop, manufacture and commercialize migalastat HCl. In consideration of the license grant, the Company received an upfront, license payment of \$30 million from GSK and was eligible to receive further payments of approximately \$173.5 million upon the successful achievement of development, regulatory and commercialization milestones, as well as tiered double-digit royalties on global sales of migalastat HCl. GSK and the Company were jointly funding development costs in accordance with an agreed upon development plan. Additionally, GSK purchased approximately 6.9 million shares of the Company's common stock at \$4.56 per share, a 30% premium on the average price per share of the Company's stock over a 60 day period preceding the closing date of the transaction. The total value of this equity investment to the Company was approximately \$31 million.

On July 17, 2012, the Company entered into the Expanded Collaboration Agreement with GSK pursuant to which the Company and GSK will continue to develop and commercialize migalastat HCI, currently in Phase 3 development for the treatment of Fabry disease. The Expanded Collaboration Agreement amends and replaces in its entirety the "Original Collaboration Agreement" for the development and commercialization of migalastat HCl. Under the terms of the Expanded Collaboration Agreement, the Company and GSK will co-develop all formulations of migalastat HCl for Fabry disease, including the development of migalastat HCl co-formulated with an investigational enzyme replacement therapy (ERT) for Fabry disease (the "Co-formulated Product") in collaboration with another GSK collaborator JCR Pharmaceutical Co., Ltd. The Company will commercialize all migalastat HCl products for Fabry disease in the United States while GSK will commercialize all such products in the rest of the world.

The exclusive license granted to GSK under the Original Collaboration Agreement to commercialize migalastat HCl worldwide was replaced under the Expanded Collaboration Agreement, which grants two exclusive licenses: (i) an exclusive license from GSK to the Company to commercialize migalastat HCl in the United States, and (ii) an exclusive license from the Company to GSK to commercialize migalastat HCl in the rest of world. Amicus and GSK each have a license to manufacture migalastat HCl for commercialization of monotherapy and chaperone-ERT co-administration migalastat HCl products while GSK maintains an exclusive license to manufacture such products for development purposes (subject to limited exceptions) and to manufacture the Co-formulated Product. In the event of a change of control in the Company during the term of the Expanded Collaboration Agreement, GSK has the option to purchase an exclusive license to develop, manufacture and commercialize migalastat HCl in the United States.

GSK is eligible to receive U.S. regulatory approval milestones totaling \$20 million for migalastat HCl monotherapy and migalastat HCl-ERT coadministration, and additional regulatory approval and product launch milestone payments totaling up to \$35 million within seven years following the launch of the Co-formulated Product. The Company will also be responsible for certain pass-through milestone payments and single-digit royalties on the net U.S. sales of the Co-formulated Product that GSK must pay to a third party. In addition, the Company is no longer eligible to receive any milestones or royalties it would have been eligible to receive under the Original Collaboration Agreement other than a \$3.5 million clinical development milestone achieved in the second quarter of 2012 and paid by GSK to Amicus in the third quarter of 2012.

The Company and GSK will continue to jointly fund development costs for all formulations of migalastat HCl in accordance with agreed upon development plans pursuant to which the Company and GSK will fund 25% and 75% of such costs, respectively, for the monotherapy and co-administration development of migalastat HCl for the remainder of 2012 and 40% and 60%, respectively, thereafter. Costs for the development of the Co-formulated Product are also split 40% and 60% between Amicus and GSK, respectively.

Additionally, simultaneous with entry into the Expanded Collaboration Agreement, the Company and GSK entered into a the SPA pursuant to which GSK purchased approximately 2.9 million shares of Amicus common stock at a price of \$6.30 per share. The total value of this equity investment to the Company is approximately \$18.6

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million and increases GSK's ownership position in the Company to 19.9%. GSK purchased approximately 6.9 million shares for an aggregate investment of approximately \$31 million in connection with entry into the Original Collaboration Agreement in 2010.

Under the Original Collaboration Agreement, the upfront license fee, together with the premium received on the stock purchase, was being recognized as Collaboration Revenue over the original development period. In addition, the Company was receiving reimbursements of research expenditures under the cost sharing arrangement which was being accounted for as research revenue on the statement of operations. Under the Expanded Collaboration Agreement, the Company will continue to receive research expense reimbursements for the development of migalastat HCl but may be required to pay contingent milestones to GSK in the future related to the US commercial rights to migalastat HCl.

In accordance with the revenue recognition guidance related to multiple-element arrangements, the Company identified all of the deliverables at the inception of the Expanded Collaboration Agreement. The significant deliverables were determined to be the rest of world licensing rights to migalastat HCl, the research services to continue and complete the development of migalastat HCl and the delivery of the Company's common stock. The Company determined that the rest of world licensing rights and the research services represent one unit of accounting as none of these deliverables on its own has standalone value separate from the other. The Company also determined that the delivery of the Company's common stock does have standalone value separate from the rest of world licensing rights and the research services. As a result, the Company's common stock was considered a separate unit of accounting and was accounted for as an issuance of common stock. However, as the Company's common stock was sold at a premium to the market closing price, the premium amount paid over the market closing price was determined to be additional consideration paid to the Company for the collaboration agreement and was included as consideration for the single unit of accounting (rest of world licensing rights and research services) identified above.

In evaluating the impact of the Expanded Collaboration Agreement, the Company applied the accounting guidance regarding the impact of potential future payments it may make in its role as a vendor (Amicus) to its customer (GSK) and evaluated if these potential future payments could be a reduction of revenue from GSK. If the potential future payments to GSK are:

- · A payment for an identifiable benefit, and
- The identifiable benefit is separable from the existing relationship between the Company and GSK, and
- The identifiable benefit can be obtained from a party other than GSK, and
- The Company can reasonably estimate the fair value of the identifiable benefit,

then the potential future payments would be treated separately from the collaboration and research revenue. However, if all these criteria are not satisfied, then the potential future payments are treated as a reduction of revenue.

Accordingly, the Company does not believe that, for accounting purposes, the new US licensing rights to migalastat HCl obtained from GSK represent a separate, identifiable benefit from the licenses in the Original Collaboration Agreement. The contingent amounts payable to GSK are not sufficiently separable from GSK's original license and the research and development reimbursements such that Amicus could not have entered into a similar exchange transaction with another party. Additionally, the Company cannot reasonably estimate the fair value of the US licensing rights to migalastat HCl.

The Company determined that the potential future payments to GSK would be treated as a reduction of revenue and that the total amount of revenue to be received under the arrangement is no longer fixed or determinable as the contingent milestone payments are subject to significant uncertainty.

As a result, the Company will no longer recognize any of the upfront license fee and premium on the equity purchase from GSK until such time the arrangement consideration becomes fixed or determinable, because an indeterminable amount may ultimately be payable back to GSK. These amounts (the balance of the unrecognized upfront license fee and the premium on the equity purchases) will be classified as deferred reimbursements on the balance sheet.

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The recognition of Research Revenue is also affected by the determination that the overall total arrangement consideration is no longer fixed and determinable, despite the fact that the research activities will continue and that the research expense reimbursements by GSK to Amicus will be received as the research activities related to the reimbursement would have already been completed. Therefore any research reimbursements from GSK will be recorded as deferred reimbursements on the balance sheet and not recognized until the total arrangement consideration becomes fixed and determinable.

As a result, all revenue recognition was suspended until the total arrangement consideration becomes fixed and determinable. In addition, future milestone payments made by the Company will be applied against the balance of this deferred reimbursements account. Revenue recognition for research expense reimbursements, the original upfront, and the equity premiums will resume once the total arrangement consideration becomes fixed and determinable which will occur when the balance of the deferred reimbursements account is sufficient to cover all the remaining contingent milestone payments.

Under the Original Collaboration Agreement, the Company evaluated the contingent milestones and determined that they were substantive milestones and would be recognized these as revenue in the period that the milestone is achieved. The Company determined that the research based milestones were commensurate with the enhanced value of each delivered item as a result of the Company's specific performance to achieve the milestones. The research based milestones would have related to past performances when achieved and were reasonable relative to the other payment terms within the Original Collaboration Agreement. In June 2012, the Company achieved a clinical development milestone and recognized \$3.5 million of milestone revenue. Under the terms of the Expanded Collaboration Agreement, the Company is no longer entitled to receive any milestone payments from GSK.

In December 2009, the Company initiated and completed a facilities consolidation effort, closing one of its subleased locations in Cranbury, NJ. The Company recorded a charge of \$0.7 million during the fourth quarter of 2009 for minimum lease payments of \$0.5 million and the write-down of fixed assets in the facility.

The following table summarizes the restructuring charges and utilization for the nine months ended September 30, 2012 (in thousands):

	Balance as of ccember 31, 2011	Charges	Cash Payments	Adjustments	Balance as of September 30, 2012
Facilities consolidation	\$ 38		\$ (3	8)	\$

#### Note 9. Subsequent Events

The Company evaluated events that occurred subsequent to September 30, 2012 through the date of issuance of these financial statements and there were no material recognized or non-recognized events during this period.

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

## Overview

Amicus Therapeutics, Inc. (Amicus) is a biopharmaceutical company focused on the discovery, development and commercialization of orallyadministered, small molecule drugs known as pharmacological chaperones, a novel, first-in-class approach to treating a broad range of diseases including lysosomal storage diseases and diseases of neurodegeneration. We believe that our pharmacological chaperone technology, our advanced product pipeline, especially our lead product candidate, migalastat HCl, and our strategic collaboration with GSK uniquely position us as a leader in the development of treatments for rare and orphan diseases.

We are focused on the development of pharmacological chaperone monotherapy programs and pharmacological chaperones in combination with enzyme replacement therapy (ERT), the current standard of treatment for Fabry and other lysosomal storage disease. In 2012, we are advancing two pharmacological chaperone monotherapy programs for genetic diseases:

- Migalastat HCl for patients with Fabry disease identified as having alpha-galactosidase A (alpha-Gal A) mutations amenable to chaperone therapy, and
- AT3375 for Parkinson's disease in Gaucher disease carriers and potentially the broader Parkinson's population.

Our pharmacological chaperone-ERT combination programs for 2012 include:

- · Migalastat HCl co-administered with ERT for patients with Fabry disease receiving ERT treatment with any genetic mutation,
- · Migalasat HCl co-formulated with a proprietary preclinical ERT,
- · AT2220 (duvoglustat HCl) co-administered with ERT for Pompe disease,
- · AT3375 and afegostat tartrate co-administered with ERT for Gaucher disease, and
- Several new, undisclosed pharmacological chaperone programs focused on the combination of chaperones with ERTs for additional lysosomal storage diseases.

Our novel approach to the treatment of human genetic diseases consists of using pharmacological chaperones that selectively bind to the target protein, increasing the stability of the protein and helping it fold into the correct three-dimensional shape. This allows proper trafficking of the protein within the cell, thereby increasing protein activity, improving cellular function and potentially reducing cell stress. We have also demonstrated in preclinical studies that pharmacological chaperones can further stabilize normal, or "wild-type" proteins. This stabilization could lead to a higher percentage of the target proteins folding correctly and more stably, which can increase cellular levels of that target protein and improve cellular function, making chaperones potentially applicable to a wide range of diseases.

Our lead product candidate, migalastat HCl for Fabry disease, is in late Phase 3 development. We are developing and commercializing migalastat HCl with an affiliate of GSK pursuant to the Expanded Collaboration Agreement entered into in July 2012. Our partnership with GSK allows us to utilize GSK's significant expertise in clinical, regulatory, commercial and manufacturing matters in the development in migalastat HCl. In addition, the cost-sharing arrangements under the Expanded Collaboration Agreement provide us with financial strength and allow us to continue the development of migalastat HCl while also advancing our other programs. We also believe this collaboration is important in validating our status as a leader in the development of treatments for rare diseases given the increasing focus placed on the rare disease field.

Our Phase 3 clinical development program for the use of migalastat HCl as monotherapy in Fabry disease includes two global registration studies for patients with Fabry disease identified as having alpha-Gal A mutations amenable to migalastat HCl: Study 011 and Study 012. We completed enrollment of 67 total patients in Study 011, our placebo-controlled Phase 3 study, in December 2011 and expect results in the fourth quarter of 2012. We

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plan to use the data from Study 011 to support marketing applications for the U.S. Food and Drug Administration (FDA) and other regulatory agencies. Study 012 is our second phase 3 study for migalastat HCl intended to support the worldwide registration of migalastat HCl for Fabry disease. We dosed the first patient in Study 012 in September 2011 to compare the safety and efficacy of migalastat HCl and ERT (agalsidase beta or agalsidase alfa) and achieved target enrollment in October 2012 ahead of schedule.

In addition to potential benefits pharmacological chaperones may provide as a monotherapy, we also believe the use of pharmacological chaperones coadministered and co-formulated with ERT may address certain key limitations of ERT. The use of pharmacological chaperones coadministered with ERT may address certain key limitations of ERT. The use of pharmacological chaperones coadministered with ERT may significantly enhance the safety and efficacy of ERT by, among other effects, prolonging the half-life of infused enzymes in the circulation, increasing uptake of the active enzymes into cells and tissues, and increasing enzyme activity and substrate reduction in target tissues compared to that observed with ERT alone. We are evaluating the use of pharmacological chaperones co-administered with ERT in two Phase 2 clinical studies: one study evaluating the use of migalastat HCl co-administered with ERT for Fabry disease (Study 013) and another study evaluating the use of AT2220 co-administered with ERT for Pompe disease (Study 010).

We are also conducting preclinical studies with JCR Pharmaceutical Co., Ltd (JCR) evaluating migalastat HCl co-formulated with a proprietary recombinant human alpha-Gal A enzyme (JR-051). Preclinical studies conducted by Amicus, GSK and JCR suggest that this co-formulated chaperone-ERT product may provide greater alpha-Gal A enzyme uptake into tissue and markedly reduced levels of GL-3 in Fabry disease-relevant tissues compared to recombinant enzyme alone. Amicus and GSK believe that this co-formulated chaperone-ERT product for Fabry disease has the potential to enter clinical studies in 2013.

Amicus is also investigating chaperone-ERT combinations as potential next-generation treatments for Gaucher and other undisclosed lysosomal storage diseases where there are significant opportunities to improve treatment outcomes. In Gaucher disease, Amicus is continuing preclinical studies to evaluate two pharmacological chaperones, AT2101 (afegostat tartrate) and AT3375, in combination with ERT (beta-glucosidase). Both of these chaperones target the enzyme deficient in Gaucher disease.

Gaucher disease is caused by inherited genetic mutations in the GBA gene, and mutations in this gene that encodes for the GCase enzyme are the most common genetic risk factor for Parkinson's. By targeting GCase in the brain, AT3375 could potentially treat Gaucher, Parkinson's disease in Gaucher carriers, and possibly the general Parkinson's population.

We have generated significant losses to date and expect to continue to generate losses as we continue the clinical development of our drug candidates, including migalastat HCl, and conduct preclinical studies on other programs. These activities are budgeted to expand over time and will require further resources if we are to be successful. From our inception in February 2002 through September 30, 2012, we have accumulated a deficit of \$308.9 million. As we have not yet generated commercial sales revenue from any of our product candidates, our losses will continue and are likely to be substantial in the near term.

### **Program Status**

## Migalastat HCl for Fabry Disease: Phase 3 Global Registration Program

We and our partner GSK are conducting two Phase 3 global registration studies (Study 011 and Study 012) to support the global approval of migalastat HCl monotherapy for the treatment of Fabry disease. Study 011 and Study 012 are investigating migalastat HCl at an oral dose of 150 mg, administered every-other-day (QOD) to Fabry patients identified as having alpha-Gal A mutations amenable to migalastat HCl as a monotherapy. Study 011 is a randomized, placebo-controlled Phase 3 study of migalastat HCl that completed enrollment of 67 patients with Fabry disease. Results from this study are anticipated in the fourth quarter of 2012 to support subsequent marketing applications for the FDA and other regulatory agencies. We will lead all U.S. commercial activities for migalastat HCl upon approval, including pricing, marketing, patient access and reimbursement.

Study 012 is a randomized, open-label, 18-month Phase 3 study investigating the safety and efficacy of migalastat HCI compared to current standard-of-care ERTs Fabrazyme (agalsidase beta) or Replagal (agalsidase

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alfa) for Fabry disease. In October 2012, we announced that target enrollment had been achieved in Study 012.

Phase 2 and Phase 3 extension studies continue to evaluate long-term safety with migalastat HCl monotherapy in Fabry patients. As of September 30, 2012, all but one patient who has completed the six-month treatment and six-month follow-up periods in Study 011 is currently enrolled in a Phase 3 extension study. An additional 16 subjects continue in the ongoing Phase 2 extension study and have been receiving migalastat HCl for up to six years.

Pharmacological Chaperone-ERT (PC-ERT) Co-Administration for Lysosomal Storage Diseases

## Fabry Disease

Study 013 is an ongoing open-label Phase 2 study to investigate a single oral dose of migalastat HCl (150 mg or 450 mg) co-administered prior to ERT (Fabrazyme or Replagal) in males diagnosed with Fabry disease. Amicus completed enrollment in Study 013 in the third quarter 2012. When co-administered with ERT, migalastat HCl is designed to bind to and stabilize the enzyme in the circulation, independent of alpha-Gal A mutation type.

Positive preliminary results from Study 013 were announced in the first quarter 2012 in patients who received migalastat HCl 150 mg coadministered with Fabrazyme (0.5 mg/kg or 1.0 mg/kg) and updated results will be presented at a scientific conference in November 2012. Amicus and GSK, along with GSK's collaborator JCR, also continue to advance preclinical studies of migalastat HCl co-formulated with JCR's proprietary investigational ERT (JR-051, recombinant human alpha-Gal A enzyme).

# Pompe Disease

Amicus is investigating four ascending doses of AT2220 co-administered with the ERT alglucosidase alfa in a Phase 2 open-label study (Study 010) for Pompe disease. Approximately 24 patients will receive one infusion of ERT alone, and a single oral dose of AT2220 prior to the next ERT infusion. In addition to safety and pharmacokinetic effects, Study 010 will measure uptake of active enzyme in muscle tissue with and without the chaperone, three or seven days following each infusion.

Positive preliminary results from Study 010 were announced in 2012 in patients enrolled in the first three cohorts of the study at the lowest dose groups of AT2220. We have fully enrolled the fourth cohort and anticipate results during the fourth quarter 2012. Previous preclinical studies using acid alpha-glucosidase (GAA) knock-out mouse models of Pompe disease demonstrated that AT2220 co-administered with ERT increased the ERT uptake in key tissues of disease, including skeletal muscle and heart. This increased ERT uptake into muscle following AT2220-ERT co-administration corresponded in preclinical studies with greater reductions in muscle glycogen compared to ERT alone. Glycogen is the substrate that accumulates in the lysosomes of muscles in patients with Pompe disease.

In parallel with Study 010, Amicus is evaluating ERT-related immunogenicity in Pompe disease. Initial ex vivo studies were completed using T cells from 50 healthy donor blood samples and demonstrated that the addition of AT2220 may reduce the immunogenicity of Myozyme and Lumizyme. Results from these studies may help guide further investigation of the effects of AT2220 or immune response to ERT in future clinical studies.

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Gaucher Disease and Other Lysosomal Storage Diseases

We are also investigating chaperone-ERT combinations as potential next-generation treatments for Gaucher and other undisclosed lysosomal storage diseases where we believe there are significant opportunities to improve treatment outcomes. In Gaucher disease, we are continuing preclinical studies to evaluate two pharmacological chaperones, AT2101 (afegostat tartrate) and AT3375, in combination with ERT (beta-glucosidase). Both of these chaperones target the enzyme deficient in Gaucher disease.

## GSK and Other Potential Alliances and Collaborations

As discussed, we are co-developing migalastat HCl with GSK pursuant to the Expanded Collaboration Agreement. In addition we continually evaluate other potential collaborations and business development opportunities that would bolster our ability to develop therapies for rare and orphan diseases including licensing agreements and acquisitions of businesses and assets. We believe such opportunities may be important to the advancement of our current product candidate pipeline, the expansion of the development of our current technology, gaining access to new technologies and in our transformation from a development stage company to a commercial biotechnology company.

#### **Financial Operations Overview**

#### Revenue

On July 17, 2012, we entered into the Expanded Collaboration Agreement with GSK pursuant to which we will continue to co-develop and commercialize with GSK, migalastat HCl, currently in Phase 3 development for the treatment of Fabry disease and we will commercialize all migalastat HCl products in the United States while GSK will commercialize all such products in the rest of the world. Due to a change in the accounting for revenue recognition for the Expanded Collaboration Agreement, all revenue recognition will be suspended until the total arrangement consideration becomes fixed and determinable. Any payments received from GSK will be recorded as deferred reimbursements on the balance sheet. In addition, future milestone payments we may pay GSK will be applied against the balance of this deferred reimbursements account. Revenue recognition would resume once the total arrangement consideration becomes fixed and determinable which would occur when the balance of the deferred reimbursements account is sufficient to cover all the remaining contingent milestone payments. As a result, for the three months ended September 30, 2012, we did not recognize any revenue related to Collaboration and Milestone Revenue or Research Revenue. For the three months ended September 30, 2011, we recorded \$1.7 million and \$4.1 million of Collaboration and Milestone Revenue and Research Revenue, respectively. There is no cash effect of this change in accounting, and there is no scenario where Amicus would have to refund any of the upfront payment, milestone payments, or research reimbursement payments.

In the Original Collaboration Agreement, GSK paid us an initial, non-refundable license fee of \$30 million and a premium of \$3.2 million related to GSK's purchase of an equity investment in Amicus which was being recognized as Collaboration Revenue on a straight-line basis over the development period. For the nine months ended September 30, 2012 and 2011, we recognized \$6.8 million and \$5.0 million, respectively, as Collaboration and Milestone Revenue. For the nine months ended September 30, 2012 and 2011, we recognized \$11.6 million and \$10.8 million, respectively, as Research Revenue.

#### **Research and Development Expenses**

We expect to continue to incur substantial research and development expenses as we continue to develop our product candidates and explore new uses for our pharmacological chaperone technology. However, we will share future research and development costs related to migalastat HCl with GSK in accordance with the Expanded Collaboration Agreement. Research and development expense consists of:

- · internal costs associated with our research and clinical development activities;
- payments we make to third party contract research organizations, contract manufacturers, investigative sites, and consultants;

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- technology license costs;
- manufacturing development costs;
- · personnel related expenses, including salaries, benefits, travel, and related costs for the personnel involved in drug discovery and development;
- activities relating to regulatory filings and the advancement of our product candidates through preclinical studies and clinical trials; and
- facilities and other allocated expenses, which include direct and allocated expenses for rent, facility maintenance, as well as laboratory and other supplies.

We have multiple research and development projects ongoing at any one time. We utilize our internal resources, employees and infrastructure across multiple projects. We record and maintain information regarding external, out-of-pocket research and development expenses on a project specific basis.

We expense research and development costs as incurred, including payments made to date under our license agreements. We believe that significant investment in product development is a competitive necessity and plan to continue these investments in order to realize the potential of our product candidates. From our inception in February 2002 through September 30, 2012, we have incurred research and development expense in the aggregate of \$304.8 million.

The following table summarizes our principal product development programs, including the related stages of development for each product candidate in development, and the out-of-pocket, third party expenses incurred with respect to each product candidate (in thousands).

Projects	 Three Mor Septem 2011	 	 Nine Mont Septem 2011		F (ir	eriod from ebruary 4, 2002 ception) to otember 30, 2012
Third party direct project expenses						
Migalastat HCl (Fabry Disease — Phase 3)	\$ 5,385	\$ 2,658	\$ 13,613	\$ 12,927	\$	78,262
Afegostat tartrate (Gaucher Disease — Phase 2*)	15	36	(186)	78		26,193
AT2220 (Pompe Disease — Phase 2)	53	5	98	5		13,248
Neurodegenerative Diseases (Preclinical)	745	(27)	1,694	314		8,922
Combination studies (Fabry & Pompe - Phase 2; Gaucher -						
Preclinical) (3)	717	1,078	886	3,267		6,217
Total third party direct project expenses	6,915	 3,750	 16,105	 16,591		132,842
Other project costs (1)						
Personnel costs	4,715	5,439	14,439	16,084		109,335
Other costs (2)	2,081	2,310	5,911	6,551		62,669
Total other project costs	 6,796	 7,749	 20,350	 22,635		172,004
	· · · · ·	 <u> </u>	 	 ·		
Total research and development costs	\$ 13,711	\$ 11,499	\$ 36,455	\$ 39,226	\$	304,846

(1) Other project costs are leveraged across multiple projects.

(2) Other costs include facility, supply, overhead, and licensing costs that support multiple clinical and preclinical projects.

(3) Combination studies include co-administration and co-formulation.

\* We do not plan to advance afegostat tartrate into Phase 3 development at this time.

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of our product candidates. As a result, we are not able to reasonably estimate the period, if any, in which material net cash inflows may commence from our product candidates, including migalastat HCl or any of

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our other preclinical product candidates. This uncertainty is due to the numerous risks and uncertainties associated with the conduct, duration and cost of clinical trials, which vary significantly over the life of a project as a result of evolving events during clinical development, including:

- · the number of clinical sites included in the trials;
- the length of time required to enroll suitable patients;
- the number of patients that ultimately participate in the trials;
- · the results of our clinical trials; and
- · any mandate by the FDA or other regulatory authority to conduct clinical trials beyond those currently anticipated.

Our expenditures are subject to additional uncertainties, including the terms and timing of regulatory approvals, and the expense of filing, prosecuting, defending and enforcing any patent claims or other intellectual property rights. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. In addition, GSK has considerable influence over and decision-making authority related to our migalastat HCl program. A change in the outcome of any of the foregoing variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development, regulatory approval and commercialization of that product candidate. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those which we currently anticipate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development. Drug development may take several years and millions of dollars in development costs.

## General and Administrative Expense

General and administrative expense consists primarily of salaries and other related costs, including stock-based compensation expense, for persons serving in our executive, finance, accounting, legal, information technology and human resource functions. Other general and administrative expense includes facility-related costs not otherwise included in research and development expense, promotional expenses, costs associated with industry and trade shows, and professional fees for legal services, including patent-related expense and accounting services. From our inception in February 2002 through September 30, 2012, we spent \$128.2 million on general and administrative expense.

## Interest Income and Interest Expense

Interest income consists of interest earned on our cash and cash equivalents and marketable securities. Interest expense consists of interest incurred on our equipment financing agreement.

## **Critical Accounting Policies and Significant Judgments and Estimates**

The discussion and analysis of our financial condition and results of operations are based on our financial statements, which we have prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments, including those described in greater detail below. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While there were no significant changes during the quarter ended September 30, 2012 to the items that we disclosed as our significant accounting policies and estimates described in Note 2 to the Company's financial statements as contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2011, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our financial condition and results of operations.

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#### **Revenue Recognition**

We recognize revenue when amounts are realized or realizable and earned. Revenue is considered realizable and earned when the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the price is fixed or determinable; and (4) collection of the amounts due are reasonably assured.

In multiple element arrangements, revenue is allocated to each separate unit of accounting and each deliverable in an arrangement is evaluated to determine whether it represents separate units of accounting. A deliverable constitutes a separate unit of accounting when it has standalone value and there is no general right of return for the delivered elements. In instances when the aforementioned criteria are not met, the deliverable is combined with the undelivered elements and the allocation of the arrangement consideration and revenue recognition is determined for the combined unit as a single unit of accounting. Allocation of the consideration is determined at arrangement inception on the basis of each unit's relative selling price. In instances where there is determined to be a single unit of accounting, the total consideration is applied as revenue for the single unit of accounting and is recognized over the period of inception through the date where the last deliverable within the single unit of accounting is expected to be delivered.

Our current revenue recognition policies, which were applied in fiscal 2010, provide that, when a collaboration arrangement contains multiple deliverables, such as license and research and development services, we allocate revenue to each separate unit of accounting based on a selling price hierarchy. The selling price hierarchy for a deliverable is based on (i) its vendor specific objective evidence (VSOE) if available, (ii) third party evidence (TPE) if VSOE is not available, or (iii) estimated selling price (BESP) if neither VSOE nor TPE is available. We would establish the VSOE of selling price using the price charged for a deliverable when sold separately. The TPE of selling price would be established by evaluating largely similar and interchangeable competitor products or services in standalone sales to similarly situated customers. The best estimate of selling price would be established considering internal factors such as an internal pricing analysis or an income approach using a discounted cash flow model.

We also consider the impact of potential future payments we make in our role as a vendor to our customers and evaluate if these potential future payments could be a reduction of revenue from that customer. If the potential future payments to the customer are:

- · A payment for an identifiable benefit, and
- · The identifiable benefit is separable from the existing relationship between us and our customer, and
- · The identifiable benefit can be obtained from a party other than the customer, and
- We can reasonably estimate the fair value of the identifiable benefit,

then the payments are accounted for separately from the revenue received from that customer. If, however, all these criteria are not satisfied, then the payments are treated as a reduction of revenue from that customer.

If we determine that any potential future payments to our customers are to be considered as a reduction of revenue, we must evaluate if the total amount of revenue to be received under the arrangement is fixed and determinable. If the total amount of revenue is not fixed and determinable due to the uncertain nature of the potential future payments to the customer, then any customer payments cannot be recognized as revenue until the total arrangement consideration becomes fixed and determinable.

The reimbursements for research and development costs under collaboration agreements that meet the criteria for revenue recognition are included in Research Revenue and the costs associated with these reimbursable amounts are included in research and development expenses.

In order to determine the revenue recognition for contingent milestones, we evaluate the contingent milestones using the criteria as provided by the FASB guidance on the milestone method of revenue recognition at the inception of a collaboration agreement. The criteria requires that (i) we determine if the milestone is commensurate with either our performance to achieve the milestone or the enhancement of value resulting from our activities to achieve

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the milestone, (ii) the milestone be related to past performance, and (iii) the milestone be reasonable relative to all deliverable and payment terms of the collaboration arrangement. If these criteria are met then the contingent milestones can be considered as substantive milestones and will be recognized as revenue in the period that the milestone is achieved.

When we are required to estimate accrued expenses because we have not yet been invoiced or otherwise notified of actual cost, we identify services that have been performed on our behalf and estimate the level of service performed and the associated cost incurred. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us. Examples of estimated accrued expenses include:

- · fees owed to contract research organizations in connection with preclinical and toxicology studies and clinical trials;
- · fees owed to investigative sites in connection with clinical trials;
- · fees owed to contract manufacturers in connection with the production of clinical trial materials;
- · fees owed for professional services, and
- $\cdot$   $\;$  unpaid salaries, wages and benefits.

### **Stock-Based Compensation**

We apply the fair value method of measuring stock-based compensation, which requires a public entity to measure the cost of employee services received in exchange for an award of equity instruments based upon the grant-date fair value of the award. We chose the "straight-line" attribution method for allocating compensation costs and recognized the fair value of each stock option on a straight-line basis over the vesting period of the related awards.

We use the Black-Scholes option pricing model when estimating the value for stock-based awards. Use of a valuation model requires management to make certain assumptions with respect to selected model inputs. Expected volatility was calculated based on a blended weighted average of historical information of our stock and the weighted average of historical information of similar public entities for which historical information was available. We will continue to use a blended weighted average approach using our own historical volatility and other similar public entity volatility information until our historical volatility is relevant to measure expected volatility for future option grants. The average expected life was determined using a "simplified" method of estimating the expected exercise term which is the mid-point between the vesting date and the end of the contractual term. As our stock price volatility has been over 75% and we have experienced significant business transactions (Shire and GSK collaborations), we believe that we do not have sufficient reliable exercise data in order to justify a change in the use of the "simplified" method of estimating the expected exercise term of employee stock option grants. The risk-free interest rate is based on U.S. Treasury, zero-coupon issues with a remaining term equal to the expected life assumed at the date of grant. Forfeitures are estimated based on voluntary termination behavior, as well as a historical analysis of actual option forfeitures. The weighted average assumptions used in the Black-Scholes option pricing model are as follows:

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2011		2012	2011		2012		
Expected stock price volatility	78.4%		76.2%		78.8%		77.5%	
Risk free interest rate	1.3%		0.9%		2.0%		0.8%	
Expected life of options (years)	6.25		6.25	(	6.25		6.25	
Expected annual dividend per share	\$ 0.00	\$	0.00	\$ (	0.00	\$	0.00	
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#### Warrants

The warrants issued in connection with the March 2010 registered direct offering are classified as a liability. The fair value of the warrants liability is evaluated at each balance sheet date using the Black-Scholes valuation model. This model uses inputs such as the underlying price of the shares issued when the warrant is exercised, volatility, risk free interest rate and expected life of the instrument. Any changes in the fair value of the warrants liability is recognized in the consolidated statement of operations. The weighted average assumptions used in the Black-Scholes valuation model for the warrants December 31, 2011 and September 30, 2012 are as follows:

	December 31,	2011	September 30, 2012
Expected stock price volatility		67.3%	76.0%
Risk free interest rate		0.28%	0.19%
Expected life of warrants (years)		2.17	1.42
Expected annual dividend per share	\$	0.00	\$ 0.00

#### Basic and Diluted Net Loss Attributable to Common Stockholders per Common Share

We calculated net loss per share as a measurement of the Company's performance while giving effect to all dilutive potential common shares that were outstanding during the reporting period. We had a net loss for all periods presented; accordingly, the inclusion of common stock options and warrants would be anti-dilutive. Therefore, the weighted average shares used to calculate both basic and diluted earnings per share are the same.

The following table provides a reconciliation of the numerator and denominator used in computing basic and diluted net loss attributable to common stockholders per common share and pro forma net loss attributable to common stockholders per common share:

<u>(In thousands, except per share amount)</u> Historical	 Three Mor Septem 2011	 led 2012	 Nine Mon Septem 2011	 
Numerator: Net loss attributable to common stockholders	\$ (9,759)	\$ (16,290)	\$ (35,750)	\$ (38,770)
Denominator: Weighted average common shares outstanding - basic and diluted	 34,979,702	 48,513,647	 34,544,768	 44,255,885

Dilutive common stock equivalents would include the dilutive effect of common stock options and warrants for common stock equivalents. Potentially dilutive common stock equivalents totaled approximately 8.5 million and 10.4 million for the nine months ended September 30, 2011 and 2012, respectively. Potentially dilutive common stock equivalents were excluded from the diluted earnings per share denominator for all periods because of their anti-dilutive effect.

#### **Results of Operations**

# Three Months Ended September 30, 2012 Compared to Three Months Ended September 30, 2011

*Revenue*. On July 17, 2012, we entered into the Expanded Collaboration Agreement with GSK pursuant to which we will continue to co-develop and commercialize with GSK, migalastat HCl, currently in Phase 3 development for the treatment of Fabry disease and we will commercialize all migalastat HCl products in the United States while GSK will commercialize all such products in the rest of the world. Due to the accounting conclusion for revenue recognition as a result of the Expanded Collaboration Agreement, all revenue recognition will be suspended until the total arrangement consideration becomes fixed and determinable. Any payments received from

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GSK including the future research and development reimbursements and the unamortized upfront payments from the Original Collaboration Agreement, will be recorded as deferred reimbursements on the balance sheet. In addition, future milestone payments we may pay GSK will be applied against the balance of this deferred reimbursements account. Revenue recognition would resume once the total arrangement consideration becomes fixed and determinable which would occur when the balance of the deferred reimbursements account is sufficient to cover all the remaining contingent milestone payments. As a result, for the three months ended September 30, 2012, we did not recognize any revenue related to Collaboration and Milestone Revenue or Research Revenue. For the three months ended September 30, 2011, we recorded \$1.7 million and \$4.1 million of Collaboration and Milestone Revenue and Research Revenue, respectively. There is no cash effect of this change in accounting, and there is no scenario where Amicus would have to refund any of the upfront payment, milestone payments, or research reimbursement payments.

Prior to the Expanded Collaboration Agreement, the upfront license fee was being recognized as Collaboration Revenue on a straight-line basis over the development period. For the nine months ended September 30, 2012 and 2011, we recognized \$6.8 million and \$5.0 million, respectively, as Collaboration and Milestone Revenue. For the nine months ended September 30, 2012 and 2011, we recognized \$11.6 million and \$10.8 million, respectively, as Research Revenue.

*Research and Development Expense.* Research and development expense was \$11.5 million for the three months ended September 30, 2012, representing a decrease of \$2.2 million or 16% from \$13.7 million for the three months ended September 30, 2011. The variance was primarily attributable to decrease in contract research and manufacturing costs due to the decreased costs within the Fabry program.

*General and Administrative Expense*. General and administrative expense was \$5.0 million for the three months ended September 30, 2012, representing an increase of \$0.2 million or 4% from \$4.8 million for the three months ended September 30, 2011. The increase is primarily related to increase in legal and other consultancy fees.

*Interest Income and Interest Expense*. Interest income was \$0.09 million for the three months ended September 30, 2012, representing an increase of \$0.06 million or 200% from \$0.03 million for the three months ended September 30, 2011. The increase was due to overall higher average cash and investment balances, resulting from the sale of 2.9 million shares of common stock to GSK in July 2012 and the \$3.5 million milestone payment received in August 2012. Interest expense was approximately \$0.02 million for the three months ended September 30, 2012 compared to \$0.03 for the three months ended September 30, 2011. The decrease was due to less outstanding debt during the period on the secured loan.

*Change in Fair Value of Warrant Liability.* In connection with the sale of our common stock and warrants from the registered direct offering in March 2010, we recorded the warrants as a liability at their fair value using a Black-Scholes model and remeasure the fair value at each reporting date until exercised or expired. Changes in the fair value of the warrants are reported in the statements of operations as non-operating income or expense. For the three months ended September 30, 2012, we reported a gain of \$0.6 million related to the decrease in fair value of these warrants as compared to a gain of \$3.4 million for the three months ended September 30, 2011, representing a decrease of \$2.8 million or 82%. The decrease was due to the fluctuations in the price of our common stock.

## **Results of Operations**

## Nine Months Ended September 30, 2012 Compared to Nine Months Ended September 30, 2011

*Revenue.* Prior to the Expanded Collaboration Agreement the upfront license fee was being recognized as Collaboration Revenue on a straight-line basis over the development period. For the nine months ended September 30, 2012 and 2011, we recognized \$6.8 million and \$5.0 million, respectively, as Collaboration and Milestone Revenue. For the nine months ended September 30, 2012 and 2011, we recognized \$11.6 million and \$10.8 million, respectively, as Research Revenue.

*Research and Development Expense.* Research and development expense was \$39.2 million for the nine months ended September 30, 2012, representing an increase of \$2.7 million or 7% from \$36.5 million for the nine months ended September 30, 2011. The variance was primarily attributable to higher personnel costs, an increase in license

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*General and Administrative Expense*. General and administrative expense was \$14.9 million for the nine months ended September 30, 2012, representing a decrease of \$1.1 million or 7% from \$16.0 million for the nine months ended September 30, 2011. The decrease was primarily due to additional stock option compensation expense recognized in 2011 partially offset by an increase in personnel costs associated with a severance charge of \$0.2 million in 2012.

*Interest Income and Interest Expense.* Interest income was \$0.2 million for the nine months ended September 30, 2012, compared to \$0.1 million for the nine months ended September 30, 2011. The increase is due to higher cash and investment balance. Interest expense was approximately \$0.08 million for the nine months ended September 30, 2012 compared to \$0.1 million for the nine months ended September 30, 2011. The decrease was due to less outstanding debt during the period on the secured loan.

*Change in Fair Value of Warrant Liability.* In connection with the sale of our common stock and warrants from the registered direct offering in March 2010, we recorded the warrants as a liability at their fair value using a Black-Scholes model and remeasure the fair value at each reporting date until exercised or expired. Changes in the fair value of the warrants are reported in the statements of operations as non-operating income or expense. For the nine months ended September 30, 2012, we reported an expense of \$1.9 million related to the increase in fair value of these warrants as compared to a gain of \$2.0 million for the nine months ended September 30, 2011, representing an increase in expense of \$3.9 million or 195%. The increase was due to the fluctuations in the price of our common stock.

*Other Income/Expense.* Other income for the nine months ended September 30, 2012 was \$0.02 million and represents cash received from the sale of property, plant and equipment. Other income for the nine months ended September 30, 2011 was \$0.07 million under the Qualified Therapeutic Discovery Projects tax credit and grant program.

## Liquidity and Capital Resources

## Source of Liquidity

As a result of our significant research and development expenditures and the lack of any approved products to generate product sales revenue, we have not been profitable and have generated operating losses since we were incorporated in 2002. We have funded our operations principally with \$148.7 million of proceeds from redeemable convertible preferred stock offerings, \$75.0 million of gross proceeds from our IPO in June 2007, \$18.5 million of gross proceeds from our Registered Direct Offering in March 2010, \$65.6 million of gross proceeds from our stock offering in March 2012, \$49.9 from GSK's investments in the Company in October 2010 and July 2012, and \$80.0 million from non-refundable license fees from collaborations. In the future, we expect to fund our operations, in part, through the receipt of cost-sharing from GSK.

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The following table summarizes our significant funding sources as of September 30, 2012:

Funding	Year	No. Shares	Approximate Amount (1) (in thousands)
Series A Redeemable Convertible Preferred Stock	2002	444,443	\$ 2,500
Series B Redeemable Convertible Preferred Stock	2004, 2005, 2006, 2007	4,917,853	31,189
Series C Redeemable Convertible Preferred Stock	2005, 2006	5,820,020	54,999
Series D Redeemable Convertible Preferred Stock	2006, 2007	4,930,405	60,000
Common Stock	2007	5,000,000	75,000
Upfront License Fee from Shire	2007	—	50,000
Registered Direct Offering	2010	4,946,524	18,500
Upfront License Fee from GSK	2010	—	30,000
Common Stock GSK	2010	6,866,245	31,285
Common Stock	2012	11,500,000	65,550
Common Stock GSK	2012	2,949,581	18,582
		47,375,071	\$ 437,605

#### (1) Represents gross proceeds

In addition, in conjunction with the GSK collaboration, we received reimbursement of research and development expenditures from the date of the agreement (October 28, 2010) through September 30, 2012 of \$20.1 million. We also received \$31.1 million in reimbursement of research and development expenditures from the Shire collaboration from the date of the agreement (November 7, 2007) through year-end 2009.

As of September 30, 2012, we had cash, cash equivalents and marketable securities of \$106.2 million. We invest cash in excess of our immediate requirements with regard to liquidity and capital preservation in a variety of interest-bearing instruments, including obligations of U.S. government agencies and money market accounts. Wherever possible, we seek to minimize the potential effects of concentration and degrees of risk. Although we maintain cash balances with financial institutions in excess of insured limits, we do not anticipate any losses with respect to such cash balances.

## Net Cash Used in Operating Activities

Net cash used in operations for the nine months ended September 30, 2011 was \$36.9 million due primarily to the net loss for the nine months ended September 30, 2011 of \$35.8 million and the change in operating assets and liabilities of \$7.6 million. The change in operating assets and liabilities consisted of an increase in receivables from GSK related to the collaboration agreement of \$3.8 million; a decrease in deferred reimbursements of \$2.3 million related to the recognition of the upfront payment from GSK for the collaboration agreement; and an increase in prepaid expenses of \$0.8 million.

Net cash used in operations for the nine months ended September 30, 2012 was \$26.4 million, due primarily to the net loss for the nine months ended September 30, 2012 of \$38.8 million and the change in operating assets and liabilities of \$4.4 million. The change in operating assets and liabilities consisted of a decrease in receivables from GSK related to the collaboration agreement of \$1.9 million; a decrease of \$2.8 million in prepaid assets primarily related to a receivable from the sale of state net operating loss carry forwards, or NOLs; a decrease of \$0.3 in non-current assets related to the return of the security deposit on the terminated lease; a decrease in deferred reimbursements of \$0.3 million related to the recognition of the upfront payment from GSK for the collaboration agreement through June 30, 2012 and a decrease in accounts payable and accrued expenses of \$0.3 million related to program expenses.

## Net Cash Provided By/ (Used in) Investing Activities

Net cash provided by investing activities for the nine months ended September 30, 2011 was \$30.8 million. Net cash provided by investing activities reflects \$78.3 million for the sale and redemption of marketable securities

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partially offset by \$47.1 million for the purchase of marketable securities and \$0.4 million for the acquisition of property and equipment.

Net cash used in investing activities for the nine months ended September, 2012 was \$56.0 million. Net cash used by investing activities reflects \$47.4 million for the purchase of marketable securities offset by \$99.3 million for the sale and redemption of marketable securities and \$4.2 million for the acquisition of property and equipment.

## Net Cash (Used in)/Provided by Financing Activities

Net cash used in financing activities for the nine months ended September 30, 2011 was \$0.6 million, consisting primarily of \$0.9 million of payments on our secured loan agreement and capital lease obligations. The payments were partially offset by \$0.4 million of cash proceeds from the exercise of stock options.

Net cash provided by financing activities for the nine months ended September 30, 2012 was \$81.0 million, consisting of \$80.2 million from the issuance of common stock, \$1.0 million as proceeds from the new secured loan agreement with SVB and \$1.0 million from the exercise of stock options. This was partially offset by the payments of our secured loan agreement of \$1.1 million.

#### **Funding Requirements**

We expect to incur losses from operations for the foreseeable future primarily due to research and development expenses, including expenses related to conducting clinical trials. Our future capital requirements will depend on a number of factors, including:

- the progress and results of our clinical trials of our drug candidates, including migalastat HCl;
- the continuation of our collaboration with GSK and GSK's achievement of milestone payments thereunder;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our product candidates including those testing the use of pharmacological chaperones co-administered with ERT and for the treatment of diseases of neurodegeneration;
- the costs, timing and outcome of regulatory review of our product candidates;
- the number and development requirements of other product candidates that we pursue;
- the costs of commercialization activities, including product marketing, sales and distribution;
- the emergence of competing technologies and other adverse market developments;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property related claims;
- the extent to which we acquire or invest in businesses, products and technologies; and
- · our ability to establish collaborations and obtain milestone, royalty or other payments from any such collaborators.

We do not anticipate that we will generate revenue from commercial sales until at least 2014, if at all. In the absence of additional funding, we expect our continuing operating losses to result in increases in our cash used in operations over the next several quarters and years. We believe that our existing cash and cash equivalents and short term investments will be sufficient to cover our cash flow requirements for 2013.

#### Financial Uncertainties Related to Potential Future Payments

#### Milestone Payments

We have acquired rights to develop and commercialize our product candidates through licenses granted by various parties. While our license agreements for migalastat HCl and AT2220 do not contain milestone payment obligations, two of these agreements related to afegostat tartrate do require us to make such payments if certain specified pre-commercialization events occur. Upon the satisfaction of certain milestones and assuming successful development of afegostat tartrate, we may be obligated, under the agreements that we have in place, to make future milestone payments aggregating up to approximately \$7.9 million.

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In addition, under the Expanded Collaboration Agreement, GSK is eligible to receive U.S. regulatory approval milestones totaling \$20 million for migalastat HCl monotherapy and migalastat HCl for co-administration with ERT, and additional regulatory approval and product launch milestone payments totaling up to \$35 million within seven years following the launch of the Co-formulated Product. However, such potential milestone payments are subject to many uncertain variables that would cause such payments, if any, to vary in size.

Under our license agreements, if we owe royalties on net sales for one of our products to more than one licensor, then we have the right to reduce the royalties owed to one licensor for royalties paid to another. The amount of royalties to be offset is generally limited in each license and can vary under each agreement. For migalastat HCl and AT2220, we owe royalties only to Mt. Sinai School of Medicine (MSSM). We would expect to pay royalties to all three licensors with respect to afegostat tartrate should we advance afegostat tartrate to commercialization.

In accordance with our license agreement with MSSM, in the third quarter of 2012, we paid \$0.4 million of the \$3.5 million milestone payment received from GSK to MSSM. In the fourth quarter of 2010, we paid \$3 million of the \$30 million upfront payment received from GSK to MSSM. We will also be obligated to pay MSSM royalties on worldwide net sales of migalastat HCl.

Whether we will be obligated to make milestone or royalty payments in the future is subject to the success of our product development efforts and, accordingly, is inherently uncertain.

### ITEM 3. Quantitative and Qualitative Disclosures about Market Risk

Market risk is the risk of change in fair value of a financial instrument due to changes in interest rates, equity prices, creditworthiness, financing, exchange rates or other factors. Our primary market risk exposure relates to changes in interest rates in our cash, cash equivalents and marketable securities. We place our investments in high-quality financial instruments, primarily money market funds, corporate debt securities, asset backed securities and U.S. government agency notes with maturities of less than one year, which we believe are subject to limited interest rate and credit risk. The securities in our investment portfolio are not leveraged, are classified as available-for-sale and, due to the short-term nature, are subject to minimal interest rate risk. We currently do not hedge interest rate exposure and consistent with our investment policy, we do not use derivative financial instruments in our investment portfolio. At September 30, 2012, we held \$106.2 million in cash, cash equivalents and available for sale securities and due to the short-term maturities of our investments, we do not believe that a 10% change in average interest rates would have a significant impact on our interest income. Our outstanding debt has a fixed interest rate and therefore, we have no exposure to interest rate fluctuations.

We have operated primarily in the U.S., although we do conduct some clinical activities outside the U.S. While most expenses are paid in U.S. dollars, there are minimal payments made in local foreign currency. If exchange rates undergo a change of 10%, we do not believe that it would have a material impact on our results of operations or cash flows.

## **ITEM 4. CONTROLS AND PROCEDURES**

As of the end of the period covered by this Quarterly Report on Form 10-Q, an evaluation of the effectiveness of our disclosure controls and procedures (pursuant to Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)) was carried out under the supervision of our Principal Executive Officer and Principal Financial Officer, with the participation of our management. Based on that evaluation, the Principal Executive Officer and the Principal Financial Officer concluded that, as of the end of such period, our disclosure controls and procedures are effective in recording, processing, summarizing and reporting, on a timely basis, information required to be disclosed by us in the reports that we file or submit under the Exchange Act and are effective in ensuring that information required to be disclosed by us in the reports that 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.

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During the fiscal quarter covered by this report, there has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II. OTHER INFORMATION

## **ITEM 1. LEGAL PROCEEDINGS**

We are not a party to any material legal proceedings.

#### **ITEM 1A. RISK FACTORS**

There have been no material changes with respect to the Risk Factors disclosed in our Quarterly Report on Form10-Q for the period ended June 30, 2012.

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

#### **Recent Sales of Unregistered Securities**

None.

## **Use of Proceeds**

#### Initial Public Offering

Our initial public offering of common stock was effected through a Registration Statement on Form S-1 (File No. 333-141700) that was declared effective by the Securities and Exchange Commission (SEC) on May 30, 2007. We registered an aggregate of 5,750,000 shares of our common stock. On June 5, 2007, at the closing of the offering, 5,000,000 shares of common stock were sold on our behalf at an initial public offering price of \$15.00 per share, for aggregate offering proceeds of \$75.0 million. The initial public offering was underwritten and managed by Morgan Stanley, Merrill Lynch & Co., JPMorgan, Lazard Capital Markets and Pacific Growth Equities, LLC. Following the sale of the 5,000,000 shares, the public offering terminated.

After deducting expenses of approximately \$6.9 million, we received net offering proceeds of approximately \$68.1 million from our initial public offering. As of September 30, 2012, we have used the proceeds of approximately \$68.1 million for clinical development of our projects, research and

development activities relating to additional preclinical projects and to fund working capital and other general corporate purposes.

## March 2010 Registered Direct Offering

In March 2010, we sold 4,946,524 shares of our common stock and warrants to purchase 1,854,946 shares of common stock in a registered direct offering to a select group of institutional investors through a Registration Statement on Form S-3 (File No. 333-158405) that was declared effective by the SEC on May 27, 2009. The shares of common stock and warrants were sold in units consisting of one share of common stock and one warrant to purchase 0.375 shares of common stock at a price of \$3.74 per unit. The warrants have a term of four years and are exercisable any time on or after the six month anniversary of the date they were issued, at an exercise price of \$4.43 per share. The aggregate offering proceeds were \$18.5 million. Leerink Swann LLC served as sole placement agent for the offering. Following the sale of the common stock and warrants, the public offering terminated.

We paid Leerink Swann a placement agency fee equal to 5.7% of the aggregate offering proceeds, approximately \$1.05 million. The net proceeds of the offering were approximately \$17.1 million after deducting the placement agency fee and all other estimated offering expenses. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

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As of September 30, 2012, we have used the proceeds of approximately \$17.1 million to further advance the development of our lead product candidate, migalastat HCl, and the completion of certain activities required for the submission of a license application globally, as well as for general corporate matters.

### March 2012 Stock Offering

In March 2012, the Company sold 11.5 million shares of its common stock at a public offering price of \$5.70 through a Registration Statement on Form S-3 that was declared effective by the SEC on May 27, 2009. The aggregate offering proceeds were \$65.6 million. Leerink Swann LLC and Cowen and Company served as placement agents for the offering.

We paid Leerink Swann LLC and Cowen and Company a placement agency fee equal to 5.0% of the aggregate offering proceeds, approximately \$3.3 million. The net proceeds of the offering were approximately \$62.0 million after deducting the placement agency fee and all other estimated offering expenses. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

As of September 30, 2012, we had invested the \$62.1 million in net proceeds from our registered direct offering in money market funds and in investment-grade, interest bearing instruments, pending their use. Through September 30, 2012, we have not used the net proceeds from this offering. We intend to use the proceeds from this offering to advance the clinical and preclinical development of our pharmacological chaperone monotherapy, co-formulation and co-administration programs, especially our lead program migalastat HCl for Fabry disease to potentially enter into collaborations, alliances and other business development opportunities including the acquisition of preclinical-stage, clinical-stage and marketed products that are consistent with our strategic plan and support our continued transformation to a commercial biotechnology company, and for other general corporate purposes.

The foregoing represents our best estimate of our use of proceeds for the period indicated.

#### **Issuer Purchases of Equity Securities**

There were no purchases of our common stock for the three months ended September 30, 2012.

## ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

## **ITEM 4. MINE SAFETY DISCLOSURES**

None.

## **ITEM 5. OTHER INFORMATION**

None.

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### **ITEM 6. EXHIBITS**

Exhibit Number	Description
3.1 (1)	Restated Certificate of Incorporation
3.2 (2)	Amended and Restated By-laws
+10.1	Amended and Restated License and Expanded Collaboration Agreement dated as of July 17, 2012 by and between the Registrant and Glaxo Group Limited

- +10.2 Stock Purchase Agreement dated as of July 17, 2012 by and between the Registrant and Glaxo Group Limited
- 31.1\* Certification of Principal Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated pursuant to the Securities Exchange Act of 1934, as amended
- 31.2\* Certification of Principal Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated pursuant to the Securities Exchange Act of 1934, as amended
- 32.1\* Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 101.INS XBRL Instance Document
- 101.SCH XBRL Schema Document
- 101.CAL XBRL Calculation Linkbase Document
- 101.DEF XBRL Extension Definition Linkbase Document
- 101.LAB XBRL Label Linkbase Document
- 101.PRE XBRL Extension Presentation Linkbase Document
- (1) Incorporated by reference to Exhibit 3.1 to our Annual Report on Form 10K filed on February 28, 2012
- (2) Incorporated by reference to Exhibit 3.4 to our Registration Statement on Form S-1
- + Confidential treatment has been requested as to certain portions of the document, which portions have been omitted and filed separately with the Securities and Exchange Commission.
- These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of Amicus Therapeutics, Inc., whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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#### SIGNATURES

AMICUS THERADELITICS INC

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

	AMICOS THERAPEOTICS, INC.
Date: November 5, 2012	By: /s/ JOHN F. CROWLEY
	John F. Crowley Chairman and Chief Executive Officer (Principal Executive Officer)
Date: November 5, 2012	By: /s/ WILLIAM D. BAIRD III
	William D. Baird III Chief Financial Officer (Principal Financial Officer)
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- + Confidential treatment has been requested as to certain portions of the document, which portions have been omitted and filed separately with the Securities and Exchange Commission.
- These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of Amicus Therapeutics, Inc., whether made before or after the date hereof, regardless of any general incorporation language in such filing.

<sup>(1)</sup> Incorporated by reference to Exhibit 3.1 to our Annual Report on Form 10K filed on February 28, 2012

Portions of this exhibit have been omitted and filed separately with the Secretary of the Securities and Exchange Commission (the "Commission") pursuant to an application for confidential treatment filed with the Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended. Such portions are marked as indicated below.

## AMENDED AND RESTATED LICENSE AND EXPANDED COLLABORATION AGREEMENT

THIS AMENDED AND RESTATED LICENSE AND EXPANDED COLLABORATION AGREEMENT (the "<u>Agreement</u>") is made as of the 17<sup>th</sup> day of July, 2012 (the "<u>Restatement Effective Date</u>") by and between **Amicus Therapeutics, Inc.**, a Delaware corporation having a place of business at 1 Cedar Brook Drive, Cranbury, New Jersey, 08512 ("<u>Amicus</u>") and **Glaxo Group Limited**, a company organized under the laws of England and Wales with its registered office address at Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex, UB6 0NN, England ("<u>GSK</u>"). Amicus and GSK are each referred to herein by name or as a "<u>Party</u>" or, collectively, as the "<u>Parties</u>".

# **RECITALS**

WHEREAS, Amicus has developed Compound (as defined below), and owns or controls, solely or jointly with GSK, certain intellectual property rights related thereto;

WHEREAS, the Parties previously entered into a certain License and Collaboration Agreement dated October 28, 2010 ("<u>Original Agreement</u>"), pursuant to which Amicus granted to GSK exclusive, worldwide, rights to Compounds and Products (each as defined below) and pursuant to which Amicus and GSK have collaborated and are collaborating on the Development of the Compound and Product;

WHEREAS, contemporaneously with the Original Agreement, the Parties entered into a certain Stock Purchase Agreement dated October 28, 2010 ("<u>Prior Equity Agreement</u>"), pursuant to which GSK purchased shares of common stock of Amicus;

WHEREAS, the Parties now desire to amend the Original Agreement and to restate the Original Agreement in its entirety through this Agreement, to provide for, among other matters, the reversion to Amicus of the rights for the Commercialization of Compound and Products in the United States, including the rights to Commercialize Co-Formulation Products in the United States, in consideration of, among other things, the elimination of GSK's outstanding milestone and royalty payment obligations to Amicus under the Original Agreement in connection with the Development and Commercialization of Compound and Products outside of the United States; all on the terms and conditions set forth in this Agreement; and

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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WHEREAS, contemporaneously with this Agreement, the Parties have executed a Stock Purchase Agreement, pursuant to which GSK will purchase additional shares of common stock of Amicus, as set forth in such Stock Purchase Agreement.

NOW, THEREFORE, in consideration of the mutual agreements contained herein and other good and valuable consideration, the sufficiency of which is hereby acknowledged, the Parties agree as follows:

## I. <u>DEFINITIONS</u>

Unless specifically set forth to the contrary herein, the following terms, whether used in the singular or plural, shall have the respective meanings set forth below:

1.1 "<u>011 Phase III Clinical Study</u>" means the Phase III Clinical Study sponsored, as of the Restated Effective Date, by GSK in the United States and by Amicus outside of the United States, and identified by the ClinicalTrials.gov Identifier NCT00925301.

1.2 "<u>012 Phase III Clinical Study</u>" means the Phase III Clinical Study sponsored, as of the Restated Effective Date, by GSK in the United States and by Amicus outside of the United States, and identified by the ClinicalTrials.gov Identifier NCT01218659.

1.3 "2011 Carry-Forward Amount" means US\$\*\*\*\*\*\*.

1.4 "<u>AAA</u>" has the meaning ascribed to that term in Section 16.2.2.

1.5 "<u>Abandoning Party</u>" has the meaning ascribed to that term in Section 7.4.

1.6 "<u>Act</u>" means the United States Food, Drug and Cosmetic Act of 1938, as amended from time to time, and its implementing regulations.

1.7 "<u>Affected Area</u>" has the meaning ascribed to that term in Section 14.2 (as applicable to Section 14.2) and in Section 14.3 (as applicable to Section 14.3).

1.8 "<u>Affiliate</u>" means, with respect to any specified Person, at any time, a Person that, directly or indirectly, through one or more intermediaries, controls, or is controlled by, or is under common control with, such specified Person at such time. For purposes of this definition and Section 1.33, "control," when used with respect to any specified Person, shall mean (a) the direct or indirect ownership of more than fifty percent (50%) (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the total voting power of securities or other evidences of ownership interest in such Person or (b) the power to direct or cause the direction of the management and policies of such Person, directly or indirectly, whether through ownership of voting securities, by contract or otherwise; and the terms "controlling" and "controlled" have meanings correlative to the foregoing.

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

1.9 "<u>Agreement</u>" means this Amended and Restated License and Expanded Collaboration Agreement, which pursuant to Section 16.8 below replaces the Original Agreement in its entirety as of the Restatement Effective Date.

1.10 "<u>Alliance Manager</u>" has the meaning ascribed to that term in Section 4.2.2.

1.11 "<u>Amicus</u>" has the meaning ascribed to that term in the first paragraph of this Agreement.

1.12 "<u>Amicus Aggregate Existing Development Cost Cap</u>" means \*\*\*\*\*, which amount is equal to the aggregate of Amicus' share of the Development Costs specified in the Existing Development Plan for each of the calendar years beginning with calendar year 2011 up to and including calendar year 2015.

1.13 "<u>Amicus Annual Existing Development Cost Cap</u>" means: (a) for calendar year 2012, \*\*\*\*\*\* (which amount is equal to twenty-five percent (25%) of the total Development Costs for the calendar year 2012, as set forth in the Existing Development Plan) plus the 2011 Carry-Forward Amount, for a total of \*\*\*\*\*; (b) for calendar years 2013, 2014 and 2015 \*\*\*\*\*, and \*\*\*\*\*, respectively (which amount is equal to forty percent (40%) of the total Development Costs for the applicable calendar year, as set forth in the Existing Development Plan), and (c) for each calendar year thereafter, if applicable, \*\*\*\*\* (which amount is equal to forty percent (40%) of the total Development Plan), in each case, as adjusted in accordance with Section 5.1.4(b). For clarity, the Amicus Annual Existing Cost Cap shall not apply to costs incurred by Amicus to perform any Amicus Territory Required Activities.

1.14 "<u>Amicus Auditor</u>" has the meaning ascribed to that term in Section 3.9.

1.15 "<u>Amicus House Marks</u>" has the meaning ascribed to that term in Section 6.3.

1.16 "<u>Amicus Indemnitees</u>" has the meaning ascribed to that term in Section 15.1.

1.17 "<u>Amicus Intellectual Property</u>" means Amicus Patents, Amicus Know-How, and any and all copyrights that are Controlled by Amicus during the Term and that pertain to the Compound and Products for the Territory.

1.18 "<u>Amicus Know-How</u>" means all confidential Know-How which (a) Amicus or its Affiliates Control as of the Effective Date; or (b) subject to Sections 12.2 and 14.4(b), is Controlled by Amicus or its Affiliates after the Effective Date and during the Term of this Agreement, and that is developed or acquired by or on behalf of Amicus or its Affiliates outside the Program and without the use of Program Improvements or Co-Formulation Product IP; in each case (a) and (b), that is reasonably necessary or actually used to Develop, Manufacture or Commercialize Products in the Field for the Territory. Notwithstanding the foregoing, Amicus Know-How shall not include:

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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(i) information which is or becomes part of the public domain through no breach of this Agreement by GSK; (ii) information which GSK can demonstrate by its written records was known by GSK or its Affiliates prior to the disclosure thereof by Amicus or its Affiliate; (iii) information which is independently developed by GSK or its Affiliates outside of the Program, so long as such development does not result from use of Amicus Know-How, and such independent development can be demonstrated by written records; and (iv) information that becomes available to GSK or its Affiliates on a non-confidential basis, whether directly or indirectly, from a Third Party who is not bound by a confidentiality obligation to Amicus or its Affiliates.

1.19 "<u>Amicus Patents</u>" means: (a) all Patents Controlled by Amicus or its Affiliates as of the Effective Date which are reasonably necessary, or actually practiced, to Develop, Manufacture or Commercialize the Compound or Products for use as a therapeutic agent, including without limitation the Patents set forth on <u>Schedule 7.2.1</u> hereto; and (b) subject to Section 12.2, all Patents Controlled by Amicus or its Affiliates after the Effective Date and during the Term of this Agreement that are reasonably necessary, or actually practiced, to Develop, Manufacture or Commercialize the Compound or Products in the Field for the Territory to the extent such Patents claim inventions within the Amicus Know-How Controlled by Amicus or its Affiliates as of the Effective Date.

1.20 "<u>Amicus Proprietary Chaperone Technology</u>" means Amicus's proprietary technology used in connection with a small molecule drug that selectively binds to the active site of a target enzyme resulting in enzyme stabilization, improved trafficking, less aggregation, and/or increased activity of the enzyme, including all associated Patents and Know-How Controlled by Amicus in the Territory.

1.21 "<u>Amicus Prosecuted Patents</u>" has the meaning ascribed to that term in Section 7.2.2.

1.22 "<u>Amicus Protective Action</u>" has the meaning ascribed to that term in Section 8.2.

1.23 "Amicus Reimbursement Trigger Event" has the meaning ascribed to that term in Section 5.1.5(c).

1.24 "<u>Amicus Territory</u>" means the United States.

1.25 "<u>Amicus Territory Required Activities Information</u>" has the meaning ascribed to that term in Section 5.1.5(c).

1.26 "<u>Amicus Territory Required Activities</u>" means any clinical trials, studies, or other activities, and any Post Marketing Commitments, in each case that are required or requested by a Regulatory Authority after the Restatement Effective Date in connection with obtaining or maintaining Market Approval of a Product in the Amicus Territory and that are determined in accordance with Section 5.1.5 to be specific to the Amicus Territory. For clarity, Amicus Territory Required Activities shall not include those Development activities that are set forth in a

Development Plan and that are generally required in accordance with applicable Laws to obtain Regulatory Approval for a Product in the Amicus Territory.

1.27 "<u>Amicus Wind-Down Period</u>" has the meaning ascribed to that term in Section 14.2.9.

1.28 "Available JR051 Monotherapy Clinical Trial Data" has the meaning ascribed to that term in Section 5.1.6(a).

1.29 "Background License Agreements" means the agreements, letters, and other documents listed in <u>Schedule 1.29</u>.

1.30 "<u>BLA</u>" means a Biologics License Application (or supplement thereto) as defined in the United States Public Health Service Act and Food, Drug and Cosmetic Act and the regulations promulgated thereunder.

1.31 "<u>Business Day</u>" means any day, other than a Saturday or a Sunday, in which banks in New York, New York, United States and in London, England are open for business, excluding any days on which GSK's corporate headquarters or Amicus's corporate headquarters are closed.

1.32 "<u>Chairperson</u>" has the meaning ascribed to that term in Section 4.1.2.

1.33 "<u>Change of Control</u>" means either: (a) a sale of all or substantially all of the assets of a Party in one or a series of integrated transactions not in the ordinary course of business to a Third Party; or (b) the acquisition of control (as defined in Section 1.8) of a Party by a Third Party by means of any transaction or series of related transactions to which such Party is a party (including, any stock acquisition, merger or consolidation); \*\*\*\*\*\*. For clarity, a Change of Control would not include any transaction or series of transactions in which the holders of voting securities of a Party outstanding immediately prior to such transaction continue to retain (either by such voting securities remaining outstanding or by such voting securities being converted into voting securities of the surviving entity), as a result of shares in the Party held by such holders prior to such transaction, fifty percent (50%) or more of the total voting power represented by the voting securities of the acquiring entity outstanding immediately after such transaction or series of transactions.

1.34 "<u>Claim</u>" means any action, appeal, petition, plea, charge, complaint, suit, demand, litigation, arbitration, mediation, hearing, inquiry, investigation, or similar event, occurrence, or proceeding.

1.35 "<u>Co-Administration Product</u>" has the meaning ascribed to that term in Section 1.45.

1.36 "<u>Co-Development Opt-Out Effective Date</u>" has the meaning ascribed to that term in Section 5.4.2.

- Material has been omitted and filed separately with the Commission.

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1.37 "<u>Co-Development Opt-Out Notice</u>" has the meaning ascribed to that term in Section 5.4.2.

1.38 "<u>Co-Development Opt-Out Right</u>" has the meaning ascribed to that term in Section 5.4.1.

1.39 "<u>Co-Development Opt-Out</u>" has the meaning ascribed to that term in Section 5.4.1.

1.40 "<u>Co-Formulation Development Plan</u>" has the meaning ascribed to that term in Section 5.1.1(b).

1.41 "<u>Co-Formulation MTA</u>" means that certain materials transfer agreement entered into between JCR and Amicus with the consent of, and acknowledged by, GSK, dated as of \*\*\*\*\*\*, as may be amended.

1.42 "<u>Co-Formulation Product</u>" means a pharmaceutical preparation that incorporates the Compound formulated together with the Co-Formulation Product ERT Enzyme.

1.43 "<u>Co-Formulation Product ERT Enzyme</u>" means (a) JR051; or \*\*\*\*\*.

1.44 "<u>Co-Formulation Product IP</u>" means any and all Know-How and Patents arising, during the period from the Effective Date to the Restatement Effective Date under the Original Agreement or during the Term of this Agreement, from the conduct of activities with respect to the Development of a Co-Formulation Product under the Original Agreement or the Agreement, including (a) the conduct of activities pursuant to the Co-Formulation MTA, or (b) the conduct of activities pursuant to the Co-Formulation Development Plan; in each case where such activities are conducted by or on behalf of Amicus, GSK, their respective Affiliates or (sub)licensees, or by an agent designated by GSK or Amicus to conduct such activities. Notwithstanding the proviso in Section1.108, as between Amicus and GSK, JCR shall be deemed an agent of GSK with respect to all activities conducted by or on behalf of JCR in connection with this Agreement and, as between Amicus and GSK, all such activities conducted by JCR in connection with this Agreement shall be deemed to have been conducted by GSK under this Agreement. Co-Formulation Product IP expressly excludes the: Amicus Intellectual Property, Amicus Proprietary Chaperone Technology, GSK Background IP, Program Improvements, Program Patents and GSK In-Licensed Background ERT IP.

1.45 "<u>Combination Therapy</u>" means the use of the Compound or a Product in combination with one or more other active ingredients. Drug delivery vehicles, adjuvants (except as expressly set forth in this definition below) and excipients shall not be deemed to be "active ingredients", and their presence shall not be deemed to create a Combination Therapy. Combination Therapy includes, but is not limited to: (a) adjuvant use of the Compound or a Product with an ERT; (b) co-administration of the Compound or a Product with an ERT, regardless of the order or form in which the co-administration is performed ("<u>Co-Administration Product</u>"); (c) a Co-Formulation Product; or

(d) subject Section 5.3.2 a pharmaceutical preparation that incorporates the Compound formulated together with an ERT.

1.46 "<u>Commercialize</u>" or "<u>Commercialization</u>" means activities directed to obtaining pricing and reimbursement approvals for, marketing, advertising, promoting, detailing, distributing, importing, or selling a Product in the Field in the Territory and post-launch medical education, planning, product support and medical efforts related to a Product in the Field in the Territory. For clarity, "Commercialize" and "Commercialization" shall not include Development or Manufacturing.

1.47 "<u>Commercially Reasonable Efforts</u>" means that level of efforts and resources required to carry out a particular task or obligation in an active and sustained manner, consistent with the usual practice followed by a Party in the exercise of reasonable business discretion relating to other pharmaceutical products owned by it, or to which it has exclusive rights, which are of similar market potential and at a similar stage in development or product life, taking into account issues of patent coverage, safety and efficacy, scientific and product profile, the regulatory structure involved, and the strategic value and profitability of the product (including, without limitation, pricing and reimbursement status achieved). A Party may not consider payments required to be made hereunder when determining its Commercially Reasonable Efforts with regards to a Product or its obligations under this Agreement.

1.48 "<u>Compound</u>" means migalastat, as described in <u>Schedule 1.48</u>, and includes (a) any compounds with alternative names but with the same chemical structure as migalastat, and (b) any metabolites, prodrugs, isomers and enantiomers (excluding the isomer/enantiomer "1-deoxynorjirimycin" or "(2R,3R,4R,5S)-2-(hydroxymethyl)piperidine-3,4,5-triol"), esters, salts, hydrates, solvates, and polymorphs thereof, whether alone or in a mixture.

1.49 "<u>Confidential Information</u>" means in the case of one Party (the "<u>disclosing Party</u>"), that Party's or its Affiliate's (and, with respect to GSK, including JCR's) know-how and financial or other confidential or proprietary information that is Controlled by that Party or its Affiliates and made available (in whatever form and whether prior to, on, or after the Effective Date) to the other Party (the "<u>receiving Party</u>") in connection with this Agreement or generated pursuant to this Agreement. Notwithstanding the foregoing, Confidential Information shall not include:

any of its Affiliates;

(a) information which is or becomes part of the public domain through no breach of this Agreement by the receiving Party or ffiliates;

(b) information which the receiving Party can demonstrate by its written records was known by the receiving Party or any of its Affiliates prior to the disclosure thereof by the disclosing Party;

(c) information which is independently developed by the receiving Party or any of its Affiliates, so long as such development does not result from use of Confidential

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Information of the disclosing Party, and such independent development can be demonstrated by written records of the receiving Party or any of its Affiliates; and

(d) information that becomes available to the receiving Party or its Affiliates on a non-confidential basis, whether directly or indirectly, from a Third Party who is not bound by a duty of confidentiality to the disclosing Party.

1.50 "<u>Confidentiality Agreement</u>" means the Confidentiality Agreement between Amicus and GSK dated as of \*\*\*\*\* and amended as of \*\*\*\*\*\*

1.51 "<u>Control</u>" or "<u>Controlled</u>" means, with respect to any compound, material, information, or intellectual property right, that a Party owns or has a license to use, commercialize, manufacture, market, distribute or sell, and has the ability to grant to the other Party a license or a sublicense (as applicable under this Agreement) to such compound, material, information, or intellectual property right as provided for herein without violating (i) the terms of any agreement or other arrangements with any Third Party existing at the time such Party would be first required hereunder to grant the other Party such license or sublicense or (ii) any Law applicable to such license or sublicense.

1.52 "<u>Cooperating Party</u>" has the meaning ascribed to that term in Section 11.2.2.

1.53 "<u>Current Good Manufacturing Practices</u>" or "<u>cGMP</u>" means the standards relating to manufacturing practices for fine chemicals, intermediates, bulk products or finished pharmaceutical products: (a) detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Parts 210 and 211 and The Rules Governing Medicinal Products in the European Community, Volume IV Good Manufacturing Practice for Medicinal Products, as each may be amended from time to time; and/or (b) outside the United States and European Union, promulgated by any Regulatory Authority having jurisdiction over the manufacture of fine chemicals, intermediates, bulk products or finished pharmaceutical products; and subject to any arrangements, additions or clarifications agreed to from time to time by the Parties in a quality agreement.

1.54 "Develop" or "Development" means all activities related to (a) non-clinical and clinical research and drug development (including preclinical testing and clinical trials) related to obtaining, maintaining and/or expanding Marketing Approval (excluding pricing and reimbursement approvals), (b) Post Marketing Commitments;(c) manufacturing activities for the purposes of producing clinical supplies (or materials used in preclinical testing or research), as well as test method development and stability testing and process development and validation for a Product prior to the first Marketing Approval of such Product (including manufacturing batches for validation and registration purposes), formulation development, delivery system development, quality assurance and quality control development for clinical supplies, and (d) statistical analysis, regulatory affairs, and activities directed towards obtaining Marketing Approval (excluding regulatory activities directed to obtaining pricing and reimbursement approvals) and clinical study regulatory activities

(excluding regulatory activities directed to pricing and reimbursement approvals); in each case, with respect to the Products in the Field for the Territory. For clarity, "Develop" and "Development" shall not include Manufacturing or Commercialization.

1.55 "Developing Party" has the meaning ascribed to that term in Section 5.3

1.56 "Development Costs" has the meaning ascribed to that term in <u>Schedule 5.1.4</u>.

1.57 "<u>Development Plan</u>" means the Existing Development Plan for the Development of a Monotherapy Product and for a Co-Administration Product, and any amendments thereto in accordance with Section 5.1.4(b), and/or the Co-Formulation Development Plan and any amendments thereto in accordance with Section 5.1.4(b), as applicable.

1.58 "<u>disclosing Party</u>" has the meaning ascribed to that term in Section 1.49.

1.59 "Discriminatory Conduct" has the meaning ascribed to that term in Section 6.1.3(b).

1.60 "Dispute" has the meaning ascribed to that term in Section 16.2.1.

1.61 "Effective Date" means October 28, 2010, the effective date of the Original Agreement.

1.62 "<u>EMA</u>" means the European Medicines Agency of the European Union or any successor entity thereto having similar responsibilities with respect to pharmaceutical products, such as the Products.

1.63 "Equity Agreement" means the stock purchase agreement attached hereto as Exhibit A.

1.64 "<u>ERT</u>" means enzyme replacement therapy.

1.65 "Escalation Notice" has the meaning ascribed to that term in Section 4.1.5(a).

1.66 "Excluded Item" has the meaning ascribed to that term in Section 11.1.2.

1.67 "Existing Development Plan" has the meaning ascribed to that term in Section 5.1.1(a).

1.68 "Expanded Major Market Country" means \*\*\*\*\*.

1.69 "<u>Ex-U.S. Commercialization Plan</u>" means the strategic plan for the marketing, promotion and other Commercialization activities for Products in the GSK Territory, as prepared by GSK in accordance with GSK's normal and customary format and process for such plans, and which will include, in reasonable scope and detail, plans for implementation of Commercialization

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activities in the GSK Territory (consistent with the guidelines set forth in the Global Commercialization Plan), and as amended from time to time by GSK during the Term.

1.70 "<u>Ex-U.S. Commercialization Strategy</u>" means the marketing strategy for Products in the GSK Territory determined by GSK under the global guidelines as set forth in the Global Commercialization Plan and reviewed by the Joint Commercialization Subcommittee, including product positioning, pricing, reimbursement, education programs, medical affairs, publications, sales messages, marketing, and distribution, as such strategy may be amended by GSK from time to time during the Term.

1.71 "FDA" means the United States Food and Drug Administration or any successor entity thereto having similar responsibilities with respect to pharmaceutical products, such as the Products.

1.72 "<u>Field</u>" means any and all uses or purposes, including, without limitation, the treatment, palliation, and/or prevention and diagnosis of any human or animal disease, disorder or condition, including use of a Product in combination with ERT.

1.73 "First Opt-Out Quarter" has the meaning ascribed to such term in Section 5.4.2.

1.74 "<u>\*\*\*\*\*</u>" has the meaning ascribed to that term in Section 5.1.4(b)(ii).

1.75 "<u>Force Majeure Event</u>" has the meaning ascribed to that term in Section 16.11.

1.76 <u>"\*\*\*\*\*\*</u>" has the meaning ascribed to that term in Section 3.3.3(a).

1.77 "FTE Costs" has the meaning ascribed to that term in <u>Schedule 5.1.4</u>.

1.78 "<u>FTE Rate</u>" has the meaning ascribed to that term in <u>Schedule 5.1.4</u>.

1.79 "<u>FTE</u>" has the meaning ascribed to that term in <u>Schedule 5.1.4</u>.

1.80 "<u>GAAP</u>" has the meaning ascribed to that term in Section 1.137.

1.81 "<u>Generic Equivalent</u>" means, as to a Terminated Product that has received Regulatory Approval in a particular country in the relevant Affected Area (as defined under Section 14.2 or 14.3, as applicable) and is marketed and sold by a Party in such country, a non-innovator product that: (A) (i) has obtained Regulatory Approval by means of an abbreviated NDA filed pursuant to Section 505(j) of the Act which refers to the specific Product at issue as the Reference Listed Drug (as defined in 21 C.F.R. 314.3(b) (as amended)) in the United States, or an application similar to an abbreviated NDA filed pursuant to Section 505(j) of the Act for any jurisdiction outside the United States, in each case, without the requirement of any human clinical efficacy trials; or (ii) has obtained Regulatory Approval by means of a BLA or an NDA or a comparable procedure for

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establishing bioequivalence or biosimilarity to such Terminated Product, in each case, without the requirement of any human clinical efficacy trials; and (B) is bioequivalent or bio-similar to such Terminated Product; and (C) is legally marketed in such country by an entity other than such Party, its Affiliates or Sublicensees.

1.82 "Global Commercialization Plan" has the meaning ascribed to that term in Section 6.1.

1.83 "GSK" has the meaning ascribed to that term in the first paragraph of this Agreement.

1.84 "<u>GSK Auditor</u>" has the meaning ascribed to that term in Section 3.8.

1.85 "<u>GSK Background IP</u>" means all Patents and/or Know-How which: (a) GSK or its Affiliates Controlled as of the Effective Date, or (b) are developed by or on behalf of GSK or its Affiliates after the Effective Date or acquired or otherwise Controlled by GSK or its Affiliates after the Effective Date, in each case (a) or (b), outside the Program and without the use of Program Improvements or Co-Formulation Product IP; or (c) any manufacturing technology or manufacturing process intellectual property owned or Controlled by GSK or its Affiliates as of the Restatement Effective Date, and any improvements made thereto; excluding the GSK Monotherapy Product Manufacturing Improvements.

1.86 "<u>GSK House Marks</u>" has the meaning ascribed to that term in Section 6.3.

1.87 "GSK Indemnitees" has the meaning ascribed to that term in Section 15.2.

1.88 "<u>GSK In-Licensed Background ERT IP</u>" means all Patents and Know-How to which GSK has acquired an exclusive license or other rights from JCR pursuant to the GSK/JCR Master Agreement, including any manufacturing technology or manufacturing process intellectual property owned or Controlled by JCR as of the Restatement Effective Date, and any improvements or modifications thereto.

1.89 "<u>GSK/JCR Master Agreement</u>" means that certain Master Agreement by and between JCR, GlaxoSmithKline K.K. and Glaxo Group Limited, dated \*\*\*\*\*\*, and as amended, and including any addendums thereto (the "<u>GSK/JCR Agreement</u>").

1.90 "<u>GSK Monotherapy Product Manufacturing Improvements</u>" means any improvements or modifications made by or on behalf of GSK (i) after the Effective Date and in the conduct of Development activities under the Development Plan under the Original Agreement, to those certain manufacturing processes for the Manufacture of Compound or Monotherapy Products that were transferred to GSK in connection with the Manufacture technology transfer by Amicus to GSK in accordance with Section 6.5.1 of the Original Agreement and (ii) after the Restatement Date and in the conduct of Development activities under the Existing Development Plan under this

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Agreement to the manufacturing processes for the Manufacture of Compound or Products (other than the Co-Formulation Products).

- 1.91 "GSK Prosecuted Amicus Patents" has the meaning ascribed to that term in Section 7.2.1.
- 1.92 "GSK Prosecuted Improvement Patent" has the meaning ascribed to that term in Section 7.6.1(b).
- 1.93 "<u>GSK Protective Action</u>" has the meaning ascribed to that term in Section 8.2.
- 1.94 "GSK Reimbursement Trigger Event" has the meaning ascribed to that term in Section 5.1.5(c).
- 1.95 "GSK Terminated Product Royalty Term" has the meaning ascribed to that term in Section 14.2.3(b)(i).
- 1.96 "GSK Territory" means, subject to Section 14.4(a), all countries and territories of the world, excluding the United States.

1.97 "<u>GSK Territory Required Activities</u>" means any clinical trials, studies, or other activities, and any Post Marketing Commitments, in each case that are required or requested by a Regulatory Authority after the Restatement Effective Date in connection with obtaining or maintaining Market Approval of a Product in the GSK Territory and that are determined in accordance with Section 5.1.5 to be specific to the GSK Territory. For clarity, GSK Territory Required Activities shall not include those Development activities that are set forth in a Development Plan and that are generally required in accordance with applicable Laws to obtain Regulatory Approval for a Product in the GSK Territory.

1.98 "GSK Territory Required Activities Information" has the meaning ascribed to that term in Section 5.2.6(b).

1.99 "<u>GSK Trademark</u>" has the meaning ascribed to that term in Section 2.5.

1.100 "<u>GSK Wind-Down Period</u>" has the meaning ascribed to that term in Section 14.3.9.

1.101 "<u>Host Party</u>" has the meaning ascribed to that term in Section 5.2.2(a).

1.102 "IFRS" has the meaning ascribed to that term in Section 1.137.

1.103 "IND" means any Investigational New Drug Application (including any amendments thereto) filed with the FDA pursuant to 21 C.F.R. §312 before the commencement of clinical trials

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of a Product, or any comparable filings (including clinical trial applications) with any Regulatory Authority in any other jurisdiction.

- 1.104 "Indemnitee" has the meaning ascribed to that term in Section 15.3.
- 1.105 "Indemnitor" has the meaning ascribed to that term in Section 15.3.
- 1.106 "Industry Guidelines" has the meaning ascribed to that term in Section 10.1.3.
- 1.107 "Initial Press Release" has the meaning ascribed to that term in Section 11.2.1.

1.108 "JCR" means JCR Pharmaceuticals, Co., Ltd, with a place of business at 3-9 Kasuga-cho, Ashiya, Hyogo, 659-0021 Japan. As between GSK and Amicus, for the purpose of this Agreement, JCR shall be deemed a designated agent of GSK, and all activities conducted by JCR under the Co-Formulation MTA, a Co-Formulation Development Plan, or otherwise in connection with this Agreement, shall be deemed to have been conducted by GSK under this Agreement; <u>provided</u>, <u>however</u> that the foregoing shall not be construed to grant any rights or licenses to Amicus under any intellectual property owned or Controlled by JCR except as expressly set forth herein.

- 1.109 "JCR Agreements" has the meaning ascribed to that term in Section 9.3.10.
- 1.110 "JDS" has the meaning ascribed to that term in Section 4.2.3(a).
- 1.111 "Joint Commercialization Subcommittee" has the meaning ascribed to that term in Section 4.2.2(a).
- 1.112 "Joint Development Subcommittee" has the meaning ascribed to that term in Section 4.2.3.
- 1.113 "Joint Patent Subcommittee" has the meaning ascribed to that term in Section 4.2.1.
- 1.114 "Joint Program Patent" has the meaning ascribed to that term in Section 7.3.3.
- 1.115 "Joint Steering Committee" or "JSC" has the meaning ascribed to that term in Section 4.1.1.

1.116 "JR051" means the JCR proprietary enzyme alpha-Galactosidase that is internally referenced by GSK as JR051 and described in <u>Schedule 1.116</u> attached to this Agreement, including any derivatives or modifications thereof or analogs thereto.

1.117 "JR051 Monotherapy Clinical Trial Data" has the meaning ascribed to that term in Section 5.1.6.

1.118 "JR051 Opt-In Notice" has the meaning ascribed to that term in Section 5.1.6(a).

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1.119 "JSC" has the meaning ascribed to that term in Section 4.1.1.

1.120 "<u>Know-How</u>" means any proprietary or confidential technology, technical, scientific and medical information, methods of use, processes, techniques, ideas, inventions (excluding any inventions disclosed in any Patent or published Patent application), improvements, modifications, know-how, practices, trade secrets, chemistry, manufacturing and control data, quality control information and procedures, and pharmacological, toxicological and preclinical and clinical test data and results and regulatory information (including all documentation and correspondence submitted or required to be submitted to a Regulatory Authority, or received from a Regulatory Authority, in connection with a Marketing Approval in any country) and marketing, promotion and other information and materials, all of the foregoing pertaining to the Development, Manufacture and/or Commercialization of the Compound and/or Products within the Field for the Territory, but excluding Patents associated with any of the foregoing.

1.121 "<u>Launch</u>" means, on a country-by-country and Product-by-Product basis, the date of the first \*\*\*\*\* (or one of its Affiliates or sublicensees) in such country; <u>provided</u> that the Launch of a Product in a country for a particular indication shall be deemed to occur upon the first

commercial sale of a Product with labeling for such indication. Sales of a Product for registration samples, compassionate use sales, named patient use and the like, and inter-company transfers to Affiliates of a Party for resale will not constitute a Launch.

1.122 "<u>Law</u>" means all laws, statutes, regulations (including securities laws, regulations or guidances), or governmental, regulatory, or judicial orders or judgments in effect from time to time.

1.123 "Liabilities" has the meaning ascribed to that term in Section 15.1.

1.124 "<u>License</u>" has the meaning ascribed to that term in Section 2.1.

1.125 "<u>Licensed Amicus Technology</u>" means, subject to Section 12.2, all (a) Amicus Intellectual Property, (b) Program Improvements developed solely or jointly by Amicus or its Affiliates from the Effective Date and during the Term, (c) Program Patents in the Territory owned solely or jointly by Amicus or its Affiliates, and (d) Amicus's rights in and to the Co-Formulation Product IP. For the avoidance of doubt, the "Licensed Amicus Technology" shall include Amicus Proprietary Chaperone Technology, but solely to the extent such Amicus Proprietary Chaperone Technology is necessary for the Development or Manufacture of Compound and/or Products in the Territory, or Commercialization of Products in the GSK Territory.

1.126 "<u>MAA</u>" means (a) a Marketing Authorization Application filed with the EMA, seeking Regulatory Approval of a Product and all variations thereto filed with the EMA; (b) an NDA or BLA submitted to the FDA in the United States; or (c) a corresponding application for Regulatory Approval that has been submitted to a Regulatory Authority in any other jurisdiction in the GSK Territory.

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1.127 "<u>Major EU Country</u>" means the \*\*\*\*\*\*, \*\*\*\*\*\*, \*\*\*\*\*\*, \*\*\*\*\*\* or \*\*\*\*\*\*.

1.128 "Major Market" means the \*\*\*\*\*\*, each \*\*\*\*\*\* and \*\*\*\*\*\*.

1.129 "<u>Manufacture</u>" or "<u>Manufacturing</u>" means all the activities required for the production and supply of Compound and/or Product, including without limitation, purchasing raw materials, quality control and assurance, filing, finishing, labeling, packaging, qualified person release, holding, shipping and storage and the tests and analyses conducted in connection therewith. For clarity, "Manufacture" and "Manufacturing" shall not include Commercialization or Development.

1.130 "Manufacturing Costs" means \*\*\*\*\*\*.

1.131 "<u>Marketing Approval</u>" means all approvals, licenses, registrations or authorizations of the Regulatory Authority in a country, necessary for the manufacture, use, storage, import, marketing and sale of a Product in such country. For countries where governmental or other similar approval of pricing and/or reimbursement is required for marketing in such country, Marketing Approval shall not be deemed to occur until \*\*\*\*\*, as the case may be, is obtained. For clarity, however, it is understood that, as of the Effective Date, Marketing Approval in the United States shall be deemed to occur upon \*\*\*\*\*\*. In the event that any such \*\*\*\*\*\* of any governmental agency in the United States is required at the time that a Party seeks Marketing Approval for a Product in the United States, then Marketing Approval in the United States shall not be deemed to occur until \*\*\*\*\*\*. Notwithstanding the foregoing, Marketing Approval shall be deemed to have occurred for a particular indication for a Product in such jurisdiction upon the Launch of such Product in such jurisdiction with labeling for such indication.

1.132 "<u>Milestone Payment</u>" has the meaning ascribed to that term in Section 3.3.3(a).

1.133 "Milestone Per Share Price" has the meaning ascribed to that term in Section 3.3.3(b).

1.134 "<u>Monotherapy Product</u>" means a Product incorporating the Compound as the sole active ingredient.

1.135 "<u>Mount Sinai Agreement</u>" means that certain Amended and Restated Agreement between Mount Sinai School of Medicine of New York University and Amicus Therapeutics, Inc., dated October 31, 2008, and as amended.

1.136 "<u>NDA</u>" means a New Drug Application or supplemental New Drug Application as defined in Title 21 of the U.S. Code of Federal Regulations, Section 314.50, et seq., which is submitted to the FDA in order to gain the FDA's approval to commercialize a pharmaceutical product in the United States for the indications set forth in the New Drug Application or supplemental New Drug Application.

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1.137 "<u>Net Sales</u>" means the amount of gross sales of all (i) Royalty-Bearing Co-Formulation Products sold by Amicus, its Affiliates or Sublicensees or (ii) Products sold by GSK, its Affiliates, or Sublicensees or (iii) Terminated Product(s) sold by a Party, its Affiliates, or Sublicensees in the relevant Affected Area (as defined under Section 14.2 or 14.3, as applicable) (each, as applicable, a "<u>Selling Party</u>") to Third Parties less the following amounts actually and reasonably incurred, allowed, paid or accrued as reported by Amicus, its Affiliates or Sublicensees, as applicable, in its financial statements prepared in accordance with generally accepted accounting principles in the United States ("<u>GAAP</u>"), applied on a consistent basis, or by GSK, its Affiliates or Sublicensees, as applicable, in its financial statements prepared in accordance with the International Financial Reporting Standards ("<u>IFRS</u>"), applied on a consistent basis:

(a) quantity, trade and cash discounts actually allowed or given;

Products:

- (b) discounts, replacements, credits or refunds actually allowed for the return of rejected, outdated, damaged or returned
- (c) rebates, chargebacks and price adjustments actually allowed or given;

(d) sales or similar taxes (including duties or other similar governmental charges or assessments) levied, or otherwise imposed on the sale of the applicable Products to the customer (including VAT or other governmental charges measured by the billing amount, when included in such billing);

- (e) charges for freight, handling, postage, transportation, insurance and other shipping charges; and
- (f) a reasonable provision for uncollectible accounts not to exceed \*\*\*\*\*\* percent (\*\*\*\*\*\*) of gross amounts invoiced.

# provided, however, that:

(i) sales or transfers of Royalty-Bearing Co-Formulation Products between or among Amicus, any Sublicensee or any Affiliate of Amicus for resale, and sales or transfers of Products between or among GSK, any Sublicensee or any Affiliates of GSK for resale, as the case may be, shall be excluded from Net Sales calculations by Amicus or GSK, as applicable; <u>provided</u>, <u>however</u>, that the subsequent resale to a Third Party shall be included in Net Sales hereunder;

(ii) if the applicable Product is sold or transferred for consideration other than cash, the Net Sales from such sale or transfer shall be deemed the then fair market value of such Product;

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(iii) Products that are transferred or used without charge in connection with any pre-clinical or clinical trials, or for any testing, quality control, evaluation or other Development purposes, or distributed as samples or charitable donations, shall be excluded from Net Sales calculations for all purposes; and

(iv) sales or transfers of Products for registration samples, compassionate use sales, named patient use and the like, shall be excluded from Net Sales calculations for all purposes, unless the Selling Party recognizes revenue with respect to any such sales or transfers in which event such sales or transfers shall be included in Net Sales hereunder.

The Net Sales definition as applicable to Amicus may be amended upon written notice from Amicus only to extent required to reflect changes to Amicus' accounting rules that result from a merger, takeover, or change in applicable Law. The Net Sales definition as applicable to GSK may be amended upon written notice from GSK only to extent required to reflect changes to GSK's accounting rules that result from a merger, takeover, or change in applicable Law.

1.138 "<u>Non-Hosting Party</u>" has the meaning ascribed to that term in Section 5.2.2(a).

1.139 "Original Agreement" has the meaning ascribed to that term in the preambles of this Agreement.

1.140 "<u>Out-of-Pocket Expenses</u>" means amounts paid to Third Party vendors or contractors, for services or materials provided by them directly in their performance of activities reflected in the applicable Development Plan, to the extent such services or materials apply directly to a Product for the Territory. For clarity, Out-of-Pocket Expenses do not include payments for salaries or benefits, facilities, utilities, general office or laboratory supplies, insurance, information technology, and other general administrative costs of a Party.

1.141 "Overage" has the meaning ascribed to that term in Section 5.1.4(a)(iv).

1.142 "Party" or "Parties" has the meaning ascribed to that term(s) in the first paragraph of this Agreement.

1.143 "<u>Patent</u>" means any and all existing (as of the Effective Date) and future patents and patent applications in any country or jurisdiction, including but not limited to, any provisional applications, non-provisional applications, PCT applications, re-issues, re-examinations, divisionals, continuations, continuations-in-part, registrations, confirmations, validations, re-validations, renewals, and extensions of term thereof (including supplementary protection certificates and pediatric use extensions), including utility, model, and design patents.

1.144 "<u>Patent Costs</u>" means the reasonable fees and expenses paid to outside legal counsel, and filing, maintenance and other out-of-pocket expenses paid to Third Parties as incurred in connection with the prosecution and maintenance of Patents.

• Material has been omitted and filed separately with the Commission.

1.145 "<u>Per Share Price</u>" has the meaning ascribed to that term in Section 3.2.

1.146 "<u>Person</u>" means any individual, corporation (including any nonprofit corporation), general or limited partnership, limited liability company, joint venture, estate, trust, association, organization, labor union, government agency, Regulatory Authority, or other entity.

1.147 "<u>Pharmacological Chaperone</u>" means a small molecule drug that selectively binds to the active site of a target enzyme resulting in enzyme stabilization, improved trafficking, less aggregation, and/or increased activity of the enzyme.

1.148 "<u>Phase II Clinical Studies</u>" means early controlled human clinical studies conducted to obtain some preliminary data on the appropriate dose range and effectiveness of a drug in a disease or condition under study, as more fully defined in 21 C.F.R. §312.21(b) or its successor regulation, or the equivalent in any country other than the United States.

1.149 "<u>Phase III Clinical Studies</u>" means expanded and controlled human clinical studies involving administration of a drug to sufficient numbers of human patients with the goal of establishing that a drug is safe and efficacious for its intended use, and to be considered as a pivotal study for submission of an MAA, including, in the United States, a NDA or BLA as more fully defined in 21 C.F.R. §312.21(c) or its successor regulation, and including any such clinical study in any country other than the United States.

1.150 "<u>Phase IV Clinical Studies</u>" means human clinical studies, including marketing studies, epidemiological studies, modeling and pharmacoeconomic studies, investigator sponsored clinical trials and post-marketing surveillance studies, in each case (i) that are required or requested by a Regulatory Authority to be conducted for a Product after receipt of Marketing Approval for such Product in such country, as a condition of or in connection with obtaining and maintaining such Marketing Approval, (ii) subject to Section 5.3, that a Party elects to conduct in connection with or to support the TPP New Labeling for such Product within its respective Territory, or (iii) subject to Section 5.3(a), that a Party elects to conduct in support of medical affairs activities.

1.151 "<u>Post-Marketing Commitments</u>" means Phase IV Clinical Studies and other preclinical and clinical studies conducted after Marketing Approval (such as, by way of example, carcinogenicity studies, preclinical studies to establish pediatric or other dosing or safety studies, and registries) that are required or requested by a Regulatory Authority to be conducted after Marketing Approval, in connection with obtaining or maintaining such Marketing Approval.

1.152 "Prior Equity Agreement" has the meaning ascribed to that term in the preambles of this Agreement.

1.153 "<u>Product</u>" means, subject to Section 14.4(a), any pharmaceutical preparation that incorporates Compound, whether or not as the sole active ingredient, including any formulation thereof, such as intravenous, transdermal, oral, or other dosage form. For clarity, references in this

- Material has been omitted and filed separately with the Commission.

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Agreement to a "Product" include a Monotherapy Product, Co-Administration Product and/or Co-Formulation Product, as applicable.

1.154 "<u>Product Liability Claim</u>" has the meaning ascribed to that term in Section 15.4.1.

1.155 "<u>Program</u>" means all activities directed to the Development, Manufacture and/or Commercialization of Products for the Territory performed after the Effective Date under the Original Agreement or after the Restatement Effective Date under this Agreement by or on behalf of Amicus (or its Affiliates or Sublicensees) and/or GSK (or its Affiliates or Sublicensees) under this Agreement; <u>provided</u>, <u>however</u>, it is understood that all activities (a) related to the Development of Products conducted either by Amicus or GSK prior to the Effective Date, (b) pertaining to the Manufacture of JR051, (c) conducted by Amicus or its Affiliates with respect to a Terminated Product(s) in the Affected Area after a termination of this Agreement in such country(ies) or with respect to such Product(s) either by Amicus pursuant to Section 13.2 or by GSK pursuant to Section 13.3, or (d) conducted by GSK or its Affiliates with respect to a Terminated Product(s) in the Affected Area after a termination of this Agreement in such country(ies) or with respect to a Terminated Product(s) in the Affected Area after a termination of this Agreement in such country(ies) or with respect to a Terminated Product(s) in the Affected Area after a termination of this Agreement in such country(ies) or with respect to such Product(s) in the Affected Area after a termination of this Agreement in such country(ies) or with respect to such Product(s) by GSK pursuant to 13.2, or after exercise by Amicus of its Opt-Out Right in accordance with Section 5.4; in each case, will be deemed to have been conducted outside of the Program.

"Program Improvements," means, collectively, (a) the GSK Monotherapy Product Manufacturing Improvements, and (b) any and all Know-1.156 How, and other information that is developed by or on behalf of GSK (or its Affiliates or Sublicensees), or Amicus (or its Affiliates, or Sublicensees) (subject to Sections 12.2 and 14.4(b)), or jointly by or on behalf of GSK and Amicus or any of their respective Affiliates (subject to Sections 12.2 and 14.4(b)), after the Effective Date arising, during the period from the Effective Date to the Restatement Effective Date under the Original Agreement or during the Term of this Agreement, from the conduct of activities under the Original Agreement or under this Agreement, in each case with respect to Products (other than Co-Formulation Product(s)), including such activities conducted pursuant to (i) the Development Plan under the Original Agreement, (ii) the Existing Development Plan, including any modifications or amendments thereto, under this Agreement or (iii) any Amicus Territory Required Activities with respect to any Product (other than a Co-Formulation Product) or GSK Territory Required Activities with respect to any Product (other than a Co-Formulation Product), including all inventions, Know-How, and all other intellectual property rights relating to any of the foregoing; provided, however, that Program Improvements will not include Amicus Intellectual Property, GSK Background IP, GSK In-Licensed Background ERT IP, or Co-Formulation Product IP; and provided further that, Program Improvements shall not include: (a) information which is or becomes part of the public domain through no breach of this Agreement by GSK or Amicus or their respective Affiliates; (b) information which GSK can demonstrate by its written records was known by GSK or its Affiliates prior to the Effective Date excluding any information received by GSK under the terms of the Confidentiality Agreement; and (c) information which is independently developed by GSK or Amicus or their respective Affiliates outside of the Program, and such independent development can be demonstrated by written records.

• Material has been omitted and filed separately with the Commission.

1.157 "Program Patent" means a Patent or Patent application disclosing and claiming a Program Improvement.

1.158 "<u>Proof of Concept</u>" has the meaning ascribed to that term in Section 3.3.3(a).

1.159 "<u>Quarter</u>" means a calendar quarter consisting of any of the three-month periods ending on March 31, June 30, September 30 and December 31 in any particular year.

1.160 "receiving Party" has the meaning ascribed to that term in Section 1.49.

1.161 "<u>Regulatory Approval</u>" means: (a) in the United States, written notice of Marketing Approval by the FDA based on approval of an NDA or BLA, as applicable, and (b) in any country of the GSK Territory, written notice of required Marketing Approval \*\*\*\*\*\*, such acceptance not to be unreasonably withheld) by the Regulatory Authority having jurisdiction in such country; <u>provided</u> that with respect to countries in the European Union, written notice of a centralized Marketing Approval from the European Medicines Agency shall constitute written notice with respect to each and every such country.

1.162 "<u>Regulatory Assignment</u>" has the meaning ascribed to that term in Section 5.2.1(b).

1.163 "<u>Regulatory Authority</u>" means the agency, if any, of the national government of any country with which a pharmaceutical or biological therapeutic product must be registered or by which a pharmaceutical or biological therapeutic product must be approved prior to its manufacture, use, or sale in such country, <u>provided</u> that with respect to countries in the European Union, the European Medicines Agency shall constitute such an agency with respect to each and every such country in addition to any agency of a national government of such country.

- 1.164 "<u>Requesting Party</u>" has the meaning ascribed to that term in Section 11.2.2.
- 1.165 "<u>Required Activities Opt-In Notice</u>" has the meaning ascribed to that term in Section 5.1.5(c).
- 1.166 "<u>Required Changes</u>" has the meaning ascribed to that term in Section 6.5.6.
- 1.167 "<u>Restatement Effective Date</u>" has the meaning ascribed to that term in the first paragraph of this Agreement.
- 1.168 "<u>Royalty-Bearing Co-Formulation Product</u>" means a Co-Formulation Product in which the ERT enzyme is JR051.
- 1.169 "<u>Rules</u>" has the meaning ascribed to that term in Section 16.2.2.

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

1.170 "Safety Data Exchange Agreement" has the meaning ascribed to that term in Section 5.2.6(a).

1.171 "<u>Safety Issue</u>" means any unexpected or untoward adverse event related to a Product that is reported to a Party by a patient or physician, or about which a Party becomes aware, which event raises a question about patient safety or the efficacy of such Product and which event a Party considers to be serious enough to contemplate taking a prompt affirmative action with respect to such Product.

1.172 "Second Opt-Out Right" has the meaning ascribed to that term in Section 5.1.4(b)(ii).

1.173 "Selling Party" has the meaning ascribed to that term in Section 1.137.

1.174 "Senior Executives" has the meaning ascribed to that term in Section 4.1.5(a).

1.175 "Specifications" has the meaning ascribed to that term in Section 6.5.6.

1.176 \*\*\*\*\*\*.

1.177 "Subcommittee" has the meaning ascribed to that term in Section 4.2.

1.178 "<u>Sublicensee</u>" means a Third Party to whom GSK or Amicus, as applicable, has granted a right to make, have made, use, sell, market, distribute and/or promote a Product in the GSK Territory or Amicus Territory, as applicable; and "<u>Sublicense</u>" shall mean an agreement or arrangement between GSK and a Sublicensee, or between Amicus and a Sublicensee, as applicable, granting such rights. As used in this Agreement, "Sublicensee" shall not include a wholesaler, or reseller of Product who does not market such Product.

1.179 "Supply Agreement" has the meaning ascribed to that term in Section 6.5.5.

1.180 "Supply Transition Plan" has the meaning ascribed to that term in Section 6.5.1.

1.181 "<u>Target Product Profile</u>" means a voluntary format for discussions between a sponsor and FDA that may be used throughout the drug development process to pursue new indications or other substantial changes in labeling.

1.182 "<u>Term</u>" has the meaning ascribed to that term in Section 13.1.

1.183 "<u>Terminated Product(s)</u>" has the meaning ascribed to that term in Section 14.2 (as applicable to Section 14.2) and Section 14.3 (as applicable to Section 14.3).

1.184 "<u>Territory</u>" means, subject to Section 14.4(a), all countries and territories in the world.

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1.186 "Third Party Claim" has the meaning ascribed to that term in Section 15.1.

1.187 "<u>Third Party Enzyme IP</u>" has the meaning ascribed to that term in Section 10.3.3.

1.188 "<u>Total Co-Formulation Development Cost Cap</u>" means \*\*\*\*\* (which amount is equal to \*\*\*\*\* of the total Development Costs specified in the Co-Formulation Development Plan attached to this Agreement as <u>Schedule 5.1B</u> for each of the calendar years beginning with calendar year 2012 up to and including calendar year 2020).

1.189 "<u>Total Program Development Costs in the Existing Development Plan</u>" means the aggregate Development Costs for the Development of the Compound and Products specified in the Existing Development Plan for each of the calendar years beginning with calendar year 2011 up to and including calendar year 2015.

1.190 "TPP New Labeling" has the meaning ascribed to that term in Section 5.3.

1.191 "<u>Trademarks</u>" means (a) trademarks, service marks, logos, trade dress and trade names, and domain names indicating the source of goods or services, and other indicia of commercial source or origin (whether registered, common law, statutory or otherwise), (b) all registrations and applications to register the foregoing anywhere in the world, (c) all goodwill associated therewith, and (d) all rights in and to any of the foregoing.

1.192 "Trademark License Agreement" means an agreement in the form attached hereto as Exhibit C.

1.193 "Treaty" has the meaning ascribed to that term in Section 3.10.

1.194 "United States" or "U.S." means the United States, including Puerto Rico and the other territories and possessions of the United States.

1.195 "<u>US Buy-Out Option Price</u>" has the meaning ascribed to that term in Section 12.1.4.

1.196 "<u>US Buy-Out Option</u>" has the meaning ascribed to that term in Section 12.1.

1.197 "<u>U.S. Commercialization Plan</u>" means the strategic plan for the marketing, promotion and other Commercialization activities for Products in the Amicus Territory, as prepared by Amicus in accordance with Amicus' normal and customary format and process for such plans, and which will include, in reasonable scope and detail, plans for implementation of Commercialization activities in the Amicus Territory (consistent with the guidelines set forth in the Global Commercialization Plan), and as amended from time to time by Amicus during the Term.

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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1.198 "<u>U.S. Commercialization Strategy</u>" means the marketing strategy for Products in the Amicus Territory determined by Amicus under the global guidelines as set forth in the Global Commercialization Plan and reviewed by the Joint Commercialization Subcommittee, including product positioning, pricing, reimbursement, education programs, medical affairs, publications, sales messages, marketing, and distribution, as such strategy may be amended by Amicus from time to time during the Term.

1.199 "<u>Valid Claim</u>" means a claim of an issued, unexpired Amicus Patent or a Program Patent (other than a Formulation Patent or a Method of Manufacture Patent) covering i) Compound; or ii) method of use of the Compound or a Product (\*\*\*\*\*\*) which: (a) has not been revoked or held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, which decision is not appealable or has not been appealed within the time allowed for appeal; (b) has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise; or (c) has not lapsed, been cancelled or abandoned, or been dedicated to the public. For purposes of this Section 1.199, a "<u>Formulation Patent</u>" means a Patent primarily directed to an invention which is a formulation of Compound and one (1) or more excipients, and a "<u>Method of Manufacture Patent</u>" means a Patent primarily directed to an invention which is a method of manufacture of Compound or Product.

1.200 <u>Construction</u>. For purposes of this Agreement: (a) words in the singular shall be held to include the plural and vice versa as the context requires; (b) the word "including" and "include" shall be deemed to be followed by the phrase "without limitation" or like expression unless otherwise specified; (c) the terms "hereof," "herein," "herewith," and "hereunder," and words of similar import shall, unless otherwise stated, be construed to refer to this Agreement as a whole and not to any particular provision of this Agreement; (d) the word "will" shall be construed to have the same meaning and effect as the word "shall"; and (e) all references to "Section," "Article," "Schedule" and "Exhibit," unless otherwise specified, are intended to refer to a Section, Article, Schedule or Exhibit of or to this Agreement.

# II. <u>LICENSES</u>

## 2.1 License Grant to GSK from Amicus.

2.1.1 Subject to the terms and conditions of this Agreement, Amicus hereby grants to GSK the following licenses, with the right to grant sublicenses in accordance with Section 2.2, under the Licensed Amicus Technology: (i) a co-exclusive license (co-exclusive with Amicus) to Develop Products in the Field in the Territory in accordance with Article V, (ii) an exclusive license (exclusive even as to Amicus) to make, have made and otherwise Manufacture Compound and Products in the Field and anywhere in the Territory for the GSK Territory in accordance with Article VI; (iii) an exclusive license (exclusive even as to Amicus) to make, have made and otherwise Manufacture Co-Formulation Products in the Field and anywhere in the Territory for the Amicus Territory in accordance with Article VI; (iv) an exclusive license (subject to Section 6.5.3)

to Manufacture Compound and Products for use in connection with Development activities as set forth in Section 6.5.4; and (v) an exclusive license (exclusive even as to Amicus) to use, sell, offer for sale, import and otherwise Commercialize Products in the Field in the GSK Territory (collectively, the "<u>License</u>"). For clarity, nothing set forth in this Section 2.1.1 shall be construed to restrict Amicus' licenses and rights granted hereunder to make and have made and otherwise Manufacture Products (other than Co-Formulation Products) anywhere in the Territory for the Amicus Territory in accordance with Article VI, or to use, sell, offer for sale, import and otherwise Commercialize Products in the Field in the Amicus Territory.

2.1.2 Subject to Sections 5.3.2 and 10.4, and subject to the exclusive rights of Amicus under this Agreement with respect to Products in the Field in the Amicus Territory, Amicus hereby grants to GSK a worldwide, non-exclusive, fully paid-up, royalty-free, right and license, with the right to grant sublicenses, under Amicus' and its Affiliates' rights in the Program Patents and the Patents within the Co-Formulation Product IP to make, have made, use, sell, offer for sale, and import products, and to otherwise practice and exploit the Program Improvements and Co-Formulation Product IP claimed in such Program Patents within the Co-Formulation Product IP.

2.2 Sublicensees. GSK shall have the right to grant sublicenses to its current and future Affiliates (solely for so long as such entity remains an Affiliate) or to a Third Party, without the prior written consent of Amicus, under and within the scope of the licenses granted to GSK in Section 2.1.1(ii), (iii), (iv) and (v). GSK shall have the right to grant sublicenses under and within the scope of the license granted to GSK in Section 2.1.1(i): (i) without the prior written consent of Amicus, to its current and future Affiliates solely for so long as such entity remains an Affiliate; (ii)without the prior written consent of Amicus to a Third Party \*\*\*\*\*\*; (iii) without the prior written consent of Amicus to a Third Party \*\*\*\*\*\*; (iii) without the prior written consent of Amicus to a Third Party \*\*\*\*\*\*; (iii) without the prior written consent of Amicus to a Third Party \*\*\*\*\*\*; (iii) without the prior written consent of Amicus to a Third Party in \*\*\*\*\*\*; and (iv) subject to 2.2(iii), only with the prior written consent of Amicus (which consent shall not be unreasonably withheld) \*\*\*\*\*\*. In any event, GSK shall ensure that each of its Sublicensees is bound by a written agreement containing provisions at least as protective of the Compound, the Products and Amicus as this Agreement; and GSK shall remain responsible to Amicus for all activities of its Affiliates and Sublicensees to the same extent as if such activities had been undertaken by GSK itself. Promptly following the execution of each Sublicense, GSK shall provide Amicus with a redacted copy of such Sublicense (redacted solely to the extent necessary to prevent the disclosure of Third Party confidential information and not redacting any terms or information that are necessary for Amicus to determine GSK's compliance with the provisions of this Agreement with respect to the grant of such Sublicenses; granted to a Third Party in accordance with this Section 2.2 in connection with \*\*\*\*\*\*.

2.3 <u>Reversion of Rights</u>. It is understood that, as of the Effective Date, pursuant to the Original Agreement (including Sections 2.1 and 2.2 thereof), Amicus granted to GSK certain licenses and rights to use, sell, offer for sale, import and otherwise Develop, Manufacture and

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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Commercialize the Compound and Products in the Territory (as defined in the Original Agreement). As of the Restatement Effective Date, all such licenses and rights granted by Amicus to GSK shall terminate and the Agreement shall supersede and replace the Original Agreement as set forth in Section 16.8; it being understood that the licenses granted to each Party under Article 2 of the Original Agreement shall be deemed to apply to the activities conducted by a Party between the Effective Date and the Restatement Effective Date.

# 2.4 License Grant from GSK.

Subject to the terms and conditions of this Agreement, GSK hereby grants to Amicus the following licenses, with the right to 241 grant sublicenses in accordance with this Section 2.4.1 below, under all Program Improvements and Program Patents: (i) a co-exclusive license (co-exclusive with GSK) to Develop Products in the Field and in the Territory in accordance with Article V, (ii) subject to GSK's rights and obligations to Manufacture Products for Development activities as set forth in Article 6.5.4, an exclusive license (exclusive even as to GSK) to make and have made and otherwise Manufacture Compound and Products (other than Co-Formulation Products) in the Field and anywhere in the Territory for the Amicus Territory in accordance with VI; and (iii) an exclusive license (exclusive even as to GSK) to use, sell, offer for sale, import and otherwise Commercialize Products in the Field in the Amicus Territory. For clarity, nothing set forth in this Section 2.4.1. shall be construed to restrict GSK's licenses and rights granted hereunder to make, have made and otherwise Manufacture Products anywhere in the Territory for the GSK Territory in accordance with Article VI, or to use, sell, offer for sale, import and otherwise Commercialize Products in the Field in the GSK Territory. Amicus shall have the right to grant sublicenses to its current and future Affiliates (solely for so long as such entity remains an Affiliate) or to a Third Party, without the prior written consent of GSK, under and within the scope of the licenses granted to Amicus pursuant to Section 2.4.1(ii) and (iii). Amicus shall have the right to grant sublicenses (i) without the prior written consent of GSK to its current and future Affiliates solely for so long as such entity remains an Affiliate; (ii) without the prior written consent of GSK to a \*\*\*\*\*\*; and (iii) subject to 2.4(ii), only with the prior written consent of GSK (which consent shall not be unreasonably withheld), to \*\*\*\*\*\*. With respect to each such Sublicense granted by Amicus pursuant to this Section 2.4.1, Amicus shall ensure that each of its Third Party Sublicensees is bound by a written agreement containing provisions at least as protective of the Compound, the Products and GSK as this Agreement; and Amicus shall remain responsible to GSK for all activities of its Affiliates and Sublicensees to the same extent as if such activities had been undertaken by Amicus itself. Promptly following the execution of each Sublicense with a Third Party, Amicus shall provide GSK with a redacted copy of such Sublicense with a Third Party (redacted solely to the extent necessary to prevent the disclosure of Third Party confidential information and not redacting any terms or information that are necessary for GSK to determine Amicus' compliance with the provisions of this Agreement with respect to the grant of such Sublicense); provided, however, that Amicus' obligation to provide a redacted copy of any Sublicense granted by Amicus to a Sublicensee shall not apply with respect to Sublicenses granted to a Third Party in connection with Manufacturing activities with respect to Products (other than Co-Formulation Products) for the

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Amicus Territory or Commercialization activities with respect to Product(s) for the Amicus Territory.

Subject to the terms and conditions of this Agreement, GSK hereby grants to Amicus the following licenses, with the (a) right to grant sublicenses in accordance with this Section 2.4.2(a) below, under the Co-Formulation Product IP: (i) a co-exclusive license (co-exclusive with GSK) to Develop Co-Formulation Products in the Field in the Territory in accordance with Article V, and (ii) an exclusive license (exclusive even as to GSK) to use, sell, offer for sale, import and otherwise Commercialize Co-Formulation Products in the Field in the Amicus Territory. For the avoidance of doubt, nothing set forth herein shall be construed to restrict GSK's licenses and rights granted hereunder to Manufacture the Co-Formulation Products in the Field in the Territory for the GSK Territory and for the Amicus Territory in accordance with Article VI, or to Commercialize Co-Formulation Products in the Field in the GSK Territory. Nothing set forth herein shall be construed to grant to Amicus any rights under the Co-Formulation Product IP to Manufacture Co-Formulation Products. Amicus shall have the right to grant sublicenses under the licenses granted to Amicus in Section 2.4.2(a)(i) to an Affiliate (solely for so long as such entity remains an Affiliate) without the prior written consent of GSK, and to a Third Party only with the prior written consent of GSK (which consent shall not be unreasonably withheld). Amicus shall have the right to grant sublicenses to an Affiliate (solely for so long as such entity remains an Affiliate) or Third Party, in each case, without the consent of GSK, under and within the scope of the foregoing licenses granted to Amicus in Section 2.4.2(a) (ii). All Sublicenses granted by Amicus pursuant to this Section 2.4.2(a) shall be subject to the following: Amicus shall ensure that each of the Third Parties to which Amicus has granted a Sublicense in accordance with this Section 2.4.2(a) is bound by a written agreement containing provisions at least as protective of the Compound, the Products and GSK as this Agreement; and Amicus shall remain responsible to GSK for all activities of its Affiliates and Sublicensees to the same extent as if such activities had been undertaken by Amicus itself. Promptly following the execution of each sublicense with a Third Party, Amicus shall provide GSK with a redacted copy of such Sublicense with a Third Party (redacted solely to the extent necessary to prevent the disclosure of Third Party confidential information and not redacting any terms or information that are necessary for GSK to determine Amicus' compliance with the provisions of this Agreement with respect to the grant of such sublicense); provided, however, that Amicus' obligation to provide a redacted copy of any Sublicense granted by Amicus to a Sublicensee shall not apply with respect to Sublicenses granted to a Third Party in connection with Commercialization activities with respect to Co-Formulation Product(s) for the Amicus Territory.

(b) Without limiting the right and licenses granted under Sections 2.4.1, 2.4.2(a) or 2.4.3, GSK hereby irrevocably covenants from and after the Restatement Effective Date and, subject to Section 14.3.1(a), during the Term that \*\*\*\*\*\*.

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2.4.3 Subject to Sections 5.3.2 and 10.4, and subject to the exclusive rights granted to GSK under this Agreement with respect to the Products in the Field in the GSK Territory and, subject to Section 14.3.11, as applicable, with respect to the Co-Formulation Product, the exclusive Manufacturing rights granted to GSK in the Territory, GSK hereby grants to Amicus a worldwide, non-exclusive, fully paid-up, royalty-free, right and license, with the right to grant sublicenses, (a) under GSK's and its Affiliates' rights in the Program Patents to make, have made, use, sell, offer for sale, and import products, and to otherwise practice and exploit the Program Improvements and (b) under GSK's and its Affiliates' rights in the Patents within the Co-Formulation Product IP to make and have made (other than JR051 or Co-Formulation Product in which the ERT enzyme is JR051), use, sell, offer for sale and import products (other than JR051), and to otherwise practice and exploit the Patents within the Co-Formulation Product IP claimed in such Program Patents and/or Patents within the Co-Formulation Product IP.

2.5 <u>GSK Trademarks</u>. For all Trademarks Controlled by GSK or any of its Affiliates during the Term that the Joint Commercial Subcommittee determines should be used on or in connection with Products for the Amicus Territory in accordance with Section 6.3.1 (each, a "<u>GSK Trademark</u>"), GSK shall grant to Amicus a license in accordance with the terms of the Trademark License Agreement, a form of which is attached hereto as <u>Exhibit C</u>, to use the GSK Trademark(s) solely in connection with Amicus's right to (i) Develop Compound and Products in the Field in the Territory as provided in Article V, (ii) Manufacture Compound or Products in the Field anywhere in the Territory for the Amicus Territory in accordance with Article VI, and (iii) use, sell, offer for sale, distribute, promote and otherwise Commercialize Products in the Field in the Amicus Territory. Such license under the GSK Trademark(s), other than GSK House Marks, as part of a domain name.

2.6 <u>No Implied Licenses</u>. Except as expressly set forth in this Agreement or in a Trademark License Agreement, neither Party shall acquire any licenses or other intellectual property right or interest, by implication or otherwise, in any Know-How disclosed to it under this Agreement or under any Patents Controlled by the other Party or its Affiliates. Without limiting the foregoing, nothing herein shall be deemed to grant to GSK a right or license to any active pharmaceutical ingredient other than the Compound, and nothing herein shall be deemed to grant to Amicus a right or license under any of GSK's, its Affiliates' or JCR's rights in or to any enzyme used as an ERT that is owned or Controlled by GSK, its Affiliates, or JCR, except as expressly set forth herein with respect to use of JR051 solely in a Co-Formulation Product.

# III. CONSIDERATION

3.1 [Reserved]

3.2 <u>Equity Investment</u>. Pursuant to the terms of the Equity Agreement, Amicus will sell to GSK, and GSK will purchase from Amicus, Two Million Nine Hundred Forty-Nine Thousand Five Hundred Eight-One (2,949,581) shares of Common Stock of Amicus, at a per share price equal

- Material has been omitted and filed separately with the Commission.

to the greater of (a) \*\*\*\*\*\*, or (b) \*\*\*\*\*\* (the "Per Share Price"). The Equity Agreement shall be executed by the Parties on even date herewith, with GSK's payment to Amicus for such Common Stock payable within ten (10) Business days after the effective date of the Equity Agreement.

3.3 <u>Milestone Payments</u>.

3.3.1 <u>GSK Milestone Payment</u>. Subject to Section 3.10 with respect to payment of taxes, GSK will pay to Amicus Three Million Five Hundred Thousand Dollars (US\$3,500,000) following the completion of the last patient's six (6) month visit in the 011 Phase III Clinical Study. Such amount shall be paid by GSK to Amicus no later than sixty (60) days following the receipt of an invoice therefor from Amicus as provided in Section 3.6. GSK shall

notify Amicus in writing promptly, but in no event later than ten (10) days, after the achievement of such milestone event, and no invoice for payment of a milestone shall be sent by Amicus to GSK as provided herein prior to Amicus's reasonable determination that such milestone event has been achieved.

3.3.2 <u>GSK's Milestone Obligations under the Original Agreement</u>. The Parties acknowledge and agree that GSK's milestone payment obligations to Amicus as set forth in the Original Agreement shall be, as of the Restatement Effective Date, null and void and no longer in effect and that, as of the Restatement Effective Date, GSK's sole milestone obligation to Amicus shall be as set forth in this Agreement.

# 3.3.3 <u>Amicus Milestone Payments</u>.

(a) Subject to Section 3.10 with respect to payment of taxes, Amicus shall pay to GSK the milestone payments set forth below (each, a "<u>Milestone Payment</u>"), following the first achievement of each of the corresponding milestone events by Amicus, its Affiliate or Sublicensee or GSK, its Affiliates, or Sublicensee, as applicable, no later than sixty (60) days following the receipt of an invoice therefor from GSK as provided in Section 3.5.2. Any Milestone Payments set forth below and payable by Amicus shall be paid \*\*\*\*\*\*. Amicus shall notify GSK in writing promptly, but in no event later than ten (10) days, after the achievement of such milestone event, and no invoice for payment of a milestone shall be sent by GSK to Amicus as provided herein prior to GSK's reasonable determination that the corresponding milestone event has been achieved. Each of the following Milestone Payments shall be payable only once, regardless of how many times a Product achieves each milestone event and no milestones shall be paid by Amicus for milestone events that are not achieved. Notwithstanding the foregoing, with respect to the Milestone Payments regarding a Royalty-Bearing Co-Formulation Product (i.e., Milestone Payments #1, #2, #3, #4, #5, and #8), GSK shall notify Amicus in writing promptly after the achievement of the corresponding milestone event, and no invoice for payment of a milestone event, and no invoice for payment of the corresponding milestone event, and no invoice for payment of a milestone shall be sent by GSK to Amicus as provided herein prior to Amicus' receipt of written evidence of \*\*\*\*\*\*, which reflects that the amount of the corresponding Milestone Payment \*\*\*\*\*\*. In any event, Milestone Payments regarding a Royalty-Bearing Co-Formulation Product shall be payable by Amicus only to the extent \*\*\*\*\*\*.

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

Filing and Approval Milestone Event 1. ****** **	Milestone Payment (US Dollars (\$) or Japanese Yen (¥), as designated below) (Form of Payment) ******
	*****
2. ***** **	
3. ***** **	*****
4. ***** **	*****
5. ***** **	*****
6. *****	*****
7. ****	*****
8. ***** **	*****
9. *****	*****

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\*\* \*\*\*\*\*

For purposes of this Section 3.3.3(a), "<u>Achievement of Proof of Concept</u>" means \*\*\*\*\*.

(b) Notwithstanding anything to the contrary in Section 3.6, with respect to any of the Milestone Payments due under Section 3.3.3(a) that are eligible for payment, in whole or in part, in equity as specified in the milestone table set forth in Section 3.3.3(a), Amicus shall pay all or a portion of any such Milestone Payments, as applicable, (i) first, by \*\*\*\*\* and, in such an event, GSK shall \*\*\*\*\*.

3.3.4 <u>Co-Formulation Product Post-Launch Milestones</u>. If a Co-Formulation Product is Launched in the Amicus Territory and Amicus, its Affiliate or Sublicensee is selling a Co-Formulation Product in the Amicus Territory as of the occurrence of the applicable post-launch milestone set out in the table below, then Amicus shall pay to GSK the amount set forth below following the first occurrence of the corresponding post-launch milestone as set out below. Each of the milestone payments set out below shall be payable only once and no milestones shall be paid by Amicus if the milestone event does not occur in accordance with this Section 3.3.4:

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Co-Formulation Product Post-Launch Milestones:	 Milestone Payment (in US Dollars Cash)
****	\$ *****
****	\$ *****

## 3.4 <u>Royalties</u>.

3.4.1 <u>Royalties on Royalty-Bearing Co-Formulation Products in the Amicus Territory</u>. In addition to (and not in lieu of) the milestone payments to be made by Amicus as set forth in Section 3.3, and subject to Sections 3.4.2 and 14.2.3(b)(iv)(b), commencing on the date of Launch of a Royalty-Bearing Co-Formulation Product in the Amicus Territory and during the Term, Amicus shall pay to GSK a \*\*\*\*\* royalty on Net Sales of Royalty-Bearing Co-Formulation Products by Amicus, its Affiliates and Sublicensees in the Amicus Territory in accordance with Section 3.7 below. Notwithstanding the foregoing, royalty payments pursuant to this Section 3.4.1 shall be payable by Amicus \*\*\*\*\*, which shall not be greater than \*\*\*\*\*\* percent (\*\*\*\*\*) of Net Sales of Royalty-Bearing Co-Formulation Products, and no amounts shall be paid for any other amounts of royalty payments made from \*\*\*\*\*\*.

3.4.2 Except as provided in this Section 3.4 with respect to a Royalty-Bearing Co-Formulation Product, the Parties acknowledge and agree that no royalties are payable by Amicus to GSK under this Agreement with respect to the sale or other Commercialization in the Amicus Territory of any Product. Further, it is understood that the only royalties or other amounts payable by Amicus to GSK with respect to the Development or Commercialization of Products are as set forth in this Article III, Article VIII, or Article XV, or in Sections 5.1 or 6.5 below, and Amicus shall have no other obligations to pay to GSK any amounts payable by GSK to an Affiliate or by GSK or its Affiliates to a Third Party as a result of the Development, Manufacture or Commercialization of Products in the Field for the Amicus Territory. Except as provided in Section 3.4.3(a)(ii), the Parties acknowledge and agree that no royalties are payable by GSK to Amicus under this Agreement with respect to the Development, Manufacture or Commercialization of Products in the Section 3.4.2 shall be deemed to limit a Party's payment obligations pursuant to Section 5.4 below or, following an applicable termination of this Agreement, pursuant to Article XIV below.

# 3.4.3 Third Party Obligations.

# (a) <u>Third Party Payments</u>.

(i) Amicus shall be solely responsible for payment of any and all royalties and other payments (including but not limited to fees, upfront payments, milestone payments and royalties) owed by Amicus to a Third Party for the Development or Manufacture of all

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Products in the Territory or for the Commercialization of all Products in the Amicus Territory pursuant to any Background License Agreements that are in effect as of the Effective Date of the Agreement.

(ii) Subject to Section 14.3.3(b)(iv)(b), GSK shall be solely responsible for, and shall reimburse Amicus as set forth in Section 3.7 for any and all payments as set forth on the attached <u>Schedule 3.4.3</u> (and as may be modified in accordance with Section 3.4.3(b) below) that are owed by Amicus to the Mount Sinai School of Medicine of New York pursuant to the Mount Sinai Agreement as a result of the Manufacture or Commercialization of Products in the Field for the GSK Territory. Such payments shall be made by GSK to Amicus for the period of time during which GSK, its Affiliates and/or Sublicensees have rights to Manufacture and/or Commercialize Products in the GSK Territory and such amounts are payable to Mount Sinai School of Medicine of New York University under the Mount Sinai Agreement as a result of Manufacture or Commercialization of Products in the Field for the GSK Territory.

(b) In the event that Amicus intends to modify any of the terms of a Background License Agreement pertaining to (i) the amounts payable under such Background License Agreement by reason of the Development, sale or other Commercialization of Products in the GSK Territory, (ii) the term for which royalties with respect to sales of Products in the GSK Territory are payable, or (iii) the scope of any rights or obligations granted to GSK under this Agreement, Amicus shall provide notice of such intent to GSK within a reasonable period of time (but in no event longer than five (5) Business days) prior to making any such modifications. If such modifications would increase any amounts payable by reason of the Development, sale or other Commercialization of Products in the GSK Territory or the term for which royalties with respect to sales of Products in the GSK Territory are payable or otherwise materially and adversely modify the scope of any rights or obligations granted to GSK under this Agreement, Amicus shall not proceed to so modify any such Background License Agreement without the prior consent and approval of GSK (such approval not to be unreasonably withheld).

(c) GSK shall be solely responsible for payment of any and all amounts, including upfront payments, license fees, milestones and royalties, owed to any Third Party under any agreement with a Third Party with respect to the Third Party Enzyme IP that are negotiated and obtained by GSK in accordance with Section 10.3.3.

## 3.5 <u>Method of Payment</u>.

3.5.1 Unless otherwise agreed by the Parties, all amounts owed by a Party to another Party under this Agreement and payable in cash shall be paid in U.S. dollars, by bank wire transfer in immediately available funds to an account designated in an invoice from the Party to which such payments are due, which invoice should include bank details, the contact name for any issue resolution and be marked for the attention of the Alliance Manager of the Party to whom such

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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payment is due. All amounts owed by GSK to Amicus hereunder shall be paid by an entity resident in the United Kingdom from a bank account located in the United Kingdom.

3.5.2 Unless otherwise expressly stated herein, all payments made by one Party to the other pursuant to this Agreement shall be made within sixty (60) days following receipt by such Party of an invoice from the other Party for such amounts; provided that in the case of any payments made by Amicus pursuant to Section 3.4.1, such payments shall be made within sixty (60) days following receipt by Amicus of an invoice and written evidence of payment \*\*\*\*\*\* of such corresponding royalty payments owed under \*\*\*\*\*\* in accordance with Section 3.7.

3.6 <u>Foreign Exchange</u>. Unless otherwise agreed by the Parties, all payments to be made by either Party to the other Party under this Agreement shall be made in United States dollars. In the case of any amounts payable or receivable in a foreign currency, the Parties shall use the spot exchange rate sourced from Bloomberg/Reuters.

3.7 <u>Reports and Royalty Payment</u>. Commencing with the first Quarter in which the first Launch of a Royalty-Bearing Co-Formulation Product in the Amicus Territory occurs, and for each Quarter thereafter for so long as Amicus owes a royalty to GSK under Section 3.4, Amicus shall, within \*\*\*\*\* after the end of the applicable Quarter, submit to GSK, together with Amicus' payment for the royalties due for each Quarter, a written report showing the actual Net Sales and the royalties payable in accordance with Section 3.4 in each case in U.S. dollars. Such report shall be in the format reasonably requested

by GSK, including any such information regarding the Net Sales of Royalty-Bearing Co-Formulation Products in the Amicus Territory and calculation of such royalties as may be requested by GSK to comply with its obligations under the GSK/JCR Master Agreement. \*\*\*\*\*\*, GSK shall issue an invoice to Amicus for reimbursement of such amounts together with \*\*\*\*\*\* in accordance with Section 3.4.1. Similarly, commencing with the first Quarter in which the first Launch of a Product in the GSK Territory occurs, and for each Quarter thereafter during the Term, GSK shall, within \*\*\*\*\*\* after the end of the applicable Quarter, submit to Amicus, together with GSK's payment for the royalties due for each Quarter, a written report showing the Net Sales of Products and any royalties payable by GSK pursuant to Section 3.4.3(a)(ii) and/or Section 5.4 and 14.2, as applicable. Such reports shall be in the format reasonably requested by Amicus and shall include equivalent information to that provided by Amicus in the reports provided by Amicus to GSK pursuant to this Section 3.7 and such other information regarding the Net Sales of Products in the GSK Territory and calculation of such royalties as may be requested by Amicus to comply with its obligations under any Background License Agreement.

3.8 <u>GSK Records</u>. GSK will keep, and will require any Affiliates and Sublicensees to keep, for three (3) years from the end of the Quarter to which they pertain, or such longer period as may be required by applicable Law, complete and accurate books of account and records, including with respect to Development Costs and amounts spent on research and Development in accordance with this Agreement, as well as with respect to sales of Products in the GSK Territory, in sufficient detail to allow amounts payable to Amicus hereunder to be determined accurately. Amicus will have

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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the right during such three (3) year period to appoint an independent certified public accountant reasonably acceptable to GSK (the "Amicus Auditor") to inspect those books or records of GSK for the purpose of determining the applicable amounts payable to Amicus pursuant to this Agreement. Upon not less than sixty (60) days' prior written notice from Amicus, GSK will make such books and records and the books and records of its Affiliates available (including any sales reports received from its Sublicensees selling Products in the GSK Territory) for inspection by such Amicus Auditor during regular business hours at such place or places where such records are customarily kept, for the sole purpose of verifying the amounts payable hereunder. The Amicus Auditor will disclose to Amicus only the amount and accuracy of payments reported and actually paid or otherwise payable under this Agreement. The Amicus Auditor will send a copy of the report to GSK at the same time it is sent to Amicus. \*\*\*\*\*\*. Notwithstanding the foregoing, in the event that Amicus demonstrates sufficient cause, giving due consideration to each of the Parties' resources, to support the conduct of an additional inspection pursuant to this Section 3.9 within the same calendar year, the Parties shall discuss in good faith whether to require such additional inspection to take place; <u>provided</u> that GSK may not unreasonably withhold its consent to such an inspection. The Amicus Auditor shall be obligated to execute a reasonable confidentiality agreement prior to commencing any such inspection. Inspections conducted under this Section 3.8 shall be at the expense of Amicus; <u>provided</u>, <u>however</u>, that if the designated auditor discovers an underpayment to Amicus of \*\*\*\*\*\* or more for any period covered by the inspection between the payments GSK has made under this Agreement and the payments actually owed to Amicus under this Agreement, then GSK will bear all reasonable costs and expenses associated with such audit and any amounts underpaid by GSK that a

3.9 <u>Amicus Records</u>. Amicus will keep, and will require its Affiliates and Sublicensees to keep, for three (3) years from the end of the Quarter to which they pertain, or such longer period as may be required by applicable Law, complete and accurate books of account and records, including with respect to Development Costs and amounts spent on research and Development undertaken in accordance with this Agreement, as well as with respect to Net Sales of Royalty-Bearing Co-Formulation Products, in sufficient detail to allow amounts payable to GSK hereunder to be determined accurately. GSK will have the right during such three (3) year period to appoint an independent certified public accountant reasonably acceptable to Amicus (the "<u>GSK Auditor</u>") to inspect those books or records of Amicus for the purpose of determining the applicable amounts payable to GSK pursuant to this Agreement. Upon not less than sixty (60) days' prior written notice from GSK, Amicus will make such books and records and the books and records of its Affiliates available (including any sales reports received from its Sublicensees selling Royalty-Bearing Co-Formulation Products in the Amicus Territory) for inspection by such GSK Auditor during regular business hours, at such place or places where such records are customarily kept, for the sole purpose of verifying the amounts payable hereunder. The GSK Auditor will disclose to GSK only the amount and accuracy of payments reported and actually paid or otherwise payable under this Agreement. The GSK Auditor will send a copy of the report to Amicus at the same time it is sent to

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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GSK. \*\*\*\*\*\*. Notwithstanding the foregoing, in the event that GSK demonstrates sufficient cause, giving due consideration to each of the Parties' resources, to support the conduct of an additional inspection pursuant to this Section 3.9 within the same calendar year, the Parties shall discuss in good faith whether to require such additional inspection to take place; provided that Amicus may not unreasonably withhold its consent to such an inspection. The GSK Auditor shall be obligated to execute a reasonable confidentiality agreement prior to commencing any such inspection. Inspections conducted under this Section 3.9 shall be at the expense of GSK; provided, however, that if the designated auditor establishes an underpayment to GSK of \*\*\*\*\* or more for any period covered by the inspection between the payments Amicus has made under this Agreement and the payments actually owed to GSK under this Agreement for a period covered by the inspection, then Amicus will bear all reasonable costs and expenses associated with such audit and any amounts underpaid by Amicus that are established shall be paid by Amicus to GSK, together with interest on such underpaid amounts at the rate set forth in Section 16.12. GSK agrees to treat all information learned in the course of any audit or inspection as Confidential Information of Amicus.

3.10 <u>Taxes</u>.

3.10.1 Amicus warrants that Amicus is a resident for tax purposes of the United States of America and that Amicus is entitled to relief from United Kingdom income tax under the terms of the double tax agreement between the United Kingdom and the United States of America (the "<u>Treaty</u>"). Amicus shall notify GSK immediately in writing in the event that Amicus ceases to be entitled to such relief.

3.10.2 GSK shall cooperate with Amicus in obtaining formal certification of Amicus's entitlement to relief under the Treaty. Amicus agrees to indemnify and hold harmless GSK against any loss, damage, expense or liability arising in any way from a breach of the above warranties or any future claim by a United Kingdom tax authority alleging that GSK was not entitled to deduct withholding tax on such payments at source at the Treaty rate. The royalty and other payments under this Agreement shall not be reduced by any taxes required to be withheld by any taxing authority outside of the United Kingdom.

3.10.3 If GSK assigns this Agreement to an Affiliate and GSK or its Affiliate becomes liable to withhold any taxes from payments under this Agreement, then GSK or its Affiliate shall pay to Amicus the full amount of any payment required to be paid, unreduced by any withholding tax and shall pay any amount owed to the relevant tax authority; provided, however, that to the extent Amicus is able to obtain credit for any taxes withheld against Amicus' tax liability and actually realizes a reduction in its tax liability as a result of the utilization of such credit, Amicus shall refund to GSK the amount of such net tax savings, as determined in the reasonable discretion of Amicus.

3.10.4 All sums payable under this Agreement are exclusive of value added tax and any other sales taxes. The Parties agree that, where appropriate, the Parties shall provide each other

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with a valid tax invoice, and against such invoice, the Parties shall pay the amount of any such tax to the other Party. Should such amounts of tax be refunded subsequently by the fiscal authorities, the Party receiving the refund shall immediately notify the other Party and refund these monies within thirty (30) days of receipt of such funds.

## IV. GOVERNANCE

## 4.1 Joint Steering Committee.

4.1.1 <u>Existing JSC</u>. Amicus and GSK shall continue to use the joint steering committee (the "<u>Joint Steering Committee</u>" or "<u>JSC</u>") that was formed under the Original Agreement to oversee the Development and Commercialization of Products, and to review and coordinate the Development of the Products in the Field in the Territory, subject to the terms and conditions of Articles V and VI herein.

4.1.2Membership. The Joint Steering Committee will be composed of six (6) representatives: three (3) representatives nominated by Amicus and three (3) representatives nominated by GSK. Each such representative on the Joint Steering Committee shall be a senior executive or other member of senior management (or their designees who shall have the necessary authority to make decisions as such senior executives or other members of senior management, as applicable) of the respective Party or an Affiliate of such Party, and in each case such representatives shall have significant experience and responsibility for oversight of Products and shall be empowered by the Party whom they represent to make decisions that are binding upon such Party with respect to the Development, Manufacture and/or Commercialization, as applicable, of the Product. Each Party may also have its Alliance Manager attend Joint Steering Committee meetings as non-voting participants. GSK and Amicus will each be entitled to replace its representatives on the Joint Steering Committee in its sole discretion at any time during the Term with representatives of similar experience and level of responsibility. The Joint Steering Committee shall be chaired by a GSK representative (the "Chairperson"), and the Chairperson shall be responsible for, among other similar tasks as necessary, (a) calling and managing the conduct of meetings, (b) preparing and issuing minutes of each such meeting within thirty (30) days thereafter, and (c) preparing and circulating an agenda for the upcoming meeting, but shall have no final decision-making authority. For clarity, the Chairperson shall include in the upcoming agenda any items reasonably requested by any other JSC representative. With the consent of the other Party (such consent not to be unreasonably withheld), other employees or consultants of GSK or Amicus or their respective Affiliates may attend Joint Steering Committee meetings to present information or participate in discussions on an ad hoc basis as non-voting participants or observers. The Parties shall cause their respective members on the Joint Steering Committee to act in good faith in carrying out their activities on the Joint Steering Committee.

4.1.3 <u>Duties of the Joint Steering Committee</u>. The Joint Steering Committee will:

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(a) Review and approve the Development Plans (and the associated budgets for Development Costs included therein) on an annual basis, including any amendments and updates thereto;

(b) Oversee the implementation of the Development Plans by the Parties and each Party's progress towards completion of the activities allocated to such Party under the Development Plans;

(c) Review and approve changes to the Development Plans;

(d) Review and if applicable in accordance with Section 5.1.1(c), approve any necessary amendments to the Development Plans to include Phase IV Clinical Studies, Post-Marketing Commitments, Amicus Territory Required Activities, or GSK Territory Required Activities, if applicable;

(e) Review and approve changes to the Global Commercialization Plan;

(f) Oversee the coordination of global Commercialization activities of Products in the Field and in the Territory during the Term consistent with the Global Commercialization Plan;

(g) Oversee the global Development activities, including all filings and interactions with Regulatory Authorities with respect to obtaining Marketing Approvals for Products in the Amicus Territory and in the Expanded Major Market countries in the GSK Territory;

(h) Designate a Trademark(s) for use on each Product in the Territory;

(i) Subject to Section 11.2, oversee strategy for publications and presentations of clinical trial results and other scientific

information; and

(j) Decide any disputes elevated to the Joint Steering Committee from a Subcommittee in accordance with Section 4.1.5, including any such disputes elevated to the Joint Steering Committee from the Joint Commercialization Subcommittee in accordance with Section 4.2.2 and from the Joint Development Subcommittee in accordance with Section 4.2.3; and

the Parties.

Perform such other duties as are specifically assigned to the JSC in this Agreement or otherwise agreed to in writing by

4.1.4 <u>Committee Meetings</u>. The Joint Steering Committee shall meet at least once per Quarter, or more or less often as otherwise agreed to by the Parties. Joint Steering Committee meetings may be conducted by telephone, video-conference or in person as agreed to by the Parties. Unless otherwise agreed by the Parties, all in-person meetings for the Joint Steering Committee shall be held on an alternating basis between Amicus' facilities and GSK's facilities. Each Party shall

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bear its own personnel and travel costs and expenses relating to Joint Steering Committee or Subcommittee meetings, and such expenses shall not be included in Development Costs.

4.1.5 <u>Decision-Making</u>. Decisions of the Joint Steering Committee shall be made by unanimous vote, with each Party having (1) vote and with at least one (1) representative from each Party participating in any vote. Each Party will use reasonable efforts to achieve consensus on the Joint Steering Committee. In the event that the Joint Steering Committee fails to reach unanimous agreement with respect to a particular matter within its authority within thirty (30) days of the date such matter was first presented to the Joint Steering Committee, then such matter shall be resolved, as follows:

(a) <u>Disputes Related to Development and Regulatory Issues</u>. Either Party may, by written notice to the other Party (an "<u>Escalation Notice</u>"), refer such disputes regarding Development of a Product in the Territory or regulatory issues relating to a Product in the Territory to the Chief Executive Officer of Amicus (or his/her designee) and the GSK Head of Rare Diseases Business Unit (or his/her designee) (the "<u>Senior Executives</u>"). The Parties' respective Senior Executives shall meet promptly, but in any event within thirty (30) days following the referral of such matter to the Senior Executives, and shall negotiate in good faith to resolve such matter. If the Senior Executives are unable to resolve such dispute within ten (10) days following the initial meeting of such Senior Executives, then, except as expressly set forth in Section 4.1.5(a), (i), (ii) or (iii) below, the dispute shall be resolved by the GSK Chairman for Research and Development, and such decision by the GSK Chairman of Research and Development shall become the final decision of the JSC with respect to the dispute specified in the applicable Escalation Notice.

(i) With respect to any such dispute related to the initiation, design, content or conduct of any Amicus Territory Required Activities, if the Senior Executives are unable to resolve such dispute, such dispute will not be resolved by the GSK Chairman for Research and Development, but rather shall be resolved by the Chief Executive Officer of Amicus and such decision by the Chief Executive Officer of Amicus shall become the final decision of the JSC with respect to the dispute; and

(ii) With respect to any such dispute related to the initiation, design, content or conduct of any GSK Territory Required Activities, if the Senior Executives are unable to resolve such dispute, such dispute will not be resolved by the GSK Chairman for Research and Development, but rather such dispute shall be resolved by the GSK Head of Rare Diseases Business Unit (or his or her designee) and such decision by the GSK Head of Rare Diseases Business Unit (or his or her designee) shall become the final decision of the JSC with respect to the dispute; and

(iii) With respect to any such dispute related to amendments to be made to the Co-Formulation Development Plan in accordance with Section 5.1.1(c) below that could result in the amount of Development Costs that Amicus is required to fund pursuant to

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Section 5.1.4(a)(iv) below to exceed the Total Co-Formulation Development Cost Cap, such dispute shall not be resolved by the GSK Chairman of Research and Development and shall be resolved in accordance with Section 5.1.4(b)(ii) below.

(b) <u>Disputes Related to Manufacturing</u>. With respect to any dispute related to the Manufacturing of a Product, each Party shall have final decision-making authority to the extent the matter pertains to the Manufacturing of a Product for such Party's territory (i.e., GSK shall have final decision making authority to the extent the matter pertains to Manufacturing of Products for, by, or on behalf of GSK for use or sale in the GSK Territory and Amicus shall have final decision making authority to the extent the matter pertains to Manufacturing of Products for, by, or on behalf of Amicus for use or sale in the Amicus Territory), without the need to further escalate such dispute.

(c) <u>Disputes Related to Commercialization of Product</u>. With respect to any dispute related to the Commercialization of a Product, each Party shall have final decision making authority to the extent the matter pertains to the Commercialization of a Product in such Party's respective Territory (i.e., GSK shall have final decision making authority to the extent the matter pertains to Commercialization of Products in the GSK Territory and Amicus shall have final decision making authority to the extent the matter pertains to Commercialization of Products in the Amicus Territory), without the need to further escalate such dispute; <u>provided</u> that each Party shall exercise its final-decision making authority with respect to matters pertaining to Commercialization in its respective Territory in a manner that is consistent with the Global Commercialization Plan. In addition, with respect to any dispute relating to the Global Commercialization Plan, including any changes thereto, neither Party shall have final decision making authority if the Parties are unable to mutually agree in accordance with Section 6.1.

4.2 <u>Subcommittees</u>. From time to time, the Joint Steering Committee may establish subcommittees to oversee particular projects or activities within the scope of authority of the Joint Steering Committee, as it deems necessary or advisable (each, a "<u>Subcommittee</u>"). Unless otherwise set forth in the Agreement, each Subcommittee shall consist of such number of representatives of each Party as the Joint Steering Committee determines is appropriate from

time to time. Each Subcommittee shall meet with such frequency as the Joint Steering Committee shall determine. Each Subcommittee shall operate by unanimous vote in all decisions, with each Party having one (1) vote and with at least one (1) representative from each Party participating in such vote. If, with respect to a matter that is subject to a Subcommittee's decision-making authority, the Subcommittee cannot reach unanimity, except with respect to the Joint Patent Subcommittee, the matter shall be immediately referred to the Joint Steering Committee, which shall resolve such matter in accordance with Section 4.1.5.

4.2.1 <u>Joint Patent Subcommittee</u>. Amicus and GSK shall continue to use the joint Patent Subcommittee ("<u>Joint Patent Subcommittee</u>") that was formed under the Original Agreement to oversee the Patent issues pertaining to the Compound and Products. The Joint Patent

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Subcommittee will be composed of one (1) representative (or such other number of representatives as the Parties may agree) from each of the Parties. The Joint Patent Subcommittee will serve as the forum to review and discuss and decide, in the first instance, all matters relating to Patents and Know-How included in Amicus Intellectual Property, Program Improvements and Program Patents, and Co-Formulation Product IP. The Joint Patent Subcommittee shall select Patent counsel to file and prosecute Patent applications included in Amicus Intellectual Property, or constituting Program Patents, and constituting Co-Formulation Product IP and will promptly report all discussions and decisions to the Joint Steering Committee. The Joint Patent Subcommittee shall operate by unanimous vote in all decisions, with each Party having one (1) vote and with at least one (1) representative from each Party participating in such vote. If the Joint Patent Subcommittee is unable to agree on any matter considered by the Joint Patent Subcommittee within ten (10) days after first considering such matter, it shall seek the opinion of mutually acceptable outside counsel's opinion, such matter shall be referred to the Senior Executives for resolution. If, after referral to the Senior Executives, notwithstanding anything to the contrary in Section 4.1.5, the matter has not been resolved, the Senior Executive of Amicus, not GSK, shall make the final decision with respect to any dispute pertaining to a Patent for which Amicus has responsibility for the prosecution and maintenance of such Patent pursuant to Section 7.2, 7.3, or 7.6 below (which decision shall become the decision of the Joint Patent Subcommittee, any of the ten (10) days time limits in this Section 4.2.1 may be shortened.

4.2.2 Joint Commercialization Subcommittee.

(a) <u>Formation</u>. Promptly after the Restatement Effective Date, the Parties will form a joint commercialization Subcommittee ("<u>Joint Commercialization Subcommittee</u>") to oversee, coordinate and review the conduct of the Commercialization and marketing activities for Products in the GSK Territory and Amicus Territory in accordance with the Global Commercialization Plan. The Joint Commercialization Subcommittee will be composed of at least two (2) representative(s) (or such other number of representatives as the Parties may agree) from each of the Parties. The Joint Commercialization Subcommittee shall provide regular updates to the JSC as provided in Section 4.2.2(c) to ensure that the JSC is informed of all activities conducted by, and decisions made by, the Joint Commercialization Subcommittee.

(b) <u>Duties</u>. The Joint Commercialization Subcommittee will:

(i) Develop the Global Commercialization Plan for the Parties' mutual agreement in accordance with Section 6.1 and the Global Commercialization Plan guidelines attached hereto as <u>Schedule 6.1</u>;

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(ii) Subject to Section 6.1, oversee, coordinate and implement the Global Commercialization Plan during the Term, including reviewing any and all changes thereto;

Territory;

(iii) Designate and approve GSK Trademark(s) to be used by each Party in connection with the Products in the

(iv) Oversee and coordinate the Commercialization activities in accordance with the Global Commercialization Plan for Products in the Field and in the GSK Territory and the Amicus Territory during the Term;

(v) Review the Ex-U.S. Commercialization Plan, Ex-U.S. Commercialization Strategy, U.S. Commercialization Plan and U.S. Commercialization Strategy, including any amendments and updates thereto and the implementation of the Ex-U.S. Commercialization Plan and Ex-U.S. Commercialization Strategy by GSK, its Affiliates and Sublicensees and of the U.S. Commercialization Plan and U.S. Commercialization Strategy by Amicus, its Affiliates and Sublicensees, in each case with the goal to ensure that such Commercialization Plans and Commercialization Strategies are consistent with the guidelines and principles set forth in the Global Commercialization Plan;

(vi) Provide a forum for the Parties to exchange information and coordinate their respective activities as set forth in this Agreement with respect to matters pertaining to the Commercialization for Products in the GSK Territory and the Amicus Territory, as applicable; and

(vii) Perform such other duties as are specifically assigned to the Joint Commercialization Subcommittee in this Agreement or delegated to the Joint Commercialization Subcommittee by the JSC.

(c) <u>Decision-Making; Reports</u>. It is understood and agreed that the Joint Commercialization Subcommittee shall function primarily to facilitate coordination of global Commercialization activities of the Parties with respect to all Product(s) Commercialized in the Territory hereunder. The Joint Commercialization Subcommittee shall provide quarterly summary updates to the JSC with respect to activities conducted by the Joint Commercialization Subcommittee hereunder. Except with respect to decisions made by the Joint Commercialization Subcommittee with respect to activities of the Parties and the state of the state of the Parties and the state of the st

the matters set forth in Section 4.2.2(b)(iii), which shall be fully and finally determined by the GSK representatives on the Joint Commercialization Subcommittee without escalation to the JSC and without being submitted for resolution in accordance with Section 16.2.3, any and all disputes at the JCS level shall be referred to the JSC as provided in Section 4.2 above. Any disputes of the JSC with respect to any such matters shall be determined in accordance with Section 4.1.5(c).

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## 4.2.3 Joint Development Subcommittee.

(a) Formation. Amicus and GSK shall continue to work through the current medicine development team for global development of the Product(s) and such medicine development team as modified herein shall be, as of the Restatement Effective Date, deemed the Joint Development Subcommittee ("JDS"). In addition, the Joint Steering Committee may elect, upon recommendation of the JDS if necessary, to divide the Joint Development Subcommittee into two (2) or more Joint Development Subcommittees, each with the responsibility for a specific Product under this Agreement. The Joint Development Subcommittee shall be chaired by a GSK representative, who shall be responsible for, among other similar tasks, (a) calling and managing the conduct of meetings, (b) preparing and issuing minutes of each such meeting within thirty (30) days thereafter and (c) preparing and circulating an agenda for the upcoming meeting, but shall not have any final decision making authority. The chairperson of the JDS shall include in the upcoming agenda any items reasonably requested by any other JDS member. The total number of representatives on the JDS shall be (13) representatives. Each Party will designate six (6) of its representatives on the JDS, and GSK shall designate a seventh (7<sup>th</sup>) representative to serve as Chairperson of the JDS Either Party may invite additional employees of such Party to attend certain JDS meetings as appropriate on an ad hoc basis as non-voting observers, subject to the confidentiality provisions of Article XI. In addition, with respect to Joint Development Subcommittee meetings regarding the Development of the Co-Formulation Product and/or activities pursuant to the Co-Formulation Development Plan, GSK may elect for designated individuals from JCR to attend and participate in such Joint Development Subcommittee meetings, solely in the capacity of designated GSK agents. The Joint Development Subcommittee shall have global oversight and shall review and approve the global activities and Development Plans for Development of all Product(s) in the Territory, subject to the terms and conditions set forth in this Article IV and in Article V. The Joint Development Subcommittee shall provide regular updates to the JSC as provided in Section 4.2.3(c) to ensure that the JSC is informed of all activities conducted by, and decisions made by, the Joint Development Subcommittee.

(b) <u>Duties</u>. The Joint Development Subcommittee will:

(i) Subject to Section 5.1.1(a) and (b), develop and discuss the Development Plans for all activities to be conducted in the Territory with respect to each Product;

(ii)Subject to Section 5.1.1(c), review and approve any and all changes to the Development Plans in the GSK<br/>Amicus Territory;(iii)Coordinate and oversee any and all Development activities for Products in the GSK Territory and in the<br/>Oversee the budget for the conduct of activities under each Development Plan;

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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(v) Subject to Section 5.1.5, coordinate and oversee all Post-Marketing Commitment activities and coordinate all Amicus Territory Required Activities and GSK Territory Required Activities;

(vi) Subject to Section 5.3, determine, coordinate and oversee strategy for establishing and expanding labeling of the Products in the Amicus Territory or GSK Territory, as applicable,

scientific information;

(vii) Subject to Section 11.2, oversee strategy for publications and presentations of clinical trial results and other

(viii) Subject to Section 6.5.4, determine and coordinate amounts of clinical supply of Compound and Product(s) required by each Party for the conduct of activities pursuant to the Development Plan(s); and

(ix) Perform such other duties as are specifically assigned to the Joint Development Subcommittee in this Agreement or delegated to the Joint Development Subcommittee by the JSC.

(c) <u>Decision-making; Reports</u>. Decisions of the Joint Development Subcommittee shall be made by unanimous vote, with each of Amicus and GSK having one (1) vote and with at least one (1) representative from each Party participating in any vote. The Joint Development Subcommittee shall provide quarterly summary updates to the JSC with respect to activities conducted by the Joint Development Subcommittee hereunder. It is understood and agreed that all disputes at the JDS level shall be referred to the JSC as provided in Section 4.2 above. Any disputes of the JSC with respect to any such matters shall be determined in accordance with Section 4.1.5(a).

4.3 <u>Alliance Managers</u>. Each Party has appointed a representative ("<u>Alliance Manager</u>") to facilitate communications between the Parties and to act as a liaison between the Parties with respect to such matters as the Parties may mutually agree in order to maximize the efficiency of the collaboration. Unless replaced by a Party in accordance with this Section 4.3, each Party's Alliance Manager as of the Restatement Effective Date shall continue as such Party's Alliance Manager for the collaboration. Each Alliance Manager shall be permitted to attend meetings of the JSC, JDS, and JCS as a nonvoting observer, subject to the confidentiality provisions of Article XI. Each Party may replace its Alliance Manager with an alternative representative at any time with prior written notice to the other Party.

4.4 <u>General Communications</u>. Each Party shall keep the other Party informed, by way of updates to the Joint Steering Committee at its meetings and as otherwise specified in this Agreement, or as reasonably requested by the other Party, as to its progress and activities relating to the Development of the Products in the Territory (including with respect to regulatory matters and meetings with Regulatory Authorities in such Party's territory), and the Commercialization of the

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Products in such Party's respective territory (i.e., in the case of GSK, the GSK Territory and in the case of Amicus, the Amicus Territory). In connection therewith, Amicus and GSK shall provide each other through the Joint Steering Committee, the Joint Development Subcommittee, and the Joint Commercialization Committee with such information regarding such progress and activities under the Development Plan and/or the U.S. Commercialization Plan or Ex-U.S. Commercialization Plan, or otherwise relating to Products, as the other Party may request from time to time.

4.5 <u>Scope of Governance</u>. Notwithstanding the creation of the Joint Steering Committee, or any Subcommittee (including the Joint Patent Subcommittee, Joint Development Subcommittee and Joint Commercialization Subcommittee), each Party shall retain the rights, powers and discretion granted to it hereunder, and neither the Joint Steering Committee nor any Subcommittee 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. Neither the Joint Steering Committee, nor any Subcommittee, will have the power to amend or modify, or waive compliance with, this Agreement, and no decision of the Joint Steering Committee, or any Party exercising a deciding vote as provided in Section 4.1.5, Section 4.2.1 or Section 4.2.2(b), as applicable, shall be in contravention of any terms and conditions of this Agreement or shall result in any obligations (including any obligation to incur or assume any financial or other commitment, including without limitation allocation of additional FTEs to the Program) being imposed on Amicus or its Affiliates, or GSK or its Affiliates, except as otherwise expressly set forth herein, without the express prior written consent of Amicus or GSK, as applicable. It is understood and agreed that issues to be formally decided by the Joint Steering Committee or such Subcommittee are only those specific issues that are expressly provided in this Agreement to be decided by the Joint Steering Committee or such Subcommittee.

# V. <u>PRODUCT DEVELOPMENT AND REGULATORY ACTIVITIES</u>

5.1 <u>Product Development</u>. Subject to Section 4.1.3(a) through (d) and (g) and Section 4.1.5, the Joint Steering Committee will oversee Development of the Products in the Territory in accordance with the then-current Development Plans (including the associated budgets). Oversight and, subject to Section 4.1.5(a), decision-making authority with respect to all Development activities for the Product(s) in the Territory, shall be the responsibility of the Joint Development Subcommittee. In addition, the Joint Development Subcommittee, subject to Section 5.5.2, shall oversee and conduct all global patient advocacy activities and, subject to Section 5.5.1, shall coordinate medical affairs activities.

# 5.1.1 <u>Development Plans</u>.

(a) <u>Existing Development Plan</u>. It is understood that during the period of time from the Effective Date and through the Restatement Effective Date, the Parties have conducted Development activities pursuant to a development plan and corresponding budget under the Original Agreement for a Monotherapy Product and a Co-Administration Product in the Field in the Territory

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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(the "Existing Development Plan"). The Existing Development Plan in effect as of the Restatement Effective Date is attached to this Agreement as <u>Schedule 5.1</u>. As of the Restatement Effective Date, the Existing Development Plan shall continue in effect with respect to the Parties' global Development of any Products (other than Co-Formulation Products) in the Territory and shall continue to govern the Development activities with respect to the existing Monotherapy Product and Co-Administration Product under this Agreement for all purposes. The Existing Development Plan may be amended from time to time by the Joint Development Subcommittee and the JSC in accordance with Section 5.1.1(c) below. Without limiting this Section 5.1.1(a) and except as set forth in Section 5.1.5, it is understood that the Existing Development Plan will at all times provide for Amicus and for GSK to have an active role in the Development activities for the Development of all Products (other than Co-Formulation Products) in the Field.

(b) <u>Co-Formulation Development Plan</u>. A preliminary Co-Formulation Development Plan and associated preliminary budget for the Development of Co-Formulation Products for intravenous and subcutaneous deliveries in the Field in the Territory is attached to this Agreement as <u>Schedule 5.1B</u> and sets out separately the Development activities for a Co-Formulation Product to be conducted by each Party following the Restatement Effective Date and a budget for such activities (the "<u>Co-Formulation Development Plan</u>"). The Co-Formulation Development Plan shall be deemed to be a Development Plan under this Agreement for all purposes, and may be amended by the Joint Development Subcommittee and the JSC in accordance with Section 5.1.1(c) below. In addition, unless expressly agreed in writing by the Joint Development Subcommittee, the Co-Formulation Development Plan shall include the use of JR051 as the Co-Formulation Product ERT Enzyme. Without limiting this Section 5.1.1(b), it is understood that the Co-Formulation Development Plan will at all times provide for Amicus and for GSK to have an active role in the Development activities for the Development of Co-Formulation Products in the Field.

(c) <u>Amendments</u>. Subject to Section 4.1.3(a) through (d) and (g), Section 4.2.3(b)(ii), and Section 5.1.4, the Joint Steering Committee shall review each of the Existing Development Plan(s) and the Co-Formulation Development Plan on an ongoing basis and no less frequently than once each calendar year and shall amend each of the then-current Existing Development Plan(s) and the then-current Co-Formulation Development Plan(s), based upon amendments made by the Joint Development Subcommittee pursuant to Section 4.2.3(b) during such calendar year and proposals made to the JSC by the Joint Development Subcommittee pursuant to Section 4.2.3(b), as necessary to include a reasonably detailed written plan of the Joint Development Subcommittee's then-current estimate of the Development activities with respect to the applicable Product(s) (and associated budget) \*\*\*\*\*\* of the period covered by such plan and an outline of Development activities with respect to the applicable Product(s) (and the associated budget for such Development activities) \*\*\*\*\*\*. Subject to Sections 4.1.5(a) and 5.1.4, the JSC shall agree upon any amendments to be made to each Development Plan, including any changes to the budget or timelines for each such Development Plan, \*\*\*\*\*\*, provided that the JSC shall, to the extent possible, \*\*\*\*\*\*. Notwithstanding the foregoing, the JSC shall agree upon any extensions to the

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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timelines in each Development Plan that result directly from (i) material changes to any activities pertaining to the goals specified in such Development Plan that are required or reasonably requested by the FDA or other Regulatory Authority in a Major Market, such that if not performed, is likely, in the reasonable judgment of the JSC, to jeopardize the receipt of Marketing Approval of a Product in any such Major Market or (ii) other factors beyond a Party's reasonable control. The preliminary agreed-upon annual allocation of Amicus and GSK FTEs with respect to the conduct of the Development activities in the Field and in the Territory for Monotherapy Products and Co-Administration Products is set forth in Schedule 5.1.1(c), attached hereto and incorporated herein by reference. The preliminary agreed-upon annual allocation of Amicus and GSK FTEs with respect to the conduct of the Development activities for Co-Formulation Product(s) in the Field and in the Territory shall be set forth in the applicable Co-Formulation Development Plan(s). Unless otherwise mutually agreed by the Parties in writing, in the event that the JDS and/or JSC modify an Existing Development Plan or a Co-Formulation Development Plan, as applicable, such that the total allocated Amicus FTEs for a given calendar year are reduced by \*\*\*\*\*\* or more under such Existing Development Plan or Co-Formulation Development Plan, as applicable, the JDS and/or JSC, as applicable, shall provide Amicus with a \*\*\*\*\* advanced written notice of such reduction in the allocation of Amicus FTEs prior to the implementation of such reduction. The Parties agree that the priority for Development activities under the then-current Existing Development Plan(s) shall be the Development activities for the Monotherapy Products in the Field and in the Territory. Notwithstanding the foregoing, at all times during the conduct of activities under the applicable Development Plan, each Party shall commit at least the minimum FTE resources allocated to such Party for the conduct of the applicable activities pursuant to such Development Plan. If the Joint Development Subcommittee and/or the JSC, as applicable, is unable to agree upon any changes to be made to a Development Plan, including the budget included therein (subject to Section 5.1.4 below), then, until such time as a revised Development Plan is approved by the JSC, or established pursuant to Section 4.1.5(a) above: (1) the then-current Development Plan shall continue to govern the Parties' respective Development activities with respect to the applicable Products under this Agreement; and (2) each Party shall be permitted to conduct and/or commence Development activities allocated to such Party in such preceding Development Plan and incur Development Costs consistent with such preceding Development Plan, which Development Costs shall be shared by the Parties in accordance with Sections 5.1.4 and 5.1.5 below and Schedule 5.1.4.

5.1.2 <u>Conduct of Development Activities</u>. Each Party shall conduct those activities allocated to such Party under the Development Plans in compliance in all material respects in accordance with good scientific and clinical practices, and Laws applicable in the country in which such activities are conducted.

5.1.3 <u>Diligence</u>. Each Party shall use Commercially Reasonable Efforts to carry out all clinical Development and other activities allocated to such Party in the Development Plans attached to this Agreement as <u>Schedules 5.1A</u> and <u>5.1B</u>. Following the Restatement Effective Date and with oversight by the Joint Development Subcommittee and the Joint Steering Committee, each of Amicus and GSK shall continue to conduct the activities allocated to Amicus or GSK, as

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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applicable, including the conduct of the existing 011 Phase III Clinical Study, the 012 Phase III Clinical Study, the 013 Clinical Study, the 014 Clinical Study, and the 015 Clinical Study; in each case as set forth in the Existing Development Plan, and as amended. Except as otherwise mutually agreed in writing by the Parties, such efforts by each Party shall include, but shall not be limited to, use of Commercially Reasonable Efforts: (a) to achieve the specific overall Development goals as set forth in the applicable Development Plan for each Product; and (b) to achieve such Development goals in accordance with the timelines specified in the applicable Development Plan. In addition, Amicus shall use its Commercially Reasonable Efforts to obtain Regulatory Approval for at least \*\*\*\*\* Monotherapy Product and \*\*\*\*\* Co-Formulation Product in the Field in the Amicus Territory.

5.1.4 <u>Allocation of Funding of Development Plans</u>. Subject to the terms and conditions of this Agreement (including Sections 5.1.5 and 5.4 below), Amicus and GSK shall share in the Development Costs to jointly fund the Development of Monotherapy Products and Co-Administration Products for the Territory pursuant to the Existing Development Plan, and Co-Formulation Products for the Territory pursuant to the Co-Formulation Development Plan as follows and in accordance with the provisions of <u>Schedule 5.1.4</u>, excluding the Amicus Territory Required Activities and the GSK Territory Required Activities.

## (a) <u>Existing Development Plan for the Monotherapy Product and Co-Administration Product</u>.

(i) Subject to Section 5.1.4(a)(iv), from the Restatement Effective Date through and until December 31, 2012, Amicus shall fund an amount equal to twenty-five percent (25%) of the Development Costs as set forth in the then-current Existing Development Plan, in each case incurred in the conduct of Development activities under and in accordance with such Development Plan; <u>provided</u> that Amicus shall not be obligated to fund more than an amount equal to the Amicus Existing Annual Cost Cap for calendar year 2012. GSK shall fund the remaining Development Costs incurred in the conduct of activities during such period pursuant to the then-current Existing Development Plan for the calendar year 2012.

(ii) Except as provided in Section 5.1.5 below and subject to Section 5.1.4(a)(iv), from January 1, 2013 and for each calendar year (or part thereof) thereafter until the Amicus Aggregate Existing Development Cost Cap is reached, Amicus shall fund on an annual basis forty percent (40%) of the Development Costs incurred under and in accordance with the then-current Existing Development Plan during each calendar year of such period; <u>provided</u> that Amicus shall not be obligated to fund more than an amount equal to the Amicus Annual Existing Development Cost Cap for each such calendar year, and GSK shall fund the remaining Development Costs incurred in the conduct of Development activities pursuant to the Existing Development Plan for each such calendar year.

(iii) To the extent that, for any calendar year commencing with calendar year 2013, Amicus has been required pursuant to Section 5.1.4(a)(ii) above to fund an amount of Development Costs less than the applicable Amicus Annual Existing Development Costs for such calendar year being less than the amount of Development Costs budgeted in the then-current Existing Development Plan for such calendar year, then the difference between the applicable Amicus Annual Existing Development Plan for such calendar year, then the difference between the applicable Amicus Annual Existing Development Plan for such calendar year, then the difference between the applicable Amicus Annual Existing Development Costs incurred under such Existing Development Plan for such calendar year actually required to be paid by Amicus pursuant to Section 5.1.4(a)(ii) above shall be carried forward into the next calendar year and added to the applicable Amicus Annual Existing Development Cost Cap for that subsequent calendar year and each subsequent year thereafter until such "carry-forward" amounts are exhausted.

#### (b) <u>Co-Formulation Development Plan</u>.

(i) Subject to Section 5.1.4(b)(ii) and Section 5.1.5, from the Restatement Effective Date through and until December 31, 2012, and for each calendar year (or part thereof) thereafter, Amicus shall fund forty percent (40%) of the actual Development Costs incurred in the conduct of Development activities under and in accordance with the then-current Co-Formulation Development Plan for each such calendar year, and GSK shall fund the remaining sixty percent (60%) of the actual Development Costs incurred in the conduct of Development Plan for each such calendar year.

(ii) If any amendments to be made to the Co-Formulation Development Plan by the Joint Development Subcommittee pursuant to Section 4.2.3(b)(ii), or by the JSC in accordance with Section 4.1.3 and Section 5.1.1(c) above, based upon proposals made to the JSC by the Joint Development Subcommittee pursuant to Section 4.2.3(b), would result in the amount of Development Costs incurred under and in accordance with the amended Co-Formulation Development Plan to meet or exceed the Total Co-Formulation Development Cost Cap, then the

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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Joint Development Subcommittee shall \*\*\*\*\*. Until such time as an amended Co-Formulation Development Plan is established pursuant to this Section 5.1.4(b)(ii): (1) the then-current Co-Formulation Development Plan shall continue to govern the Parties' respective Development activities with respect to the Co-Formulation Product under this Agreement; and (2) each Party shall be permitted to conduct and/or commence Development activities allocated to such Party in such preceding Co-Formulation Development Plan and incur Development Costs consistent with such preceding Co-Formulation Development Plan, which Development Costs shall be shared by the Parties in accordance with this Section 5.1.4 above and Section 5.1.5 below and <u>Schedule 5.1.4</u>.

5.1.5 Determination of Amicus Territory Required Activities and GSK Territory Required Activities; Opt-In Notice.

- (a) \*\*\*\*\*
- (b) \*\*\*\*\*.

(c) Amicus or GSK, as applicable, shall provide regular summary updates and reports of all then-existing data and information generated by such Party in the conduct of such Amicus Territory Required Activities or GSK Territory Required Activities, as applicable (such summary reports and updates to be provided with at least the frequency with which such reports are provided by each Party to the Joint Development Subcommittee), and shall make all data, results, information and analysis with respect to such activities available to the other Party in accordance with the terms of Section 5.2.3. If, at any time after the initiation of such activities, \*\*\*\*\*.

(i) Within \*\*\*\*\* from the receipt of an invoice:

			a)	*****
			b)	*****
5.1.6	****	*.		
	(a)	*****		
	(b)	*****		

5.1.7 <u>Use of Clinical Trial Data</u>. Subject to Section 2.1, Amicus shall make available to GSK, and GSK shall have complete access to, at no charge to GSK, all clinical trial data and all additional data resulting from any clinical trials performed by Amicus, its Affiliates, Sublicensees or licensees with respect to the Products in the Territory, including without limitation all such clinical trial data and all additional data resulting from the conduct of any Amicus Territory Required Activities or TTP New Labeling activities. Subject to Sections 5.1.4, 5.1.5, and 5.3, GSK shall be free to use all such data and information, as necessary or as required, to support the

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Development and Manufacture of the Compound and Products under the applicable Development Plan and the Commercialization of the Products in the GSK Territory, including in connection with any safety assessments, safety reports, or annual reports required to be filed with the relevant Regulatory Authority with respect to the Products in the GSK Territory, in each case accordance with the terms and conditions of this Agreement. Likewise, subject to Section 2.4, GSK shall make available to Amicus, and Amicus shall have complete access to, at no charge to Amicus, all clinical trial data and all additional data resulting from any clinical trials performed by GSK, its Affiliates, or Sublicensees with respect to the Products in the Territory, including without limitation all such clinical trial data and all additional data resulting from the conduct of any GSK Territory Required Activities or TTP New Labeling activities. Subject to Sections 5.1.4, 5.1.5, and 5.3, Amicus shall be free to use all such data and information, as necessary or as required, to support the Development and Manufacture of the Compound and Products under the applicable Development Plan and the Commercialization of the Products in the Amicus Territory, including in connection with any safety assessments, safety reports, or annual reports required to be filed with the relevant Regulatory Authority with respect to the Products in the Amicus Territory, in each case in accordance with the terms and conditions of this Agreement. For the avoidance of doubt, the foregoing obligation of GSK shall not include \*\*\*\*\*\*. For the avoidance of doubt, the Licensed Amicus Technology shall include any and all data resulting from any clinical trials performed by Amicus, its Affiliates, its Sublicensee and its licensees in the Territory with respect to the Products (excluding data resulting from any clinical trials performed with respect to products other than the Products that relate to the Amicus Proprietary Chaperone Technology), to the extent that Amicus has the right to grant to GSK access to such data from its Sublicensees and licensees. In the event that Amicus does not have the right to grant to GSK access to such data from such Sublicensees or licensees, then Amicus shall use all reasonable efforts to obtain the right, at no cost to GSK, to sublicense to GSK, or otherwise obtain the right for GSK to access and make any other use of any such clinical trial data within the scope of the License and otherwise in accordance with the terms and conditions of this Agreement; provided that in no event shall Amicus be obligated to undertake additional payment obligations to such Sublicensees or licensees in order to obtain such rights for GSK, unless GSK agrees to reimburse Amicus for such additional payment obligations with respect to the grant of rights to GSK for such clinical trial data. Similarly, the licenses granted by GSK to Amicus in Section 2.4 herein shall be deemed to include a license to any and all data resulting from any clinical trials performed by GSK, its Affiliates, its Sublicensees and its licensees in the Territory with respect to the Products (\*\*\*\*\*), in each case to the extent that GSK has the right to grant to Amicus access to such data from such Sublicensees or licensees. In the event that GSK does not have the right to grant to Amicus access to such data from such Sublicensees or licensees, then GSK shall use all reasonable efforts to obtain the right, at no cost to Amicus, to sublicense to Amicus, or otherwise obtain the right for Amicus to access and make any other use of any such clinical trial data within the scope of the licenses granted to Amicus in Section 2.4 and otherwise in accordance with the terms and conditions of this Agreement; provided that in no event shall GSK be obligated to undertake additional payment obligations to such Sublicensees or licensees in order to obtain such rights for Amicus, unless Amicus agrees to reimburse GSK for such additional payment obligations with respect to the grant of rights to Amicus for such clinical trial data.

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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## 5.2 <u>Regulatory Matters</u>.

5.2.1 <u>Assignment of, and Responsibility for, Regulatory Filings</u>. Amicus and GSK acknowledge that following the Effective Date, Amicus transferred and assigned to GSK ownership of all Marketing Approvals and other agreed upon filings (if applicable) with Regulatory Authorities for the Products in the Territory existing as of the Effective Date.

(a) As of the Restatement Effective Date, GSK shall own and shall have the sole responsibility, as overseen by the Joint Steering Committee and Joint Development Subcommittee during the Development of Products, to hold and maintain all Marketing Approvals and other filings with Regulatory Authorities for the Products in the GSK Territory during the Term; provided, however, that Amicus shall continue to hold and maintain the IND filings for the existing 011 Phase III Clinical Study, the 012 Phase III Clinical Study, the 013 Clinical Study, and the 205 Clinical Study in the GSK Territory and will continue, in collaboration with GSK and as requested by the Joint Development Subcommittee, to submit any necessary clinical study protocol amendments for such clinical studies, as necessary, in each case until the completion of the relevant clinical study , after which Amicus shall assign and transfer such IND filing for such completed clinical study to GSK in accordance with reasonable a timeline and process to be agreed between the Parties. GSK will be solely responsible for submitting to, and obtaining INDs, MAAs and/or Marketing Approvals (including pricing or reimbursement approvals) from, the applicable Regulatory Authorities in connection with the Development, Manufacture, use, and Commercialization of the Products in the GSK Territory as overseen by the Joint Steering Committee and Joint Development Subcommittee. GSK shall also be responsible for filing and maintaining any regulatory filings required to be submitted to the relevant Regulatory Authority with respect to the Products in the GSK Territory, and for obtaining any export approvals required by a relevant Regulatory Authority to import or export Compound or Products to any country within the GSK Territory or the Amicus Territory. All such activities shall be conducted via the Joint Steering Committee in accordance with the applicable Development Plan, and in accordance with the terms of this Article V.

(b) Following the Restatement Effective Date:

(i) With respect to the Monotherapy Product, subject to the oversight of the Joint Steering Committee and Joint Development Subcommittee, GSK shall hold and maintain the IND for the Monotherapy Product filed with the Regulatory Authorities in the Amicus Territory as of the Restatement Effective Date and, until the assignment and transfer of the NDA for the Monotherapy Products in the Amicus Territory to Amicus as set forth in this Section 5.2.1(b)(i), GSK shall continue to lead the liaison with, and manage, all interactions with Regulatory Authorities in the Amicus Territory with respect to the Monotherapy Products in accordance with Section 5.2.2(a). GSK shall further prepare and submit to the FDA, subject to the oversight of the Joint Steering Committee and Joint Development Subcommittee, the first NDA for a

Monotherapy Product in the Amicus Territory, and upon the earlier of (a) \*\*\*\*\*\*, or (b) \*\*\*\*\*\*, GSK shall promptly assign to Amicus ownership of all existing regulatory filings (including the IND and NDA for the Monotherapy Products, and the orphan product designation, in the Amicus Territory) for the Monotherapy Products in the Amicus Territory and transfer to Amicus the NDA, and the orphan product designation, for the Monotherapy Products in the Amicus Territory, and GSK shall, within \*\*\*\*\* thereafter or such shorter period of time to be mutually agreed by the Parties, transfer to Amicus the IND, NDA and orphan product designation for the Monotherapy Products in the Amicus Territory in accordance with a transition plan to be determined and overseen by the Joint Development Subcommittee; \*\*\*\*\*\*. Following the assignment and transfer of the NDA for the Monotherapy Products in the Amicus Territory to Amicus as set forth in this Section 5.2.1(b)(i), Amicus shall own and shall have the sole responsibility, as overseen by the Joint Steering Committee and Joint Development Subcommittee during the Development of the Products, for submitting and obtaining INDs, MAAs and/or Marketing Approvals (including pricing or reimbursement approvals) from the applicable Regulatory Authorities in connection with the Development, Manufacture, use, and Commercialization of the Monotherapy Products in the Amicus Territory and shall lead the liaison with, and manage, all interactions with Regulatory Authorities in the Amicus Territory with respect to the Monotherapy Products as set forth in and subject to Section 5.2.2(a), including responsibility for responding to any inquires of the Regulatory Authority with respect to any such regulatory filings, including the NDA for the Monotherapy Products in the Amicus Territory, and including holding any requested of required advisory committee meetings with respect thereto, in each case subject to the reasonable input and participation of GSK as set forth in Section 5.2.2(a); and Amicus shall own and shall have the sole responsibility, as overseen by the Joint Steering Committee and Joint Development Subcommittee during the Development of the Monotherapy Products, to hold and maintain all Marketing Approvals and other filings and submissions with Regulatory Authorities for the Monotherapy Products in the Amicus Territory.

(ii) Except as set forth in Section 5.2.1(b)(i) with respect to the Monotherapy Product, following the Restatement Effective Date and subject to Section 5.2.2 and the terms of this Agreement, Amicus shall be solely responsible for submitting to and obtaining from the applicable Regulatory Authorities in the Amicus Territory any new INDs, MAAs and/or Marketing Approvals in connection with activities for the Development, Manufacture (as permitted under this Agreement and the Supply Agreement), use, and Commercialization of the Products in the Amicus Territory, as overseen by the Joint Steering Committee and Joint Development Subcommittee and consistent with the then-current Development Plan for such Product. Amicus shall also be responsible for filing and any maintaining any regulatory filings required to be submitted to the relevant Regulatory Authority with respect to the Products in the Amicus Territory, including any annual reports with respect to Products in the Amicus Territory, and for obtaining any export approvals required by a relevant Regulatory Authority for Amicus to import or export Products into or out of the Amicus Territory. All such activities shall be conducted via the Joint Steering Committee and Joint Development Subcommittee in accordance with the applicable Development Plan, and in accordance with the terms of this Article V.

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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#### 5.2.2 <u>Regulatory Cooperation</u>.

From and after the Restatement Effective Date, GSK shall lead the liaison with, and manage, all interactions with (a) Regulatory Authorities in the GSK Territory in relation to Products during the Term of the Agreement, in each case subject to the reasonable input and participation of Amicus as set forth in this Section 5.2.2(a) below. From and after the Effective Date and until the assignment of the NDA for the Monotherapy Products in the Amicus Territory to Amicus as set forth in Section 5.2.1(b)(i), GSK shall lead the liaison with, and manage, all interactions with Regulatory Authorities in the Amicus Territory in relation to the Monotherapy Product. Subject to Section 4.1.5 and 5.2.1(b)(i), \*\*\*\*\*\*. In any event, the following provisions shall apply to each Party with respect to its respective territory (i.e., in the case of Amicus, the Amicus Territory and in the case of GSK, the GSK Territory) and shall also apply to GSK with respect to the Monotherapy Product in the entire Territory until the assignment and transfer of the NDA for the Monotherapy Product in the Amicus Territory to Amicus as set forth in Section 5.2.1(b)(i), after which such provisions shall only apply to GSK, with respect to the Monotherapy Product, in the GSK Territory: Each Party shall keep the other Party, via the Joint Development Subcommittee and the Joint Steering Committee informed with respect to all interactions with Regulatory Authorities in the United States or Expanded Major Markets in such Party's respective Territory, including without limitation providing a copy of all material correspondence and proposed responses to any material communications from such Regulatory Authorities to the other Party, and will reasonably consider in good faith the comments of such other Party with respect to such activities. Each Party will also provide reasonable cooperation and assistance to the other Party, as reasonably requested by the other Party, in the event that such other Party must respond to questions from Regulatory Authorities in such other Party's Territory concerning Development or Manufacturing activities conducted by or on behalf of a Party with respect to the Products. Each Party (the "Non-Hosting Party") shall have the right to have up to \*\*\*\* representatives in attendance at all meetings of the other Party (the "Host Party") with Regulatory Agencies in the United States or Expanded Major Markets in the other Party's respective Territory (i.e., with respect to Amicus, the United States, and with respect to GSK, each Major EU Country, \*\*\*\*\* and \*\*\*\*\*\*), and up to \*\*\*\*\*\* representatives in attendance at all advisory board or advisory committee meetings and discussions held by the Host Party regarding the Products; provided that if a Regulatory Authority limits the number of representatives in attendance at such meeting, then the Host Party shall have the right to have up to \*\*\*\*\*\* representatives in attendance before the Non-Hosting Party shall have the right to have up to \*\*\*\*\*\* representatives in attendance, unless the limit is \*\*\*\*\* representatives or less in total, in which case, the Non-Hosting Party shall have the right to have one (1) representative in attendance at such meeting. For clarity, prior to the assignment of the NDA for the Monotherapy Products in the Amicus Territory to Amicus as set forth in Section 5.2.1(b)(i): (i) GSK shall also continue to lead the liaison with, and manage, all interactions with Regulatory Authorities in the United States with respect to such filings; and (ii) GSK shall (A) keep Amicus and the Joint Development Subcommittee informed with respect to all interactions with Regulatory Authorities in the United States with respect to the preparation and filing of the first NDA for a Monotherapy Product in the United States, and (B) use reasonable

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

efforts in good faith to incorporate any comments of Amicus with respect to the preparation and filing such NDA in the United States.

(b) Each Party will promptly provide the other Party and to the Joint Development Subcommittee with copies of, or electronic access to, all documents and correspondence received from, or submitted to, a Regulatory Authority in the Amicus Territory and in each Expanded

Major Market in the GSK Territory, as applicable, related to a Product, including any notices of, or requests for, any substantive meetings with a Regulatory Authority in the Amicus Territory and in a Expanded Major Market country in the GSK Territory, as applicable, relating to a Product.

## 5.2.3 Exchange of Data and Know-How; Reports.

(a) During the Term, each Party shall provide to the other Party promptly upon the request of such Party (but not more frequently than \*\*\*\*\*) and at no cost or expense to such other Party (other than as provided under Sections 5.1.4, 5.1.5 and 5.3), all of such Party's Know-How within the Program Improvements and Co-Formulation Product IP arising during the conduct of activities pursuant to a Development Plan (or the Co-Formulation MTA) that is necessary or materially useful for the other Party to Develop and Manufacture Compound and Products, and Commercialize the Products in each Party's respective Territory, to the extent that such Know-How has not previously been provided to such other Party. Each Party shall provide all such Know-How in electronic form to the extent the same exists in electronic form, and shall provide copies as reasonably requested and an opportunity for the requesting Party or its designee to inspect (and copy) all other materials comprising such Know-How (including for example, original patient report forms and other original source data). The Parties will cooperate and reasonably agree upon formats and procedures to facilitate the orderly and efficient exchange of such Know-How during the Term.

(b) <u>Reports</u>. Each Party shall provide quarterly reports to the JSC and reports (at least quarterly or more frequently as requested) to the Joint Development Subcommittee in reasonable detail of all data and information generated or obtained in the course of such Party's performance of activities with respect to the Product(s) under the applicable Development Plans in each Party's respective Territory. Without limiting the foregoing, GSK shall provide in its reports under this Section 5.2.3(b) summary updates of any material Development activities and material regulatory filings and regulatory communications associated with any submissions of MAAs or other approvals for Products outside the Expanded Major Markets in the GSK Territory.

5.2.4 <u>Sharing of Regulatory Filings</u>. Without limiting Section 5.1.6 or Section 5.2.3 above, each Party shall permit the other Party access to and a right to reference and use in association with exercising its rights and performing its obligations under this Agreement, all of such Party's, and its Affiliates' and, to the extent it has the right to do so, its licensees' and Sublicensees' data, regulatory filings and regulatory communications associated with any submissions of MAAs or other approvals for Products (a) in the case of either Party, in each Major

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Market or Expanded Major Market, as applicable, in such Party's respective territory or (b) in the case of GSK, upon Amicus' request, in a country outside the Expanded Major Market in the GSK Territory.

5.2.5 <u>Clinical Trial Register</u>. Notwithstanding anything in this Agreement to the contrary, GSK shall have the right to publish in its clinical trial register the results or summaries of the results of all clinical trials for the Products conducted by either Party, their Affiliates, licensees and Sublicensees (subject to Sections 5.2.4 and 11.5) in the Territory pursuant to this Agreement. Likewise, Amicus shall have the right to publish in its clinical trial register the results or summaries of the results of all clinical trials for the Products conducted by either Party, their Affiliates, licensees and Sublicensees (subject to Sections 5.2.4 and 11.5) in the Territory pursuant to this Agreement to the extent that such results or summaries of the results of such clinical trial has been published by GSK in the GSK clinical trial register and the results or summaries of the results of such clinical trial has been published by GSK. In the GSK clinical trial register and the results or summaries of the results of a clinical trial for a Product(s) on its clinical trial registry and Amicus desires to publish in its clinical trial register the results or summaries of the such clinical trial for a Product, Amicus shall notify GSK in writing and Amicus and GSK will coordinate and agree upon a single version of such clinical trial results or summaries to be included on the clinical trial register of both Parties.

# 5.2.6 <u>Adverse Event Reporting</u>.

(a) <u>Initial Safety Data Exchange Agreement</u>. The Parties acknowledge that certain Safety Data Exchange Agreement, effective as of September 15, 2011 by and between the Parties, which was entered into pursuant to the terms of Section 5.2.6(a) of the Original Agreement.

(b) <u>Adverse Event Reporting</u>. From and after the Restatement Effective Date, as between the Parties: (i) GSK shall be responsible for the timely reporting of all Product quality complaints, adverse drug reactions/experiences/events, Product complaints and safety data relating to the Compound and Products to appropriate Regulatory Authorities in the GSK Territory in accordance with the applicable Laws of the relevant countries and Regulatory Authorities in the GSK Territory and (ii) Amicus shall be responsible for the timely reporting of all Product quality complaints, adverse drug reactions/experiences/events, Product complaints, adverse drug reactions/experiences/events, Product quality complaints, adverse drug reactions/experiences/events, Product complaints and safety data relating to the Compound and Products to appropriate Regulatory Authorities in the Amicus Territory in accordance with the applicable Laws and Regulatory Authorities in the Amicus Territory.

(c) <u>Safety Data Exchange Agreement</u>. Within a reasonable period of time after the Restatement Effective Date, the Parties shall enter into a new Safety Data Exchange Agreement, that will supersede the Safety Data Exchange Agreement described in Section 5.2.6(a) above, on terms no less stringent than those required by ICH guidelines, including: (i) providing detailed procedures regarding the maintenance of core safety information and the exchange of safety

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data relating to the Compound and Products in the GSK Territory and/or the Amicus Territory within appropriate timeframes and in an appropriate format to enable each Party to meet both expedited and periodic regulatory reporting requirements; and (ii) ensuring compliance with the reporting requirements of all applicable Regulatory Authorities on a worldwide basis for the reporting of safety data in accordance with standards stipulated in the ICH guidelines, and all applicable regulatory and legal requirements regarding the management of safety data (the "<u>Safety Data Exchange Agreement</u>"). (d) <u>Global Safety Database</u>. As between the Parties: GSK shall maintain a unified worldwide global safety database with respect to Products in the GSK Territory and the Amicus Territory.

#### 5.3 <u>New Labeling for Products</u>.

5.3.1 In the event that either Party (the "<u>Developing Party</u>") desires to conduct clinical trials in order to amend the labeling for a Product in its respective territory to \*\*\*\*\*\*, in order to \*\*\*\*\*\* and the JSC determines not to include such clinical trials in the relevant Development Plan, the Developing Party shall have the right, at its own expense, to conduct such clinical trials pertaining to \*\*\*\*\*\* outside the relevant Development Plan solely for the Developing Party's respective territory; \*\*\*\*\*\*. It is further understood that any Development and Commercialization activities with respect to the \*\*\*\*\*\* by Amicus pursuant to this Section 5.3 shall not be subject to \*\*\*\*\*; provided that \*\*\*\*\*.

5.3.2 For the avoidance of doubt, and except for the activities involving a Compound that a Party is permitted to conduct pursuant to clauses (A) and (B) of Section 10.4, neither Party shall have the right to conduct any activities with respect to Compound or Product(s) in the Territory, or to initiate activities with respect to a Combination Therapy Product that includes Compound co-formulated to an ERT enzyme that is not a Co-Formulation Product ERT Enzyme, except as set forth in this Agreement without the express written consent of the JSC and inclusion of such additional activities with respect to Compound or Product(s) in a relevant Development Plan under, and subject to the terms of, this Agreement.

#### 5.4 <u>Termination of Amicus' Co-Development Right for Product</u>.

5.4.1 Amicus may, in its sole discretion, elect to terminate its right, on a Product-by-Product basis, to co-Develop a Product with GSK pursuant to Section 5.1 and to share Development Costs incurred in the Development of such Product pursuant to Sections 5.1.4 and 5.1.5 and <u>Schedule 5.1.4</u> (such option, the "<u>Co-Development Opt-Out Right</u>"); provided that Amicus may only elect to exercise its Co-Development Opt-Out Right with respect to the Co-Formulation Product(s) under the following circumstances:

(a) \*\*\*\*\*

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(b) \*\*\*\*\*

(C) \*\*\*\*

5.4.2 Exercise of Co-Development Opt-Out. Amicus may exercise its Co-Development Opt-Out Right set forth in Section 5.4.1(a) in accordance with the procedures set forth in Section 5.1.4(b)(ii). Amicus may otherwise exercise its Co-Development Opt-Out Right by providing written notice to GSK of its desire to terminate its right with respect to a particular Product (any such notice, as well as any notice delivered by Amicus to GSK pursuant to Section 5.1.4(b)(ii) exercising Amicus' First Opt-Out Right or Second Opt-Out Right, each a "Co-Development Opt-Out Notice") at least \*\*\*\*\*\* prior to the beginning of the first Quarter in which Amicus wishes such Co-Development Opt-Out to take effect ("First Opt-Out Quarter"). Upon delivery of the Co-Development Opt-Out Notice, Amicus' Co-Development rights with respect to such Product pursuant to Section 5.1.4, shall terminate as of the first day of the First Opt-Out Quarter (the "Co-Development Opt-Out Effective Date").

5.4.3 <u>Effects of Exercise of Opt-Out Right</u>. In the event that Amicus exercises its Co-Development Opt-Out Right as set forth in this Section 5.4, then from the first day of the First Opt-Out Quarter and thereafter during the Term, the terms of Section 14.2 and 14.4 shall apply, *mutatis mutandis*, with respect to the Product(s) for which Amicus exercised its Co-Development Opt-Out Right, such that each reference to the Terminated Product(s) shall be deemed a reference to the Product(s) for which Amicus exercised its Co-Development Opt-Out Right.

5.5 Medical Affairs; Patient Advocacy.

5.5.1 <u>Medical Affairs</u>. Medical affairs activities of each Party in their respective Territory shall be overseen by the Joint Development Subcommittee; it being understood that GSK shall be solely responsible for and shall control medical affairs activities with respect to Products in the GSK Territory and Amicus shall be solely responsible for and shall control medical affairs activities with respect to Products in the Amicus Territory. For the avoidance of doubt, any decisions of a Party with respect to the conduct of medical affairs activities for a Product in such Party's Territory shall be final and shall not be subject to the terms of Sections 4.2.3(c), 4.1.5(a) or 16.2.

5.5.2 <u>Patient Advocacy</u>. The Joint Development Subcommittee shall be responsible for the oversight and control of the conduct of all global patient advocacy activities with respect to the Products in the Territory, including sponsorship of, and presentations and other disclosures made to, patient advocacy groups by a Party with respect to the Products in the Territory; <u>provided</u>, <u>however</u>, that (i) GSK shall be responsible for and control the conduct of all patient advocacy activities with respect to the Products that relate solely to the GSK Territory (including

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activities conducted in the GSK Territory with respect to a patient advocacy group located solely in the GSK Territory) and (ii) Amicus shall be responsible for and control the conduct of all patient advocacy activities with respect to the Products that relate solely to the Amicus Territory (including activities conducted in the Amicus Territory with respect to a patient advocacy group located solely in the Amicus Territory). For the avoidance of doubt, any decisions of a Party with respect to the conduct of patient advocacy activities with respect to the Products that relate solely to such Party's respective territory (including such Party's determination that such activities relate solely to such Party's respective territory) shall be final and shall not be subject to the terms of Sections 4.2.3(c), 4.1.5(a) or 16.2.

#### VI. COMMERCIALIZATION; MANUFACTURING AND SUPPLY

Commercialization Plan. The Parties will discuss, through the Joint Commercialization Subcommittee, the Commercialization of the 6.1 Products as provided in Section 4.2.2(b) and this Article VI and will agree upon a global commercialization plan (the "Global Commercialization Plan"), which will form the guiding principles for Commercialization activities for the Products in the Amicus Territory and the GSK Territory. An initial draft of the guiding principles to be used by the Joint Commercialization Subcommittee in developing the Global Commercialization Plan is attached hereto as Schedule 6.1. Promptly after the Restatement Effective Date, and in any event within \*\*\*\*\*\* prior to the first projected Launch of a Product in the Territory, the Joint Commercialization Subcommittee shall develop and the Parties shall mutually agree upon a Global Commercialization Plan in accordance with the Global Commercialization Plan guiding principles set forth on <u>Schedule 6.1</u>. Thereafter, the Joint Commercialization Subcommittee will review and make any necessary mutually-agreed upon changes to the then-current Global Commercialization Plan and will provide quarterly updates to the JSC with respect thereto in accordance with Section 4.2.2(c). The development of the Global Commercialization Plan and any changes thereto must be made by mutual agreement of the Parties, and neither Party shall have final decision making authority with respect to the Global Commercialization Plan. In the event that the JCS disagrees with respect to any proposed changes to the Global Commercialization Plan, such dispute shall be submitted for review by the JSC at the next regularly scheduled JSC meeting. If the Parties via the JSC are unable to mutually agree on such disputed proposed changes to the then-current Global Commercialization Plan, the then-current Global Commercialization Plan shall remain unmodified and such disagreement shall not be subject to further escalation or to dispute resolution in accordance with Section 4.1.5 or Section 16.2. The Parties will coordinate Commercialization activities in their respective territories, including coordination of marketing and branding activities, via the Joint Commercialization Subcommittee. Notwithstanding the foregoing, pursuant to Section 4.1.5(c), each Party shall have final decision-making authority with respect to Commercialization of Products in its respective territory pursuant to this Agreement, provided that each Party shall exercise its final decision-making authority in its respective territory in a manner that is consistent with the Global Commercialization Plan.

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6.1.1 For the GSK Territory. Prior to the anticipated Launch of the first Product in a \*\*\*\*\*\*, GSK shall prepare the Ex-U.S. Commercialization Plan, which shall include without limitation the Ex-U.S. Commercialization Strategy, and shall provide such Ex-U.S. Commercialization Plan to the Joint Commercialization Subcommittee. GSK, not less frequently than \*\*\*\*\*, will provide to the Joint Commercialization Subcommittee summary updates to the Ex-U.S. Commercialization Plan and summary updates of Commercialization activities undertaken by GSK and its Affiliates and Sublicensees pursuant to the Ex-U.S. Commercialization Plan \*\*\*\*\*. In addition, GSK will update the Joint Commercialization Subcommittee on a rolling basis during the Joint Commercialization Subcommittee's meetings with respect to activities conducted pursuant to the then-current Ex-U.S. Commercialization plan \*\*\*\*\*. GSK shall carry out all marketing, promotion and other Commercialization activities of the Products in the GSK Territory in accordance with the then-current Ex-U.S. Commercialization Plan.

6.1.2 For the Amicus Territory. Prior to the anticipated Launch of the first Product in the Amicus Territory, Amicus shall prepare the U.S. Commercialization Plan, which shall include without limitation the U.S. Commercialization Strategy, and shall provide such U.S. Commercialization Plan to the Joint Commercialization Subcommittee. Amicus, not less frequently than \*\*\*\*\*, will provide to the Joint Commercialization Subcommittee summary updates to the U.S. Commercialization Plan and summary updates of Commercialization activities undertaken by Amicus and its Affiliates and permitted sublicensees pursuant to the U.S. Commercialization Plan \*\*\*\*\*. In addition, Amicus will update the Joint Commercialization Subcommittee on a rolling basis during the Joint Commercialization Subcommittee's meetings with respect to activities conducted pursuant to the then-current U.S. Commercialization and other Commercialization activities of the Products in the Amicus Territory in accordance with the then-current U.S. Commercialization Plan.

6.1.3 <u>GSK's Responsibilities</u>. GSK shall have, in GSK's sole discretion and at its sole expense, the exclusive right to Manufacture or have Manufactured, on behalf of GSK, or its Affiliates or Sublicensees, Compounds and Products for the GSK Territory, and the exclusive right, subject to Section 6.5.4, to Manufacture Co-Formulation Products for supply to Amicus for the Amicus Territory. In addition, GSK shall have, in GSK's sole discretion and at its sole expense, the exclusive right to distribute, market, provide sales force support for, and to promote and otherwise take all actions determined by GSK to be necessary to Commercialize Products in the Field in the GSK Territory, including, without limitation, the exclusive right and responsibility for the following in the GSK Territory:

(a) determining pricing for Products in the GSK Territory and negotiating with relevant governmental authorities and agencies and MCOs to establish pricing and reimbursement for Products in the GSK Territory;

(b) managed care contracting for Products in the GSK Territory, if applicable, <u>provided</u> that GSK shall not engage in any Discriminatory Conduct with respect to

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managed care contracting or otherwise relating to the Products. For the purposes of this Section 6.1.3(b), "Discriminatory Conduct" shall be deemed to occur if a Party or its Affiliate discounts the price of or positions a Product in its managed care contracting or otherwise to benefit or increase the sales of other products of such Party or its Affiliate;

- (c) receiving, accepting and filling orders for Products from customers in the GSK Territory;
- (d) distributing Products to customers in the GSK Territory;

(e) controlling invoicing, order processing and collecting accounts receivable for sales of Products in the GSK Territory;

(f) recording sales of Products in the GSK Territory in its books of account for sales;

(g) conducting disease awareness and medical education programs in the GSK Territory; and

(h) any and all other Commercialization activities, in GSK's discretion and consistent with the Global Commercialization Plan, related to the Products in the GSK Territory.

6.1.4 <u>Amicus's Responsibilities</u>. Amicus shall have, in Amicus' sole discretion and at its sole expense, the exclusive right to Manufacture or have Manufactured, on behalf of Amicus or its Affiliates or sublicensees, Monotherapy Products and Co-Administration Products for the Amicus Territory, subject to GSK's rights and obligations to Manufacture Products for Development activities as set forth in Section 6.5.4. In addition, Amicus shall have, in Amicus' sole discretion and at its sole expense, and, using its Commercially Reasonable Efforts with respect to Co-Formulation Products only, the exclusive right to distribute, market, provide sales force support for, and to promote and otherwise take all actions determined by Amicus to be necessary to Commercialize, Products in the Field in the Amicus Territory, including, without limitation, the exclusive right and responsibility for the following in the Amicus Territory:

(a) determining pricing for Products in the Amicus Territory and negotiating with relevant governmental authorities and agencies and MCOs to establish pricing and reimbursement for Products in the Amicus Territory;

(b) managed care contracting for Products in the Amicus Territory, <u>provided</u> that Amicus shall not engage in any Discriminatory Conduct with respect to managed care (including, Medicare) contracting or otherwise relating to the Products;

(c) receiving, accepting and filling orders for Products from customers in the Amicus Territory;

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(d) distributing Products to customers in the Amicus Territory;

(e) controlling invoicing, order processing and collecting accounts receivable for sales of Products in the Amicus Territory;

(f) recording sales of Products in the Amicus Territory in its books of account for sales;

(g) conducting disease awareness and medical education programs in the Amicus Territory; and

(h) any and all other Commercialization activities, in Amicus's discretion and consistent with the Global Commercialization Plan, related to the Products in the Amicus Territory.

6.2 <u>Promotional Materials</u>. The final determination of the content, quantity, and method of distribution of any promotional materials for the Compound or Products for each Party's respective territory shall be the sole responsibility of such Party, <u>provided</u> that all such promotional materials shall be consistent with guidelines set forth in the Global Commercialization Plan. Subject to Section 6.3, each Party shall own all right, title and interest in and to all such promotional materials for the Compound or Products for each Party's respective territory created during the Term of the Agreement, including any intellectual property rights therein or attendant thereto, excluding any Trademark(s) and the House Marks of the other Party.

## 6.3 <u>Use of Trademarks and House Marks</u>.

6.3.1 The Joint Commercialization Subcommittee will determine, and the Joint Steering Committee will confirm, which GSK Trademark or GSK Trademarks will be used in marketing Products in the GSK Territory and the Amicus Territory, with the goal of identifying a global GSK Trademark for each Product that may be used in the Amicus Territory and throughout the GSK Territory. In the event that a GSK Trademark selected by the Joint Commercialization Subcommittee and Joint Steering Committee is not registerable in the Amicus Territory or throughout the GSK Territory, or is not approved by the applicable Regulatory Authorities for a Product in a country in the Territory, the Joint Commercialization Subcommittee shall have the right to select (subject to approval by the Joint Steering Committee) an alternative GSK Trademark for use in connection with such Product in such country, it being understood that the Parties shall mutually agree upon the pool of alternative GSK Trademarks for such purposes. Neither Party shall have the right to select and use a Trademark or a GSK Trademark in connection with a Product without the prior written consent and approval of the Joint Commercialization Subcommittee. All packaging and package inserts for Product in the GSK Territory will include the GSK brand name and logo or other identifying markings of GSK or its Affiliates (collectively, the "<u>GSK House Marks</u>"), and all packaging and package inserts for Product in the Amicus Territory will include the Amicus brand name and logo, or other identifying markings of

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Amicus (collectively "<u>Amicus House Marks</u>") in reasonable size and prominence as allowed by applicable Law.

6.4 <u>Product Recalls</u>. Subject to Article XV, GSK will have the responsibility for initiating and conducting any total or partial recall or market withdrawal of a Product in the GSK Territory (whether voluntary or not) and Amicus will have the responsibility for initiating and conducting any total or partial recall or market withdrawal of a Product in the Amicus Territory (whether voluntary or not); <u>provided</u> that, prior to initiating a recall of a Product pursuant to this Section 6.4, the Party proposing such recall shall notify the other Party in writing (such notification to be within twenty-four (24) hours in the event of a recall for safety or toxicity reasons), and shall consider in good faith any reasonable comments provided promptly by the other Party with respect to the initiation and/or conduct of such recall. The Parties will cooperate with and assist each other in effecting such recall or market withdrawal, including making available to the other Party, upon request, all pertinent records. Except as otherwise agreed by the Parties in writing and subject to Article XV, all costs associated with any total or partial recall or market withdrawal of a Product in each Party's respective territory shall be borne by the Party responsible for initiating and conducting such recall in the applicable territory pursuant to the first sentence of this Section 6.4; <u>provided</u> that, to the extent that such total

or partial recall or market withdrawal is a result of the other Party's (or such other Party's Third Party manufacturer's) gross negligence or failure to comply with the terms of this Agreement (or in the case of GSK, the Supply Agreement (when executed)), all such costs shall be borne by the other Party.

## 6.5 <u>Manufacturing Responsibilities</u>.

6.5.1 The Parties acknowledge and agree that, pursuant to Section 6.5.1, <u>Schedule 6.5.1</u>, and the Supply Transition Plan, in each case as set forth in the Original Agreement, Amicus transitioned responsibility for the Manufacture and supply of the Compound and Products in the Territory to GSK. Further, following the Effective Date, GSK has developed the GSK Monotherapy Product Manufacturing Improvements as set forth in the attached <u>Schedule 6.5.1</u>. Following the Restatement Effective Date, GSK and Amicus shall agree upon a timeline and transition plan as necessary (the "<u>Supply</u> <u>Transition Plan</u>") pursuant to which Amicus shall transfer to GSK or the designated Third Party CMO(s) currently used by the Parties for Manufacturing under this Agreement as of the Restatement Effective Date, and GSK shall transfer to Amicus or designated Third Party CMO(s) currently used by the Parties for Manufacturing under this Agreement as of the Restatement Effective Date, as applicable, the information (including such information generated by Amicus' or GSK's, as applicable, Third Party manufacturer(s)), as set forth in the attached <u>Schedule 6.5.1</u>. The Supply Transition Plan shall provide for reasonable assistance to establish and validate the Manufacture and supply process at a location designated by Amicus, or by GSK, as applicable. During the Term, GSK shall transfer to Amicus any additional GSK Monotherapy Product Manufacturing Improvements and Amicus shall transfer to GSK any Amicus Licensed Technology related to improvements to the manufacturing processes for the Manufacture

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of Compound or Products (other than the Co-Formulation Products), in each case, in accordance with Section 5.2.3.

6.5.2 GSK shall have the exclusive right to Manufacture Compound and Products in the Territory for Commercialization of such Products in the Field in the GSK Territory. In addition, GSK shall have the exclusive right and responsibility to Manufacture Co-Formulation Products in the Territory for Commercialization of such Co-Formulation Products in the Field in the GSK Territory and for supply of such Co-Formulation Products to Amicus for Commercialization of such Products in the Field in the Amicus Territory. The foregoing rights shall include, without limitation, the right to Manufacture all batches of drug substance and drug product (including any such batches of drug substance or drug product planned for use to support registration and validation of Product). GSK shall have the right, in accordance with the terms of this Agreement, to appoint one or more Third Parties to Manufacture Compound and Products for any of the foregoing purposes. For the avoidance of doubt, GSK shall have the ultimate decision-making authority over the use of Third Parties in its manufacturing supply chain.

6.5.3 Amicus shall have the exclusive right to Manufacture Compound and Products (other than Co-Formulation Products) in the Territory for Commercialization of such Products in the Field in the Amicus Territory, including, without limitation, the right to Manufacture all batches of drug substance and drug product (including any such batches of drug substance or drug product planned for use to support registration and validation of such Products), and shall have the right, in accordance with the terms of this Agreement, to appoint one or more Third Parties to Manufacture Compound and Products (other than Co-Formulation Products) for such purposes. Amicus shall have the right to Manufacture Compound and Products (other than Co-Formulation Products) in the Territory for Development of such Products in the Field in the Amicus Territory; <u>provided</u>, <u>however</u>, Amicus shall first obtain its, its Affiliates' and Sublicensees' requirements to conduct the Development activities allocated to Amicus, its Affiliates or Sublicensees under the thencurrent Existing Development Plan from GSK to the extent such quantities are made available to Amicus in accordance with Section 6.5.4 below. For the avoidance of doubt, Amicus shall have the ultimate decision making authority over the use of Third Parties in its manufacturing supply chain for Compound and Products (other than Co-Formulation Products).

6.5.4 <u>Clinical Supply by GSK to Amicus</u>. GSK agrees to make available, and supply to Amicus, its Affiliates, and its and its Affiliates' Sublicensees, and to GSK, its Affiliates, and its and its Affiliates' Sublicensees, such quantities of the Compound and Products that are necessary or reasonably useful, as determined by the Joint Development Committee, for Amicus and for GSK to conduct and complete the Development activities allocated to Amicus and/or its Affiliates or Sublicensees or GSK and/or its Affiliates or Sublicensee, as applicable, under and in accordance with the then-current Development Plans. \*\*\*\*\*. For clarity, \*\*\*\*\*. The Parties shall collaborate, via the Joint Development Subcommittee, to appropriately forecast the supply amounts of Compound and Products necessary for Amicus and for GSK to conduct and complete the Development activities allocated to Amicus and/or its Affiliates or Sublicensees or GSK and/or its Affiliates or Sublicensees or GSK to conduct and complete the Development activities allocated to Amicus and for GSK to conduct and complete the Development activities allocated to Amicus and/or its Affiliates or Sublicensees or GSK and/or its

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Affiliates or Sublicensee, as applicable, under and in accordance with the then-current Development Plans; and with respect to supply amounts of Co-Formulation Products, the Parties shall collaborate, via the Joint Development Committee, to appropriately forecast to GSK, on a two-year rolling basis, the amount of the Co-Formulation Product ERT Enzyme that is anticipated to be necessary to conduct and complete the Development activities under and in accordance with the then-current Co-Formulation Development Plan. Other than as expressly set forth in this Section 6.5.4, each Party shall be solely responsible for obtaining the supply of Compound for use in connection with the conduct of activities allocated to such Party under the applicable Development Plan.

6.5.5 <u>Commercial Supply of Co-Formulation Product</u>. Upon request by Amicus, GSK shall supply Amicus with Co-Formulation Product, for Commercialization in the Amicus Territory, at a price equal to GSK's Manufacturing Costs. The Parties shall enter into a separate supply agreement (the "<u>Supply Agreement</u>"), within \*\*\*\*\* following a request by either Party to do so, covering the foregoing commercial supply of Co-Formulation Product by GSK to Amicus, which shall include certain minimum order requirements, an obligation to \*\*\*\*\*\*, and which shall reflect such other terms and conditions as are reasonable and customary for pharmaceutical supply arrangements. \*\*\*\*\*\*.

6.5.6 <u>Supply of Compound and Product</u>. Any quantities of Compound or Products (other than Co-Formulation Products) to be supplied by GSK to Amicus pursuant to Section 6.5.4 will meet applicable Compound or Product specifications. The specifications for the Compound and Products (other than the Co-Formulation Product) as of the Effective Date are attached hereto as <u>Schedule 6.5.6</u>. The specifications for the Co-Formulation Product ERT Enzyme shall be agreed upon by the Parties in advance of the conduct of Manufacturing activities for the supply of such Co-Formulation Product ERT

Enzyme for use in connection with Co-Formulation Product(s). Each Party shall appoint a representative as a primary point of contact for discussions between the Parties regarding Manufacturing activities and Compound and/or Product specifications under this Agreement. Any quantities of Co-Formulation Products to be supplied by GSK to Amicus pursuant to Section 6.5.4 and/or Section 6.5.5 will meet applicable Co-Formulation Product specifications as mutually agreed upon by the Parties (such Co-Formulation Product specifications together with the Compound and Product specifications set forth on <u>Schedule 6.5.5</u>, the "<u>Specifications</u>"). Neither Party shall make any changes to the Specifications without the other Party's prior written approval; unless such changes are requested or required by a Regulatory Authority or applicable Laws ("<u>Required Changes</u>"), in which case, GSK may amend the applicable Specifications for the Co-Formulation Product and, upon reasonable prior written notice to Amicus, for any Compound or Products to be supplied by GSK pursuant to Section 6.5.4, and Amicus may amend the applicable Specifications for Compound and Products (other than Co-Formulation Products) for which Amicus is responsible; in each case in order to comply with such Required Changes and provide notice thereof to the other Party; \*\*\*\*\*\*. In addition, all quantities of Compound and Products supplied by GSK to Amicus pursuant to this Section 6.5 will not be misbranded or adulterated. All such Compound and Products supplied by GSK to Amicus pursuant to this Section 6.5 will be manufactured in accordance with cGMPs; provided, however, that GSK may supply to Amicus

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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Compound or Products not manufactured in accordance with cGMP if specifically intended for non-human testing activities allocated to Amicus under the applicable Development Plan and as agreed to in writing in advance by Amicus.

6.5.7 <u>Remaining Supply of Clinical Trial materials.</u> In the event that, following the conclusion of the Development activities by the Parties in the Territory under this Agreement, additional supply of Compound or Products exists that have not been otherwise allocated to Development activities by a Party and for which the shelf-life has not yet expired, the Parties shall discuss allocation of such additional supply to a Party for use in connection with Commercialization of the applicable Product in such Party's Territory, subject to agreement by the Parties on the appropriate payment terms for such additional supplies, such payment terms to be consistent with the terms for the cost of commercial supply of Compound and/or Product as set forth in Section 6.5.5.

6.6 <u>Commercial Transition</u>. Following the Restatement Effective Date, GSK and Amicus shall agree upon a timeline and transition plan in accordance with <u>Schedule 6.6</u> attached hereto as necessary to effect a smooth and orderly transition of the Commercialization of the Products for the Amicus Territory (the "<u>Commercial Transition Plan</u>") pursuant to which GSK shall transfer to Amicus Commercialization activities for the Amicus Territory and provide reasonable assistance with respect such Commercialization transfer in accordance with the Commercial Transition Plan.

# VII. OWNERSHIP AND INTELLECTUAL PROPERTY

7.1 <u>Ownership</u>. Subject to any license or other rights granted to GSK pursuant to the terms of this Agreement, as between the Parties, Amicus will own or Control the Amicus Intellectual Property, Amicus Confidential Information, Amicus Know-How, and Amicus House Mark owned or Controlled by Amicus in the Territory as of the Effective Date. Subject to any license or other rights granted to Amicus pursuant to the terms of this Agreement, GSK will own the GSK Confidential Information, GSK Background IP, GSK In-Licensed Background ERT IP, GSK Trademarks, and GSK House Marks owned or Controlled by GSK in the Territory as of the Effective Date or, with respect to the GSK Trademarks and the GSK In-Licensed Background ERT IP, during the Term. GSK shall own any Trademarks that are created or designated by the Parties for use on a Product in the Territory after the Effective Date.

## 7.2 Patent Applications on Licensed Amicus Technology.

7.2.1 <u>GSK Control of Prosecution</u>. Subject to any restrictions Amicus may have under any Third Party agreement covering the Amicus Patents included in the Licensed Amicus Technology (including the Background License Agreements) and subject to Section 7.2.1(a) below, GSK will assume control of, and will bear the Patent Costs associated with, prosecuting and maintaining such Patents in the Territory included in the Amicus Patents as of the Effective Date, or which may be filed in any country of the Territory after the Effective Date, to the extent the same are directed to the Compound or a Product, and/or Manufacturing and/or use thereof, in the Field in the

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

Territory, excluding those Amicus Prosecuted Patents described below in Section 7.2.2 (such Patents, excluding the Amicus Prosecuted Patents, are referred to below as the "<u>GSK Prosecuted Amicus Patents</u>"). A list of the GSK Prosecuted Amicus Patents, as of the Restatement Effective Date, is set forth on <u>Schedule 7.2.1</u> attached hereto. Amicus shall have the right, at its own cost and expense, to reasonably assist GSK in connection with the filing, prosecution and maintenance of any GSK Prosecuted Amicus Patents in the Territory. GSK shall use diligent efforts consistent with those normally employed by GSK in the course of business to prosecute and maintain the GSK Prosecuted Amicus Patents described in this Section 7.2.1 and GSK will, in a timely manner, solicit Amicus' comments regarding the prosecution and maintenance of such GSK Prosecuted Amicus Patents and review of the nature and text of any such Patent application and prosecution matters related thereto, including any correspondence between GSK and any government intellectual property or Patent authorities, agencies or other government bodies, in reasonably sufficient time prior to filing thereof, and GSK shall give due consideration to Amicus' reasonable amendments to such correspondence. Without prejudice to Section 7.2.4 in the event that GSK intends to disregard any of Amicus' amendments, GSK shall set up a meeting between Amicus' and GSK's respective patent counsels to provide explanations therefor.

(a) Amicus will control, and will bear the Patent Costs associated with, prosecuting and maintaining each GSK Prosecuted Amicus Patent in the Amicus Territory after such Patent has been issued, including but not limited to re-examination, re-issue, post-grant review, *inter partes* post-grant review and supplementary examination. GSK shall have the right, at its own cost and expense, to reasonably assist Amicus in connection with the prosecution or maintenance of such GSK Prosecuted Amicus Patent after such Patent has been issued in the Amicus Territory. Amicus will keep GSK reasonably informed with respect to such prosecution and maintenance via the Joint Patent Subcommittee and will, in a timely manner, solicit GSK's comments regarding such prosecution and maintenance, including any comments of GSK with respect to any correspondence between Amicus and any government intellectual property or Patent authorities, agencies or other government bodies, in reasonably sufficient time prior to filing thereof, and Amicus will give due consideration to GSK's reasonable comments and amendments. Without prejudice to Section 7.2.4, \*\*\*\*\*\*.

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7.2.2 <u>Amicus Prosecuted Patents</u>. Amicus will control, and will bear the Patent Costs associated with, prosecuting and maintaining the Amicus Patents identified on <u>Schedule 7.2.2</u> (together with future Patents claiming priority thereto, the "<u>Amicus Prosecuted Patents</u>"). GSK shall have the right, at its own cost and expense, to reasonably assist Amicus in connection with the filing, prosecution and maintenance of any such Amicus Prosecuted Patents in the Territory. Amicus shall use diligent efforts consistent with those normally employed by Amicus in the course of business to prosecute and maintain the Amicus Prosecuted Patents and Amicus will, in a timely manner, solicit GSK's comments regarding the prosecution and maintenance of such Amicus Prosecuted Patents and review of the nature and text of any such Patent application and prosecution matters related thereto, including any correspondence between Amicus and any government intellectual property or Patent authorities, agencies or other government bodies, in reasonably sufficient time prior to filing

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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thereof, and Amicus will give due consideration to GSK's reasonable comments and amendments. Without prejudice to Section 7.2.4, \*\*\*\*\*\*.

7.2.3 <u>Segregation of Patent Applications</u>. In the event that any Amicus Patent contains claims to the Compound and/or Products (i.e., is a GSK Prosecuted Amicus Patent) as well as the Amicus Proprietary Chaperone Technology more broadly or any other compound or product owned or controlled by Amicus, the Parties shall cooperate in good faith to segregate such Patents to allow Amicus to control the prosecution and maintenance of Patent applications and Patents pertaining to subject matter other than the Compound and/or Products. A list of such Segregated Patents as of the Restatement Effective Date is set forth on <u>Schedule 7.2.3</u> hereto.

7.2.4 <u>Additional Matters</u>. Any disagreements under this Section 7.2 shall be referred to the Joint Patent Subcommittee for resolution as provided in Section 4.2.1. For purposes of this Article VII, "prosecution and maintenance" (including variations such as "prosecute and maintain") means, with respect to a Patent, the preparing, filing, maintenance and prosecution of such Patent, as well as the conduct of interferences, oppositions, re-examination, re-issues and other similar proceedings.

#### 7.3 <u>Program Improvements; Co-Formulation Product IP</u>.

7.3.1 To the extent that a Program Improvement or Co-Formulation Product IP is developed by or on behalf of one Party, that Party will promptly disclose such Program Improvement or Co-Formulation Product IP to the Joint Patent Subcommittee in writing with all relevant data supporting such Program Improvement or Co-Formulation Product IP, as applicable.

7.3.2 Each Party will, subject to the terms of Section 7.4, be sole owner of Program Improvements and Co-Formulation Product IP invented solely by its employees and agents and the employees and agents of its respective Affiliates and will do and procure all necessary acts, and obtain all necessary assignments or other instruments as may be required to confer such sole ownership on said Party. With respect to such solely-invented Program Improvements and Co-Formulation Product IP, the Party owning such Program Improvement or Co-Formulation Product IP, as applicable, will own any applications for Patent with respect thereto and any Patents issued on such applications, unless such rights are assigned to the other Party pursuant to Section 7.4.

7.3.3 The Parties will be the joint owners of Program Improvements and Co-Formulation Product IP invented jointly by the employees and agents of the Parties or the employees and agents of their respective Affiliates and any Program Patents covering such jointly invented Program Improvements or Patents covering such jointly invented Co-Formulation Product IP, applicable (each a "Joint Program Patent"). Each Party will do and procure all necessary acts, and obtain all necessary assignments or other instruments as may be required to confer such joint ownership on the Parties.

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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7.3.4 Inventorship under this Agreement shall be determined in accordance with the patent laws of the United States.

7.4 <u>Abandonment of Patents and Applications</u>. In the event that GSK decides not to file, continue to prosecute or maintain a GSK Prosecuted Patent that falls under Section 7.2, or either Party decides not to file, maintain a Patent or to abandon a Patent application or issued Patent that falls under Section 7.3 (in either case, the "<u>Abandoning Party</u>"), such Abandoning Party will give written notice to the other Party at least \*\*\*\*\*\* prior to any public disclosure, allowing such application to go abandoned, or prior to not taking a necessary step to maintain such Patent, and the other Party will have the option of taking over the prosecution or maintenance of such application or Patent at its sole expense. If the other Party elects to take over the filing, prosecution or maintenance of such application or Patent to the Section 7.4, the Abandoning Party or Party giving permission will assign all its right, title and interest in such application or Patent to the other Party, subject to the Abandoning Party or Party giving permission retaining a non-exclusive, perpetual, irrevocable, sublicensable, fully-paid-up license from the other Party to such Patent or Patent applications, including any correspondence between the Abandoning Party and any government intellectual property or Patent authorities, agencies or other government bodies, in reasonably sufficient time prior to filing thereof, and shall give due consideration to the Abandoning Party's comments. Any disagreements hereunder shall be referred to the Joint Patent Subcommittee for resolution as provided in Section 4.2.1.

7.5 <u>Cooperation</u>. Each Party will cooperate, and will require its employees, Affiliates, consultants, and subcontractors to cooperate, and will use its reasonable efforts to require its agents to cooperate, with all reasonable requests of the other Party for assistance in preparation and prosecution and maintenance of any applications for Patent and any Patent issuing therefrom and any applications for Trademark for use with a Product and any registration issuing therefrom that is owned by the requesting Party hereunder. GSK shall be solely responsible for any and all costs associated with the GSK Trademarks and GSK House Marks, including any Trademarks owned by GSK pursuant to Section 7.1 herein. Amicus shall be solely responsible for any and all costs associated with the Amicus House Marks.

7.6 Patent Filing Procedures for Patents relating to Program Improvements; Co-Formulation Product IP.

#### 7.6.1 Program Improvement and Co-Formulation Product IP relating to Compound or Product.

(a) GSK will determine whether or not to file a Patent application covering a Program Improvement or Co-Formulation Product IP relating to Compound or a Product in the Territory. If GSK elects to file such an application, subject to Section 7.6.1(b), GSK will bear

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the Patent Costs of prosecuting and maintaining any Patents that issue thereon and will control the prosecution of such application; however, Amicus shall have the right, at its own cost and expense, to reasonably assist GSK in connection with the filing, prosecution and maintenance of any Patent applications filed under this Section 7.6.1(a). GSK shall use diligent efforts consistent with those normally employed by GSK in the course of business to prosecute and maintain any such Patent application or Patent described in this Section 7.6.1(a) and GSK will, in a timely manner, solicit Amicus' comments and review of the nature and text of any such application and prosecution and maintenance matters related thereto, including any correspondence between GSK and any government intellectual property or Patent authorities, agencies, or other government bodies, in reasonably sufficient time prior to filing thereof, and GSK shall give due consideration to Amicus' reasonable amendments to such correspondence. \*\*\*\*\*\*. Any remaining disagreements hereunder, including filing, prosecution and maintenance decisions or strategies and/or any disputes by Amicus regarding GSK's determination to disregard any of Amicus' proposed amendments provided with respect to an application for Patent or Patent described in this Section 7.6.1(a), shall be referred to the Joint Patent Subcommittee for resolution as provided in Section 4.2.1. If GSK elects not to file an application for Patent in any country in the Territory covering any such Program Improvement or Co-Formulation Product IP as a trade secret), GSK shall give Amicus notice thereof at least \*\*\*\*\*\* prior to causing in any way such Program Improvement or Co-Formulation Product IP to become unpatentable through disclosure, sale, or otherwise, and Amicus shall thereafter have the right, at its sole expense, to prosecute and maintain such Patent application in any such country. Any disagreements hereunder shall be referred to the Joint Patent Subcommittee for resolution as provided in

(b) If GSK elects to file an application for Patent in any country in the Territory covering any such Program Improvement or Co-Formulation Product IP in accordance with Section 7.6.1(a) (each a "<u>GSK Prosecuted Improvement Patent</u>"), Amicus will control, and will bear the Patent Costs associated with, prosecuting and maintaining each GSK Prosecuted Improvement Patent in the Amicus Territory after such Patent has been issued, including but not limited to re-examination, re-issue, post-grant review, *inter partes* post-grant review and supplementary examination. GSK shall have the right, at its own cost and expense, to reasonably assist Amicus in connection with the prosecution or maintenance of such GSK Prosecuted Improvement Patent after such Patent has been issued in the Amicus Territory. Amicus will keep GSK reasonably informed with respect to such prosecution and maintenance via the Joint Patent Subcommittee and will, in a timely manner, solicit GSK's comments regarding such prosecution and maintenance, including any comments of GSK with respect to any correspondence between Amicus and any government intellectual property or Patent authorities, agencies or other government bodies, in reasonably sufficient time prior to filing thereof, and Amicus will give due consideration to GSK's reasonable comments and amendments. Without prejudice to Section 7.2.4, \*\*\*\*\*\*

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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## 7.6.2 Program Improvement or Co-Formulation Product IP not relating to Compound or Product.

(a) If a Program Improvement or Co-Formulation Product IP does not relate to Compound or Product, then Amicus will determine whether or not to file a Patent application in any country on such Program Improvement or Co-Formulation Product IP. If Amicus elects to file such an application, Amicus will bear the Patent Costs of prosecuting and maintaining any Patents that issue thereon and will control the prosecution of such application; however, GSK shall have the right, at its own cost and expense, to reasonably assist Amicus in connection with the filing, prosecution and maintenance of any Patent applications filed under this Section 7.6.2(a). Amicus shall use diligent efforts consistent with those normally employed by Amicus in the course of business to prosecute and maintain any such Patent application or Patent described in this Section 7.6.2(a) and Amicus will, in a timely manner, solicit GSK's comments and review of the nature and text of any such application and prosecution and maintenance matters related thereto, including any correspondence between Amicus and any government intellectual property or Patent authorities, agencies, or other government bodies, in reasonably sufficient time prior to filing thereof, and Amicus shall give due consideration to GSK's reasonable amendments to such correspondence. \*\*\*\*\*\*. Any remaining disagreements hereunder, including filing, prosecution and maintenance decisions or strategies, shall be referred to the Joint Patent Subcommittee for resolution as provided in Section 4.2.1; and

(b) If Amicus elects not to file an application for Patent in any country in the Territory covering any such Program Improvement or Co-Formulation Product IP, Amicus shall give GSK notice thereof at least sixty (60) days prior to causing in any way such Program Improvement or Co-Formulation Product IP to become unpatentable through disclosure, sale, or otherwise, and GSK shall thereafter have the right, at its sole expense, to prosecute and maintain such Patent application in any such country. Any disagreements hereunder shall be referred to the Joint Patent Subcommittee for resolution as provided in Section 4.2.1.

## 7.7 Orange Book Listing; Patent Term Restoration and Supplemental Protection Certificates.

7.7.1 Obligations. After consultation with GSK via the Joint Patent Subcommittee and giving due consideration to any comments and recommendations of GSK, \*\*\*\*\*\*. Prior to such listings, the Parties will meet, through the Joint Patent Subcommittee, to evaluate and identify all applicable Patent rights, and subject to any restrictions Amicus may have under third party agreements covering the Amicus Patents included in the Licensed Amicus Technology (including the Background License Agreements), GSK will have the right to review, where reasonable, original records relating to any invention for which Patent rights are being considered for any such listing. \*\*\*\*\*\*. In addition, subject to any restrictions Amicus may have under third party agreements covering the Amicus Patents included in the Licensed Amicus Technology (including the Background License Agreements), \*\*\*\*\*\*. Subject to any restrictions Amicus may have under third party agreements covering the Amicus Patents included in the Licensed Amicus Technology (including the Background License Agreements), \*\*\*\*\*\*. Subject to any restrictions Amicus may have under third party agreements covering the Amicus Patents included in the Licensed Amicus Technology (including the Background License Agreements), \*\*\*\*\*\*. Subject to any restrictions Amicus may have under third party agreements covering the Amicus Patents included in the Licensed Amicus Technology (including the Background License Agreements), \*\*\*\*\*\*. The Parties will cooperate with each other in gaining Patent term extension where applicable to Products. Upon either Party's reasonable

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request, the other Party shall timely provide any documentation or other assistance required in order to obtain such Patent term extensions, subject to any restrictions either Party may have under third party agreements covering the applicable Patent (including the Background License Agreements).

#### 7.8 <u>Trademark Filing Procedures</u>. During the Term of this Agreement, \*\*\*\*\*.

#### VIII. ENFORCEMENT AND DEFENSE OF INTELLECTUAL PROPERTY

8.1 Notices. Each Party will advise the Joint Steering Committee and the Joint Patent Subcommittee promptly upon its becoming aware of: (a) any unlicensed activities which such Party believes may be an actual or impending infringement of any Patent or other proprietary right owned or applied for by it or the other Party included in the Amicus Patents, or Program Patents, or Patents included in the Co-Formulation Product IP, by a Product, or the Development, Manufacture, use, importation, or sale thereof; (b) any attack on or appeal of the grant of any Patent owned or applied for by it or the other Party to the extent containing claims to the Compound or a Product or the Development, Manufacture, use, or sale thereof; (c) any application for Patent by, or the grant of a Patent to, a Third Party in respect of rights which may be related to the Compound or a Product so as to potentially materially affect the Development, Manufacture, use, importation, or sale thereof; (d) any application made for a compulsory license under any Patent owned or applied for by it or the other Party and covering the Compound or a Product or the Development, Manufacture, use, importation, or sale thereof; or (e) any application for Patent by, or the grant of a Patent to, a Third Party in respect of rights which may be related to the same subject matter as, or conflict with, any Patent owned or applied for by it or the other Party and covering the Compound or a Product or the Development, Manufacture, use, importation, or sale thereof; which may claim the same subject matter as, or conflict with, any Patent owned or applied for by it or the other Party containing claims to the Compound or a Product, or the Development, Manufacture, use, importation, or sale thereof.

## 8.2 <u>Control of Actions</u>.

8.2.1 Subject to any restrictions Amicus may have under a Third Party agreement covering the Amicus Patents included in the Licensed Amicus Technology (including the Background License Agreements), GSK will determine whether or not to take whatever legal or other action is required in response to activities in the GSK Territory requiring notice under Section 8.1, 8.1 or 8.1 to the extent such activities specifically relate to Compound or a Product ("<u>GSK Protective Action</u>"). If GSK determines that such GSK Protective Action is warranted, in its sole discretion after reasonable consultation with Amicus via the Joint Patent Subcommittee, then, subject to any restrictions Amicus may have under a Third Party agreement covering the Amicus Patents included in the Licensed Amicus Technology (including the Background License Agreements), GSK shall, at GSK's expense, have the right to commence, prosecute and control such GSK Protective Action, including the settlement thereof and the granting of any licenses or sublicense within the scope of the License granted to GSK under any Amicus Patents, Program Patents or Patents within the Co-Formulation Product IP licensed to GSK hereunder. Amicus will cooperate with GSK in such action, including being joined as a Party to such action if such joinder is necessary for standing.

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8.2.2 Amicus will determine whether or not to take whatever legal or other action is required in response to activities in the Amicus Territory requiring notice under Section 8.1, 8.1 or 8.1 to the extent such activities specifically relate to Compound or a Product ("<u>Amicus Protective</u> <u>Action</u>"). If Amicus determines that such Amicus Protective Action is warranted, in its sole discretion after reasonable consultation with GSK via the Joint Patent Subcommittee, then Amicus shall, at Amicus' expense, have the right to commence, prosecute and control such Amicus Protective Action, including the settlement thereof and the granting of any licenses or sublicense within the scope of the licenses granted to Amicus pursuant to Section 2.4 in the Amicus Territory under any Program Patents or Patents within the Co-Formulation Product IP licensed to Amicus hereunder. GSK will cooperate with Amicus in such action, including being joined as a Party to such action if such joinder is necessary for standing.

8.2.3 In the event that the Parties determine that legal or other action is required in response to activities both in the Amicus Territory and GSK Territory, the Parties shall meet via the Joint Patent Subcommittee and shall coordinate such activities within their respective territories, including review and coordination of legal filings, strategy, and related issues in advance of taking such actions.

8.2.4 Each Party may be represented by counsel of its own selection at its own expense in a GSK Protective Action or Amicus Protective Action, as applicable. Any recovery obtained as a result of such GSK Protective Action and attributable to activities in the GSK Territory, whether by judgment, award, decree, or settlement, will, after reimbursement of the Parties for their reasonable costs and expenses associated with such GSK Protective Action, will be shared as follows: \*\*\*\*\*\*. Any recovery obtained as a result of such Amicus Protective Action and attributable to activities in the Amicus Territory, whether by judgment, award, decree, or settlement, will, after reimbursement of the Parties for their reasonable costs and expenses associated with such Amicus Protective Action, be shared as follows: \*\*\*\*\*\*. To the extent such recovery is insufficient to reimburse the Parties' associated reasonable costs and expenses fully, then a Party's share of such recovery will be the product of the total amount recovered with that Party's reasonable costs and expenses divided by the sum of both Parties' reasonable costs and expenses. The Party responsible pursuant to Section 7.2, 7.3 or 7.6 above, as applicable for prosecution and maintenance of the relevant Patent described in Section 8.1 and Section 8.1 shall determine whether or not to take whatever legal or other action is required with respect to the activities described in Section 8.1. For the avoidance of doubt, Amicus will determine and control any legal or other action in response to activities equivalent to those described in Section 8.1, Section 8.1 and Section 8.1 that do not specifically relate to Compound or Product.

8.3 <u>Trademark Infringement</u>. Notice regarding potential infringement of and control of any Protective Action relating to any GSK Trademark in any country of the Territory related to the Compound or a Product or the Development, Manufacture, use, importation, or sale thereof in the Territory will be addressed in accordance with the applicable Trademark License Agreement.

8.4 <u>Third Party Claims</u>. GSK and Amicus will each promptly notify the Joint Steering Committee and the Joint Patent Subcommittee of any Claim by a Third Party against GSK or Amicus, or any Affiliate or sublicensee of Amicus or GSK, alleging infringement of such Third Party's intellectual property rights as a result of the Development, Manufacture, marketing, sale, importation, or use of the Compound or a Product in any country. As directed by the Joint Steering Committee, the Parties will cooperate and use Commercially Reasonable Efforts to resolve such claimed infringement. Notwithstanding the foregoing, as between the Parties: (a) GSK shall be entitled, at its own expense, to lead in the defense of any such Claim by a Third Party against GSK or its Affiliates or sublicensees and shall select its counsel, and Amicus shall have the right to participate in such action, and to select its own counsel at its own expense; and (b) Amicus shall be entitled, at its own expense, to lead in the defense of any such Claim by a Third Party against Amicus or its Affiliates or sublicensees and shall select its counsel, and GSK shall have the right to participate in such action, and to select its own expense. If it appears reasonably likely that the claimed infringement will give rise to a Claim for indemnification hereunder, then the Party against whom such Claim for indemnification would be made will have the first right to defend against such Claim in accordance with Article XV.

#### IX. REPRESENTATIONS AND WARRANTIES

9.1 <u>Representations and Warranties of Both Parties</u>. Amicus and GSK each hereby represent and warrant to the other, as of the Restatement Effective Date, as follows:

9.1.1 It is a corporation, duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation and has all requisite power and authority, corporate or otherwise, to conduct its business as now being conducted, to own, lease and operate its properties and to execute, deliver and perform this Agreement.

9.1.2 No consent, approval, order or authorization of, or registration, declaration or filing with, any governmental agency is required to be obtained or made by or with respect to such Party in connection with its execution, delivery and performance of this Agreement.

9.1.3 The execution, delivery and performance by it of this Agreement and the transactions contemplated thereby have been duly authorized by all necessary corporate action and stockholder action and will not (i) violate any applicable Laws or (ii) result in a breach of or constitute a default under any material agreement, mortgage, lease, license, permit or other instrument or obligation to which it is a party or by which it or its properties may be bound or affected.

9.2 <u>Representations and Warranties of Amicus</u>. Amicus hereby represents and warrants to GSK, as of the Restatement Effective Date (unless otherwise specifically limited to the Effective Date), as follows:

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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9.2.1 It has the full right, power and authority to enter into this Agreement and to grant the License to GSK.

9.2.2 Except as otherwise may have been disclosed by Amicus to GSK prior the Restatement Effective Date, Amicus has received no notice that (a) the manufacture, sale, importation or use of the Compound within the Field as contemplated hereby infringes any Third Party rights, and (b) the Amicus Patents (to the extent representing issued Patents) are invalid or unenforceable.

9.2.3 To Amicus' knowledge, as of the Effective Date, there are no errors in the inventorship set forth in any of the Patent applications comprising Amicus Patents.

9.2.4 Except as provided or limited in Article II, as of the Effective Date, the Amicus Intellectual Property constitutes all intellectual property that is Controlled by Amicus and used in the Development and/or Manufacture of the Compound, and Amicus does not Control any additional Patents, Know-How or information that are necessary for GSK to Develop, Manufacture and Commercialize the Compound.

9.2.5 To Amicus' knowledge, as of the Effective Date, no Third Party Controls any Patent that is necessary for GSK to Develop, Manufacture and Commercialize the Compound as such activities are currently conducted or currently proposed to be conducted in the Amicus Territory or the GSK Territory.

9.2.6 It has not previously granted any right, license or interest in or to the Amicus Patents, or any portion thereof, that is in conflict with the rights or licenses granted to GSK under this Agreement.

9.2.7 As of the Effective Date and, to Amicus' knowledge as of the Restatement Effective Date, there are no investigations, inquiries, actions or other proceedings pending before any Regulatory Authority with respect to the Compound, and Amicus has not received written notice threatening any such investigation, inquiry, action or other proceeding.

9.2.8 As of the Effective Date, the Development of the Compound by or on behalf of Amicus has been conducted in compliance in all material respects with all applicable Laws; and, as of the Restatement Effective Date, neither Amicus nor to Amicus' knowledge, its Third Party contractors, have received any written notice which has led Amicus to believe that any of the Regulatory Approvals relating to the Compound or a Product developed by Amicus are not currently in good standing with the FDA or EMA and Amicus has no knowledge that any of its Third Party contractors has developed Compound or a Product in a manner that does not comply in all material respects with all applicable Laws.

9.2.9 Other than the Background License Agreements, as of the Effective Date, there are no other agreements to which Amicus is a party or, to Amicus' knowledge, as of the

Restatement Effective Date, that would prevent Amicus from performing its obligations under this Agreement or GSK from exercising the rights under the Amicus Intellectual Property under and in accordance with the License.

9.2.10 To its knowledge, there is no pending or threatened product liability action in relation to the Compound, and it is not aware of any grounds for any such product liability action.

9.2.11 The Development of the Co-Formulation Product(s) by or on behalf of Amicus (and excluding any such Development by or on behalf of GSK) has been, to the knowledge of Amicus, conducted in compliance in all material respects with all applicable Laws; and Amicus has no knowledge that any of its Affiliates or Third Party collaborators or contractors has developed the Co-Formulation Product(s) in a manner that does not comply in all material respects with all applicable Laws.

9.2.12 Amicus has all material permits, licenses, franchises, authorizations, orders and approvals of, and has made all filings, applications and registrations with, governmental entities that are required in order to permit Amicus to own or lease properties and assets and to carry on its business as presently conducted that are material to Amicus. Amicus has complied and is in compliance in all material respects with all statutes, laws, regulations, rules, judgments, orders and decrees of all governmental entities applicable to it that pertain to its business, including but not limited to compliance with the U.S. Foreign Corrupt Practices Act of 1977 (FCPA) (15 U.S.C. §§ 78dd-1, et seq.) and any applicable similar laws in foreign jurisdictions in which Amicus is currently, or has previously, conducted its business or is currently, or has previously, conducted clinical trials. Amicus has not received any notice from a governmental entity alleging noncompliance with any such applicable statutes, laws, regulations, rules, judgments, orders or decrees of any governmental entities.

9.3 <u>Representations and Warranties of GSK</u>. GSK hereby represents and warrants to Amicus, as of the Restatement Effective Date, as follows:

9.3.1 It has the full right, power and authority to enter into this Agreement and to grant the licenses to Amicus as purported to be granted pursuant to this Agreement.

9.3.2 It has all necessary rights from JCR and sufficient legal or beneficial title in the Co-Formulation Product IP and the GSK In-Licensed Background ERT IP to grant to Amicus the rights and licenses as purported to be granted pursuant to this Agreement.

9.3.3 It has not previously granted any right, license or interest in or to the Co-Formulation Product IP or GSK In-Licensed Background ERT IP that is in conflict with the rights or licenses granted to Amicus under this Agreement.

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

9.3.4 Except as otherwise may have been disclosed by GSK to Amicus prior the Restatement Effective Date, \*\*\*\*\*.

9.3.5 To GSK's knowledge, \*\*\*\*\*\*.

9.3.6 As of the Restatement Effective Date, GSK has acquired, by assignment or license, from JCR and included in the licenses granted to Amicus under Article II herein all JCR intellectual property that is necessary for Amicus to conduct the Development activities allocated to Amicus under the Co-Formulation Development Plan for the Development of a Co-Formulation Product and/or to exercise Amicus' rights to Commercialize a Co-Formulation Product as set forth herein.

9.3.7 To GSK's knowledge, there are no investigations, inquiries, actions or other proceedings pending before any Regulatory Authority in the Amicus Territory with respect to the Co-Formulation Product(s), including JR051, as JR051 exists as of the Restatement Effective Date, and GSK has not received written notice threatening any such investigation, inquiry, action or other proceeding.

9.3.8 The Development of the Co-Formulation Product(s), including JR051, as JR051 exists as of the Restatement Effective Date, by or on behalf of GSK (and excluding any such Development by or on behalf of Amicus) has been, to the knowledge of GSK, conducted in compliance in all material respects with all applicable Laws; and GSK has no knowledge that any of its Affiliates or Third Party collaborators or contractors has developed the Co-Formulation Product(s), including JR051, as JR051 exists as of the Restatement Effective Date, in a manner that does not comply in all material respects with all applicable Laws.

9.3.9 There are no other agreements to which GSK is a party or, to GSK's knowledge, that would prevent GSK from performing its obligations under this Agreement or Amicus from exercising the rights under and in accordance with the licenses granted by GSK to Amicus herein.

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9.4 <u>Mutual Limitations on Warranties</u>. OTHER THAN THE REPRESENTATIONS AND WARRANTIES MADE BY THE PARTIES PURSUANT TO SECTIONS 9.1 AND 9.2, THE PARTIES DISCLAIM ANY AND ALL OTHER REPRESENTATIONS AND WARRANTIES WHETHER EXPRESS OR IMPLIED, INCLUDING ANY REPRESENTATIONS OR

WARRANTIES OF NON-INFRINGEMENT, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE OR ANY REPRESENTATIONS OR WARRANTY ARISING FROM COURSE OF DEALING OR USAGE OF TRADE.

#### X. <u>COVENANTS</u>

#### 10.1 Conduct of Activities.

10.1.1 Throughout the Term, Amicus and GSK will comply in all material respects with all applicable Laws, including all applicable anti-bribery and anti-corruption Laws, concerning the Development, Manufacture, and Commercialization of the Compound or Products.

10.1.2 Neither Amicus nor GSK, nor any of their respective employees, consultants, agents or representatives who shall be undertaking any activities related to this Agreement or the subject matter thereof, shall have been debarred or shall be the subject of debarment or other disciplinary proceedings by the FDA or any Regulatory Authority in the Territory.

10.1.3 Amicus covenants that, as of the Restatement Effective Date, Amicus shall conduct all sales, marketing, medical affairs, and other activities allocated to Amicus hereunder in the Amicus Territory: (i) in compliance with all applicable Laws; (ii) consistent with applicable Industry Guidelines; and (iii) in compliance with Amicus' then-current compliance systems, policies, processes and procedures. For purposes of this Section 10.1.3, "<u>Industry Guidelines</u>" shall mean \*\*\*\*\*.

# 10.2 Background License Agreements.

10.2.1 It is understood that certain Patents and Know-How included within the Amicus Intellectual Property have been in-licensed pursuant to the Background License Agreements and that the obligations of Amicus and the rights of GSK under this Agreement shall be subject to, and limited by, the Background License Agreements.

10.2.2 It is further understood that each Background License Agreement may require that particular provisions be incorporated into a sublicense granted thereunder. The text of any such provisions in the Background License Agreements is set out on <u>Schedule 10.2</u> attached hereto and shall be deemed incorporated by reference into this Agreement. GSK agrees to be bound by the provisions set out on <u>Schedule 10.2</u> to the extent applicable to GSK in its capacity as a sublicensee under each Background License Agreement and, to the extent required by any Background License Agreement, the relevant Third Party licensor shall be deemed to be a third party beneficiary of this Agreement. In addition, GSK, in its capacity as a sublicensee under the applicable Background License Agreement. In addition, GSK, in its capacity as a sublicensee under the applicable Background License Agreement. agrees under such Background License Agreement, as set forth on <u>Schedule 10.2</u>.

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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10.2.3 Except as the Parties may otherwise mutually agree or as provided in Section 3.4.3(b), Amicus shall not amend, without the prior written consent of GSK (such consent not to be unreasonably withheld or delayed), or voluntarily terminate, its rights under any Background License Agreement in any manner that would materially and adversely affect GSK's rights and licenses under this Agreement. Amicus shall promptly notify GSK of any notice of breach delivered by it, or any termination or amendment of any of the Background License Agreements solely if such notice of breach, termination, or amendment materially and adversely affects GSK's rights and licenses under this Agreement.

#### 10.3 <u>\*\*\*\*\*; Third Party Obligations</u>.

10.3.1 All activities performed by JCR under this Agreement shall be deemed to be activities conducted by GSK and GSK shall remain responsible to Amicus for all activities of JCR under this Agreement to the same extent as if such activities had been undertaken by GSK itself.

10.3.2 \*\*\*\*\*\*.

10.3.3 GSK covenants that, in the event that GSK determines in good faith that any Third Party intellectual property rights are necessary in order to Develop, Manufacture or Commercialize the JR051 as a component of a Co-Formulation Product(s) (collectively, the "<u>Third Party Enzyme IP</u>"), then GSK shall be \*\*\*\*\*; it being understood that such Third Party rights shall be deemed to be included within Co-Formulation Product IP and subject to the terms and conditions of this Agreement accordingly.

10.4 Non-Compete. \*\*\*\*\*\*

#### XI. CONFIDENTIAL INFORMATION

#### 11.1 <u>Confidentiality</u>.

11.1.1 During the Term and for five (5) years thereafter, each Party will keep, and cause its Affiliates and sublicensees, if any, to keep confidential Information of the other Party, and neither Party, nor any of its Affiliates or sublicensees, if any, will use or disclose the Confidential Information of the other Party except as expressly permitted in this Agreement. The Parties acknowledge that Confidential Information may have been disclosed by either Party or its Affiliates to the other Party or its Affiliates pursuant to the Confidentiality Agreement will be deemed Confidential Information of the disclosing Party within the meaning of this Agreement and subject to the terms hereof.

11.1.2 The fact that a particular item of information is not or has ceased to be Confidential Information by virtue of one or more of the exclusions specified in the definition of Confidential Information (the "Excluded Item") shall not relieve the Party who obtained or received

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the Excluded Item from that Party's obligation of confidentiality and non-use (a) as to any other item of Confidential Information of the other Party or (b) as to the relationship of the Excluded Item to any other item of Confidential Information of the other Party.

11.1.3 Each Party hereby acknowledges that the Confidential Information of the other Party is highly valuable, proprietary, and confidential and that any use or disclosure of the other Party's Confidential Information, including any disclosures made to any Person or governmental agency in connection with the conduct of a clinical study pursuant to a Development Plan, will be made only to the extent reasonably necessary to carry out such Party's responsibilities or exercise the rights granted to, or reserved by it, under this Agreement. Any disclosure of the other Party's Confidential Information shall be made to an officer, employee, agent, or permitted sublicensee or contractor of a Party or any of its Affiliates only if such officer, employee, agent, or permitted of the confidential nature thereof and shall have agreed to hold such information in confidence and not to use such Confidential Information under confidentiality provisions at least as stringent as those provided in this Agreement, and each Party shall be responsible for any breach of such obligation of confidentiality by its or its Affiliates officers, employees, agents, permitted sublicensees and/or contractors.

11.1.4 The Parties agree that the obligations of this Section 11.1 are necessary and reasonable in order to protect the Parties' respective businesses, and that monetary damages alone may be inadequate to compensate a Party for any breach by the other Party or any of its Affiliates or their respective officers, employees, or agents of its covenants and agreements set forth herein. The Parties agree that any breach or threatened breach of this Section 11.1 may cause irreparable injury to the injured Party for which damages may not be an adequate remedy and that, in addition to any other remedies that may be available, in Law and equity or otherwise, such Party will be entitled to seek equitable relief against the breach or threatened breach of the provisions of this Section 11.1.

# 11.2 Disclosure of Terms; Public Announcements.

11.2.1 <u>Press Release</u>. Notwithstanding Section 11.3 below, the Parties have agreed on an initial press release of the transaction contemplated by this Agreement which is attached hereto as <u>Exhibit B</u> (the "<u>Initial Press Release</u>"). The Initial Press Release may be issued or used by each Party individually or by the Parties jointly on or after the Restatement Effective Date. Thereafter, each Party may disclose the information contained in such press release without need for further approval by the other.

11.2.2 <u>Further Publicity</u>. The Parties acknowledge the importance of supporting each other's efforts to publicly disclose results and significant development regarding the Products in the Amicus Territory and/or the GSK Territory and other activities in connection with this Agreement that reflect information that is not otherwise permitted to be disclosed under this Article XI, beyond what is required by Law, and each Party may make such public disclosures from time to time, subject to the terms set forth below in this Section 11.2.2. and Section 11.5, after good

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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faith consultation with the other Party; <u>provided</u> that if such public disclosures relate to clinical Development of a Product and are to be made by a Party prior to the earliest of (i) \*\*\*\*\*\*, or (ii) \*\*\*\*\*\*; then each Party may make such public disclosures only with the approval of the other Party, which approval shall not be unreasonably withheld. Such disclosures may include, with respect to such activities in such Party's Territory, the achievement of milestones, significant events in the Development or regulatory process and/or the Launch of a Product in a Major Market in such Party's Territory. When a Party (the "<u>Requesting Party</u>") elects to make any such public disclosure under this Section 11.2.2, it will give the other Party (the "<u>Cooperating Party</u>") at least six (6) Business days notice to review and comment on such statement, and in any event the Cooperating Party shall work diligently and reasonably regarding its review and provision of comments on the text of any proposed disclosure in an expeditious manner. The principles to be observed in such disclosures shall be accuracy, compliance with applicable Law and regulatory guidance documents, reasonable sensitivity to potential negative reactions of the FDA (and its foreign counterparts), adherence to each Party's internal guidelines and policies, and the need to keep investors informed regarding the Requesting Party's business.

11.3 <u>Confidential Terms; Required Disclosure</u>. Each Party agrees not to disclose to any Third Party the terms of this Agreement without the prior written consent of the other Party hereto, except each Party may disclose the terms of this Agreement to its advisors (including financial advisors, attorneys and accountants), actual or potential acquisition partners or private investors, and others on a need to know basis, in each case under appropriate confidentiality provisions substantially equivalent to those in this Agreement. A Party will be entitled to disclose the terms of this Agreement and/or Confidential Information of the disclosing Party where such disclosure is reasonably necessary to prosecute or defend any litigation or otherwise enforce its rights pursuant to this Agreement, or where demand for such disclosure is made on such Party or otherwise required pursuant to: (i) a valid order of a court or other governmental body or (ii) any other applicable Law; provided that if such Party, as the receiving Party, intends to make such disclosure or receives such demand, to the extent it may legally do so, the receiving Party shall give the disclosing Party prompt notice thereof to enable the disclosing Party to seek a protective order or other appropriate remedy concerning any such disclosure. The receiving Party will co-operate with the disclosing Party at the disclosing Party's expense in connection with the disclosing Party's efforts to obtain any such order or other remedy. If any such order or other remedy does not fully preclude disclosure, the receiving Party will make such disclosure only to the extent that such disclosure is legally required and subject to confidentiality, to the extent available. Notwithstanding the foregoing, the Parties agree to work together to prepare a redacted version of this Agreement to be filed by Amicus with the United States Securities Exchange Commission.

11.4 <u>Clinical Trial Register</u>. Either Party shall have the right to publish in its clinical trial register the results or summaries of the results of all clinical trials for the Compound or Products, solely in accordance with the terms set forth in Section 5.2.5 herein.

11.5 Publications. Except as otherwise expressly set forth herein and excluding publications made pursuant to Section 5.2.5 and Section 11.4, each Party shall have the right to publish manuscripts, abstracts, or other articles in scientific journals, or to make any public presentations with respect thereto, pertaining to a Product in the Territory, as follows: (a) prior to the earliest of (i) \*\*\*\*\*\*, or (ii) \*\*\*\*\*\*, neither Party shall have the right to publish any manuscripts, abstracts, or other articles in scientific journals, or to make any public presentations with respect thereto, without first obtaining the prior written consent of the other Party, which consent shall not be unreasonably withheld, and (b) regardless of whether a Party must obtain the prior written consent of the other Party before making a publication or presentation in accordance with this Section 11.5, neither Party shall publish any manuscripts, abstracts, or other articles in any scientific journals, nor make any public presentations with respect thereto, pertaining to any Product in the Territory without first following the procedures as set forth below in this Section 11.5 for review of such manuscript, abstract, article, or text of such public presentation by the other Party. In the event that either Party desires to make a publication or presentation pursuant to this Section 11.5, such Party shall provide a copy of the proposed manuscript (including abstracts, or presentation to a journal, editor, meeting, seminar or other third party) or proposed presentation to the other Party for its review and comments \*\*\*\*\*\* prior to submission of such proposed manuscript for publication and shall reasonably consider all comments of the other Party with respect thereto. The non-publishing Party shall confirm receipt of such proposed manuscript. If, during the \*\*\*\*\*\* specified above the nonpublishing Party notifies the other Party that a proposed manuscript contains patentable subject matter which requires protection, the non-publishing Party may require the delay of the publication for a period of time not to exceed \*\*\*\*\*\*, for any abstract submitted to a conference) for the purpose of allowing the pursuit of such protection; the object being to prevent either the endangerment of applications for the protection of intellectual property rights by premature publications detrimental to their novelty or the disclosure of Confidential Information. The publishing Party shall delete from the proposed manuscript prior to submission all Confidential Information of the non-publishing Party that the non-publishing Party identifies in good faith and requests to be deleted. If no prior written consent of the non-publishing Party is required as set forth above and no response is received from the non-publishing Party within \*\*\*\*\*\*, as applicable) of the date the proposed manuscript was submitted to the non-publishing Party, it may be conclusively presumed that the publication may proceed without delay; provided, however, that if the publishing Party does not receive confirmation of receipt of the proposed manuscript from the non-publishing Party prior to the expiration of such \*\*\*\*\*\*, as applicable), then the publishing Party shall use its reasonable efforts (prior to the expiration of such \*\*\*\*\*\* as applicable) to confirm with the non-publishing Party that such proposed manuscript was received for review by the non-publishing Party. Notwithstanding the foregoing, but without limiting either Party's rights under Section 11.3, in the event that a Party believes in good faith that it is obligated or appropriate to disclose any information pertaining to the safety of a Product, then such Party shall immediately notify the other Party and the Senior Executives of each Party shall meet within five (5) days thereafter to discuss disclosure of such information. In the event that the Senior Executives are unable to agree upon whether or not to disclose such information within three (3) days after such meeting, then the matter shall be referred

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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to the Joint Steering Committee, which shall meet shall meet as expeditiously as possible to fully and finally resolve the dispute.

## XII. CHANGE OF CONTROL

12.1 <u>Change of Control of Amicus</u>. In the event of a Change of Control of Amicus during the Term, subject to Section 12.1.5 below, GSK shall have a right to acquire an exclusive license to the Compound and Products in the Amicus Territory, in accordance with terms and conditions of this Article 12 (the "<u>US Buy-Out Option</u>").

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12.1.6 The only obligations of GSK and Amicus under this Section 12.1 are as expressly stated herein, and there are no further implied obligations relating to the matters contemplated herein. Without limiting the foregoing, except as expressly provided in Sections 12.1.1 and 12.1.2 above, Amicus shall have no obligation \*\*\*\*\*.

12.2 <u>Amicus Intellectual Property</u>. Notwithstanding any provision of this Agreement to the contrary, in the event of a Change of Control of Amicus, the scope of the Licensed Amicus Technology (including the Amicus Patents, Amicus Know-How and other Licensed Amicus Technology) and the Compound and Products and the rights and licenses granted to GSK with respect to the Compound and Products under this Agreement, shall not include, and nothing herein shall be construed to include, any of the Patents, Know-How or other intellectual property or subject matter that: (a) was owned or Controlled by the acquiring entity or its Affiliates prior to the closing of such Change of Control of Amicus; or (b) any intellectual property rights that the acquiring entity or any of its Affiliates develops following a Change of Control of Amicus independently, outside of the conduct of any activities under this Agreement, without using any of the (A) Licensed Amicus Technology, or (B) any of the GSK Background IP or GSK In-Licensed Background ERT IP; provided that:

12.2.1 Such acquiring entity's and its Affiliates' rights with respect to the Co-Formulation Product IP and Program Improvements, including any improvements made thereto by such acquiring entity or its Affiliates included therein, shall also be subject to the terms of Section 10.4; and

12.2.2 if, in the period from the date on which the closing of such Change of Control occurs and during the Term, the acquiring entity or any of its Affiliates make any inventions (and file applications for and obtain Patents claiming such inventions) as a result of such acquiring entity

or its Affiliates using, pursuant to the license granted from GSK to Amicus in Section 2.1.2, any Program Patents or Patents included in the Co-Formulation Product IP and such inventions of such acquiring entity or its Affiliates are dominated by the Program Patents or Patents included in the Co-Formulation Product IP, then such inventions of the acquiring entity and its Affiliates and any Patents claiming such inventions shall be deemed to be licensed to GSK pursuant to Section 2.1.1 above.

12.3 <u>Other Matters</u>. For the avoidance of doubt, except as set out in this Article XII, a Change of Control of Amicus shall not otherwise affect the rights or obligations of the Parties with respect to the Compound and Products in the Amicus Territory or the GSK Territory under this Agreement, and shall not be deemed to modify or expand the scope of either Party's rights under Article II above.

12.4 <u>Disputes</u>. Any dispute regarding this Article XII of the Agreement shall be resolved in accordance with the dispute resolution procedures set forth in Section 16.2 of the Agreement.

# XIII. TERM AND TERMINATION

13.1 <u>Term</u>. This Agreement shall commence on the Restatement Effective Date, and unless terminated earlier as provided in this Article 12.1, shall continue in full force and effect so long as a Party is Commercializing a Product pursuant to this Agreement (the "<u>Term</u>").

#### 13.2 <u>Termination for Material Breach</u>.

13.2.1 In the event that Amicus is in material default or material breach of any of its obligations hereunder, and Amicus fails to remedy such default or breach within a period of \*\*\*\*\*\* after written notice thereof was provided to Amicus by GSK, GSK may terminate this Agreement, by written notice to Amicus, as follows:

(a) in its entirety, (i) if Amicus is in material breach or material default of its obligations under \*\*\*\*\*\* or under \*\*\*\*\*; or (ii) pursuant to \*\*\*\*\*, if Amicus fails to perform its obligations under \*\*\*\*\*\* or Section 10.1.1 (\*\*\*\*\*) (it being understood that the \*\*\*\*\*cure period specified above shall not apply in the case of such termination pursuant to \*\*\*\*\*); or

(b) solely with respect to the affected Product, if: (i) Amicus is in material breach or material default of its payment obligations under \*\*\*\*\*\*, \*\*\*\*\*\*, with respect to such Product; or (ii) Amicus fails to conduct the Development activities allocated to Amicus under and in accordance with this Agreement and the relevant Development Plan for a Product, including a material breach or material default to bear Amicus' share of the Development Costs under a particular Development Plan in accordance with Section 5.1.4 and <u>Schedule 5.1.4</u>, (iii) Amicus fails to make payments as required in accordance with Section 6.5 or the applicable Supply Agreement with respect to such Product(s), or (iv) Amicus is in material breach of any of the representations or

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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warranties in Section 9.2 and such breach of such representations and warranties have a material, adverse effect on the rights or obligations of GSK bereunder.

13.2.2 In the event that GSK is in material default or material breach of any of its obligations hereunder, and fails to remedy such default or breach within a period of \*\*\*\*\* after written notice thereof was provided to GSK by Amicus, Amicus may terminate this Agreement, by written notice to GSK, as follows:

(a) in its entirety, if: (i) GSK is in material breach or material default of its obligations hereunder as a result of activities conducted \*\*\*\*\*; or (ii) pursuant to Section 15.7.2, if \*\*\*\*\* in each case with respect to the conduct of Development activities with respect to a Product(s) (it being understood that the ninety (90) day cure period specified above shall not apply in the case of such termination in accordance with \*\*\*\*\*);

(b) solely with respect to the affected Product (i.e., \*\*\*\*\*), if GSK fails to conduct the Development activities allocated to GSK under and in accordance with this Agreement and the relevant Development Plan for a Product, including a material breach or material default to bear GSK's share of the Development Costs under a particular Development Plan in accordance with Section 5.1.4 and <u>Schedule 5.1.4</u>;

(c) solely with respect to the Co-Formulation Product (i.e., in all countries of the Territory), if (i) GSK is in material breach or material default of its obligations pursuant to \*\*\*\*\* as a result of GSK \*\*\*\*\*; or (ii) GSK is in breach of any of the representations or warranties in Section 9.3 and such breach of such representations and warranties have a material, adverse effect on the rights or obligations of Amicus hereunder, or any of the covenants in \*\*\*\*\*, \*\*\*\*\*\* or \*\*\*\*\*;

(d) solely with respect to a particular Expanded Major Market Country, if GSK is in material breach or material default of its obligations under \*\*\*\*\* in such Expanded Major Market Country;

(e) to the extent such default or breach pertains to a particular Product(s) in a particular Expanded Major Market Country(ies), then on an affected Product-by-affected Product basis in each affected Expanded Major Market Country(ies) in which GSK is in such material breach or material default.

Any termination by a Party pursuant to this Section 13.2 shall become effective at the end of the applicable \*\*\*\*\*\* cure period unless the breaching Party has cured any such breach or default prior to the expiration of such \*\*\*\*\*\* period.

13.3 <u>Termination for Convenience</u>. GSK may terminate this Agreement in its entirety, or on a Product-by-Product basis, or an Expanded Major Market Country-by-Expanded Major Market Country basis, for any reason whatsoever, upon \*\*\*\*\* prior written notice to Amicus; <u>provided</u> that

GSK shall not have the right to terminate this Agreement with respect to the Monotherapy Product in the Amicus Territory pursuant to this Section 13.3 prior to earlier of: (i) \*\*\*\*\*\*, or (ii) the \*\*\*\*\*\* anniversary of the Restatement Effective Date; provided, however, that in the event of (A) a material change in the applicable Law or applicable regulatory guidance in the GSK Territory with respect to the applicable Product(s), that results in, or that is probable to result in, the inability of GSK to obtain Marketing Approval for a Monotherapy Product in any Expanded Major Market Country within the GSK Territory, or (B) the occurrence of a material Safety Event with respect to the Monotherapy Product, the foregoing restriction with respect to termination of this Agreement by GSK pursuant to this Section 13.2 with respect to the Monotherapy Product shall no longer apply and GSK shall have the right to exercise its termination right upon \*\*\*\*\* written notice as set forth above in this Section 13.3.

13.4 <u>Bankruptcy</u>. Either Party may terminate this Agreement in its entirety at any time during the Term by giving written notice to the other Party if the other Party files in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of the Party or of its assets, or if the other Party is served with an involuntary petition against it, filed in any insolvency proceeding, and such petition will not be dismissed within \*\*\*\*\* after the filing thereof, or if the other Party makes a general assignment for the benefit of creditors.

13.5 <u>By Mutual Consent</u>. The Parties may terminate this Agreement in its entirety or on a Product-by-Product or country-by-country basis at any time and for any reason during the Term upon their mutual written agreement.

#### XIV. EFFECTS OF TERMINATION

14.1 <u>Accrued Obligations</u>. The expiration or termination of this Agreement for any reason shall not release either Party from any liability that, at the time of such expiration or termination, has already accrued to the other Party or that it is attributable to a period prior to such expiration or termination, nor will any termination of this Agreement preclude either Party from pursuing any and all rights and remedies it may have under this Agreement, or at law or in equity, with respect to breach of this Agreement.

14.2 <u>Rights upon Termination by GSK for Amicus Breach; Exercise by Amicus of its Opt-Out Rights</u>. If GSK terminates this Agreement pursuant to Section 13.2, either in its entirety or with respect to a particular Product(s), or if Amicus exercises its Co-Development Opt-Out Right pursuant to Section 5.4 with respect to a particular Product(s) (including, for clarity, if Amicus exercises its First Opt-Out Right or Second Opt-Out Right pursuant to Section 5.1.4(b)(ii) with respect to a Co-Formulation Product), then the provisions of this Section 14.2 shall apply. As used in this Section 14.2 below, "Affected Area" shall mean the Amicus Territory and "Terminated Product(s)" shall mean the Compound and all Products in the case of termination of this Agreement in its entirety, or the terminated Product(s) in the case of termination of this Agreement with respect

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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to such Product(s), or if Amicus exercises its Co-Development Opt-Out Right, the Product(s) for which Amicus has exercised such Co-Development Opt-Out Right.

#### 14.2.1 Licenses.

(a) Effective upon such termination or the Co-Development Opt-Out Effective Date, as applicable, and solely with respect to each of the Terminated Product(s), the License in Section 2.1.1 shall terminate and shall be replaced with the following: Amicus hereby grants to GSK an exclusive, \*\*\*\*\* and license, with the right to grant sublicenses, under all Licensed Amicus Technology, to make, have made, use, sell, offer for sale, and import such Terminated Product(s) in the Field and in the Territory. For clarity, the License in Section 2.1.1 shall not be amended or modified by this Section 14.2.1(a) for any non-Terminated Product and shall continue in effect in accordance with its terms with respect to each non-Terminated Product (including, for clarity, and if applicable, with respect to each Product for which Amicus has not exercised its Opt-Out right). The license granted by Amicus to GSK in Section 2.1.2 shall also survive any such termination.

(b) Effective upon such termination or the Co-Development Opt-Out Effective Date, and solely with respect to each of the Terminated Product(s), the rights and licenses granted by GSK to Amicus pursuant to Section 2.4.1 and, if applicable, Section 2.4.2 above shall terminate; provided that Amicus shall continue to have a non-exclusive license under the relevant intellectual property described in such sections for the purposes of permitting Amicus to comply with its obligations under this Section 14.2 for the applicable periods described under this Section 14.2 below. \*\*\*\*\*.

14.2.2 <u>Assumption of Development and Commercialization Activities for Terminated Product(s)</u>. With respect to each of the Terminated Product(s), following the effective date of any such termination or the Co-Development Opt-Out Effective Date, as applicable, and in each case, in accordance with the terms of this Section 14.2, \*\*\*\*\*.

14.2.3 <u>Payment Obligations</u>. Subject to Sections 14.1 and 14.2.4, all of Amicus' payment obligations under Section 3.3, Section 3.4 and Section 5.1 with respect to the Terminated Product(s) shall terminate effective as of the effective date of such termination or the Co-Develoment Opt-Out Effective Date, as applicable, and thereafter, GSK shall make the following payments to Amicus with respect to the Terminated Product(s), as follows:

(a) <u>Milestones Payments:</u> GSK will pay to Amicus the milestone payments set out below following the first achievement by GSK, its Affiliate or Sublicensee of each of the corresponding milestone events that are achieved after the effective date of such termination or the Co-Development Opt-Out Effective Date, as applicable, such milestone payment to be made by GSK no later than \*\*\*\*\*\* following the receipt of an invoice from Amicus therefor. GSK shall notify Amicus in writing promptly, but in no event later than \*\*\*\*\*\* after the first achievement of

each of the following milestone events, and no invoice for payment of a milestone shall be sent by Amicus to GSK as provided herein prior to Amicus's reasonable determination that the corresponding milestone event has been achieved. Each of the following milestone payments shall be payable only once with respect to the first Terminated Product (other than a Co-Formulation Product) to achieve such milestone event, regardless of the number of times such Terminated Product or any other Terminated Product achieves the milestone event, and no milestones shall be paid by GSK for milestone events that are not achieved after the effective date of such termination or the Co-Development Opt-Out Effective Date, as applicable. For clarity, no milestone payments shall be made with respect to a Terminated Product that is a Co-Formulation Product.

Filing and Approval Milestone Event	Milesto	Milestone Payment	
1. *****	\$	*****	
2. *****	\$	*****	
3. *****	\$	*****	
Sales Performance Milestones	Milesto	Milestone Payment	
	¢	*****	
4. *****	\$		
		2	

For purposes of Milestone 4 and Milestone 5 in the table set forth above and the calculation of the royalty tiers in the table set forth in Sections 14.2.3(b)(i)(a) below, if the Terminated Product(s) is a Product(s) other than a Co-Formulation Product, the Net Sales of all such Terminated Products in the United States \*\*\*\*\*\*.

(b) <u>Royalties</u>.

(i) Subject to Section 14.2.3(b)(ii), (iii), (iv) and (v) below, from and after (A) the effective date of such termination or the Co-Development Opt-Out Effective Date, as applicable, or (B) the date of Launch of the applicable Terminated Product, whichever of (A) or (B) is the later to occur, GSK shall pay to Amicus royalties as set forth in clause a) or b) of this Section 14.2.3(b)(i), as applicable, based on the Net Sales of the applicable Terminated Product(s) in the Affected Area during a particular calendar year, on a Terminated Product-by-Terminated Product basis, for the longer of (x) \*\*\*\*\*\*, (y) \*\*\*\*\*\*, or (z) \*\*\*\*\*\* (the "<u>GSK Terminated Product Royalty Term</u>"). Upon the expiration of the GSK Terminated Product Royalty Term for a particular Terminated Product and GSK's obligations under Sections 3.4.3(b) and 14.2.3(b)(iv)b), GSK's license with respect to such Terminated Product as set forth in Section 14.2.1 shall become a royalty-free, fully paid-up license.

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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#### a) With respect to a Terminated Product that is a Product other than a Co-Formulation Product:

Net Sales of the Terminated Product in the United States in a particular calendar year	Royalty
****	*****
****	*****
****	*****
*****	*****

b) With respect to a Terminated Product that is a Co-Formulation Product:

Net Sales of the Terminated Product in the United States in a particular calendar year *****	Royalty *****
****	*****
****	*****
****	*****

(ii) \*\*\*\*\*

(iii) <u>Generic Equivalent</u>. During the GSK Terminated Product Royalty Term, on a Terminated Product-by-Terminated Product basis, if the cumulative unit volume of Generic Equivalent(s) sold by Third Parties in the Affected Area are equal to or greater than \*\*\*\*\*\* of the combined unit volume of the applicable Terminated Product and such Generic Equivalent(s) for all indications in the aggregate in the Affected Area in any calendar quarter determined by the number of prescriptions given for such Terminated Product and such Generic Equivalent(s), in the aggregate during such calendar quarter in the Affected Area (as measured by a Scott Levin Associates audit or other mechanism mutually agreed by the Parties), then the royalty rates applicable to Net Sales of such Terminated Product in the Affected Area shall be \*\*\*\*\* of the applicable royalty rates specified above in clause a) or b) of Section 14.2.3(b)(i), as applicable, with respect to Net Sales of such Terminated Product for so long as such competition exists, and such reduced royalty shall be paid by GSK for the shorter of \*\*\*\*\*\* from the date upon which GSK's

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

royalty obligations were reduced pursuant to this Section 14.2.3(b)(iii) as a result of the sales of such Generic Equivalent(s) in the Affected Area, or \*\*\*\*\*\* from the date of the first Launch of such Terminated Product in the Affected Area, after which time, and subject to GSK's obligations under Sections 3.4.3(b)

and 14.2.3(b)(iv)b), GSK's license with respect to such Terminated Product as set forth in Section 14.2.1 shall become a fully paid-up, royalty-free right and license.

## (iv) <u>Third Party Payments</u>.

a) During the GSK Terminated Product Royalty Term for a particular Terminated Product, any milestones, royalties and/or other license payments actually paid to a Third Party by GSK, its Affiliates, or Sublicensees under a written license agreement covering intellectual property in the Affected Area which, following a reasonable evaluation in accordance with normal business practice, GSK determines is necessary to enable GSK to Develop, Manufacture or, use, import, offer for sale, sell or otherwise Commercialize such Terminated Product in the Affected Area in accordance with this Agreement such that, absent such Third Party license the Development, Manufacture or Commercialization of such Terminated Product in the Affected Area would infringe such Third Party intellectual property, then such payments shall be creditable by GSK against royalties payable to Amicus under this Section 14.2.3(b); provided that the royalties due by GSK to Amicus with respect to such Terminated Product in any Quarter shall not be so reduced by more than \*\*\*\*\*\* of the royalties that would otherwise be payable by GSK to Amicus with respect to such Terminated Product for such Quarter; provided further that GSK can credit the remainder of such amounts paid to such Third Party against future royalties payable to Amicus by GSK.

b) The obligations of GSK under Section 3.4.3(a)(ii) shall survive any such termination by GSK or any exercise by Amicus of its Co-Development Opt-Out Right, and shall continue in effect in accordance with its terms following such termination or the Co-Development Opt-Out Effective Date, as applicable, and in addition, from and after the effective date of such termination or the Co-Development Opt-Out Effective Date, as applicable, and in addition, from and after the effective date of such termination or the Co-Development Opt-Out Effective Date, as applicable, the obligations of GSK under Section 3.4.3(a)(ii) shall automatically expand to include payments owed by Amicus pursuant to the Mount Sinai Agreement as a result of the Manufacture or Commercialization of the Terminated Product(s) in the Affected Area. In addition, in accordance with Section 14.2 above, from and after of the date of termination of this Agreement by GSK with respect to the Co-Formulation Product, or the date of the Co-Development Opt-Out Effective Date with respect to a Co-Formulation Product, as applicable, \*\*\*\*\*\*.

(v) If (A) GSK terminates this Agreement in its entirety or with with respect to a Product, in each case, pursuant to Section 13.2 or (B) Amicus exercises its Co-Development Opt-Out Right pursuant to Section 5.4 with respect to the Co-Formulation Product (and not, for clarity, if Amicus exercises its Co-Development Opt-Out Right pursuant to Section 5.4 with respect to any Product other than the Co-Formulation Product), GSK may off-set Amicus' share (determined in accordance with Section 5.1.5) of any documented Development Costs (calculated in

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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the same manner as specified in <u>Schedule 5.1.5</u>) that GSK incurs directly as a result of the assumption, and the conduct of any Development activities allocated to Amicus under the relevant Development Plan for the Terminated Product(s) in effect as of the date of any such termination or the relevant Co-Development Opt-Out Effective Date, as applicable, that are assumed by GSK following such effective date of termination or such Co-Development Opt-Out Effective Date, as applicable, against any milestone or royalty payments owed by GSK to Amicus pursuant to Section 14.2.3(a) or (b).

(vi) Solely in the case that Amicus exercises its Co-Development Opt-Out Right pursuant to Section 5.4 with respect to any Product other than the Co-Formulation Product (and not for clarity GSK if terminates this Agreement pursuant to Section 13.2 or if Amicus exercises its Co-Development Opt-Out Right pursuant to Section 5.4 with respect to the Co-Formulation Product), prior to any reduction that may be taken pursuant to Section 14.2.3(b)(ii) or (iii) above, \*\*\*\*\*\*.

(vii) For purposes of this Section 14.2, "<u>Valid Claim</u>" shall have the meaning given to such term in Section 1.199 above; it being understood that, for purposes of this Section 14.2, references to a "Product" in Section 1.199 shall be deemed to refer to the applicable Terminated Product(s).

(viii) Commencing with the first Quarter in which Net Sales of a Terminated Product(s) for which GSK owes a royalty to Amicus in accordance with Section 14.2.3(b) and for each Quarter thereafter in which GSK, or any of its Affiliates or Sublicensees sell a Terminated Product(s), GSK shall, within \*\*\*\*\* after the end of the applicable Quarter, submit to Amicus, together with GSK's payment for the royalties due for each Quarter, a written report showing the Net Sales of Terminated Products, and any royalties payable by GSK pursuant to Section 14.2.3(b). Such reports shall be in the format reasonably requested by Amicus and shall include such information regarding the Net Sales of such Terminated Products and calculation of such royalties as may be reasonably requested by Amicus, including to permit Amicus to comply with its obligations under any Background License Agreement.

14.2.4 <u>Development</u>. In the event that, on the date of notice of such termination or the date of the relevant Co-Development Opt-Out Notice, as applicable, Amicus is conducting any ongoing clinical trials of any Terminated Product(s) in the Affected Area, to the extent and as requested by GSK, Amicus will promptly transition such ongoing clinical trial(s) to GSK or its designee following the effective date of termination or the date of such Co-Development Opt-Out Notice. During the shorter of (a) the period in which Amicus is performing transition activities in accordance with this Section 14.2.4, or (b) for \*\*\*\*\* following the effective date of such termination or the Co-Development Opt-Out Effective Date, as applicable, Amicus will remain responsible for Amicus' share under Sections 5.1.4 and 5.1.5 of (i) any Development Costs incurred in the continued conduct of such ongoing clinical trials and (ii) any Out-of-Pocket Expenses incurred

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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by Amicus or GSK to transition any such ongoing clinical trials (or portion thereof) to GSK or its designee, as requested by GSK.

14.2.5 <u>Committees</u>. For the avoidance of doubt, upon termination by GSK of this Agreement in its entirety pursuant to Section 13.2 or if Amicus exercises its Co-Development Opt-Out Right pursuant to Section 5.4 with respect to all Products, the Joint Steering Committee and all Subcommittees (other than the Joint Patent Subcommittee) shall cease to exist and, subject to this Section 14.2.5 below, all obligations of the Joint Steering Committee and such Subcommittees shall vest exclusively in GSK, including the right to make a final decision on matters originally within the scope of

responsibilities of the Joint Steering Committee, or any relevant Subcommittee, as applicable, subject to Section 4.4. Notwithstanding the foregoing, GSK shall not have the right to terminate and dissolve the Joint Patent Subcommittee, and the Joint Patent Subcommittee shall continue in effect with the responsibilities described in, and decisions made in accordance with, Section 4.2.1 until the last Patent application included within the Licensed Amicus Technology or Program Patents or Co-Formulation Product IP Controlled by Amicus has been granted or rejected in a final, unappealable decision by the relevant governmental authority after which GSK may terminate and dissolve the Joint Patent Subcommittee, and all obligations of the Joint Patent Subcommittee shall vest exclusively in GSK, including the right to make a final decision on matters originally within the scope of responsibilities of the Joint Patent Subcommittee, except that Amicus, not GSK, shall have the right to make the final decision with respect to any matter pertaining to (a) an Amicus Prosecuted Patent or (b) a Program Patent or Patent within the Co-Formulation Product IP, in either case, Controlled by Amicus. For the avoidance of doubt, in the event that GSK terminates the Agreement pursuant to Section 13.2 with respect to a particular Product, but does not terminate the Agreement in its entirety, or if Amicus exercises its Co-Development Opt-Out Right pursuant to Section 5.4 with respect to a particular Product, but not all Products, as applicable, then the JSC and all Subcommittees (other than the Joint Patent Subcommittee) shall continue solely with respect to the Products with respect to which this Agreement has not been terminated or with respect to which Amicus has not exercised its Co-Development Opt-Out Right, as applicable.

## 14.2.6 Additional Matters.

(a) Subject to Section 14.2.5, from and after any termination of this Agreement by GSK pursuant to Section 13.2 or the Co-Development Opt-Out Effective Date, as applicable, all of the Parties rights and obligations under Articles VII and VIII with respect to the Licensed Amicus Technology, Program Patents, Program Improvements, and Co-Formulation Product IP shall survive.

(b) From and after the termination of this Agreement by GSK pursuant to Section 13.2 with respect to one or more Products, but not this Agreement in its entirety, or from and after Amicus' exercise of its Co-Development Opt-Out Right with respect to one or more Products,

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but not all Products, all of the Parties' rights and obligations with respect to the Development and Commercialization activities for any and all non-terminated Products shall survive unchanged and continue in full force and effect.

14.2.7 <u>Non-Compete</u>. From and after any termination of this Agreement by GSK pursuant to Section 13.2 or Amicus' exercise of its Co-Development Opt-Out Right pursuant to Section 5.4, as applicable, \*\*\*\*\*.

14.2.8 <u>Transition</u>. Without limiting the foregoing, following such termination of this Agreement pursuant to Section 13.2, or the Co-Development Opt-Out Effective Date, as applicable, Amicus shall use Commercially Reasonable Efforts to cooperate with GSK and/or its designee to effect a smooth and orderly transition of any Development activities with respect to the Terminated Product(s) that were, prior to such termination or Co-Development Opt-Out Effective Date, as applicable, allocated to Amicus under the applicable Development Plan, and to effect a smooth and orderly transition of any Commercialization activities with respect to such Terminated Product(s) conducted by Amicus prior to such termination.

14.2.9 <u>Commercialization</u>. Solely in the case of a termination of this Agreement by GSK pursuant to Section 13.2, to avoid disruption of supply of any Terminated Product(s) to patients if termination occurs after the Launch of a Terminated Product(s) in the Affected Area, Amicus, its Affiliates and Sublicensees shall continue to sell the Terminated Product(s) in the Affected Area in accordance with the terms and conditions of this Agreement, for up to \*\*\*\*\* or such shorter period of time as requested by GSK as provided below, after the effective date of any such termination of this Agreement with respect to any such Terminated Product(s) ("<u>Amicus Wind-Down Period</u>"); provided that GSK may terminate the Amicus Wind-Down Period in the Affected Area upon \*\*\*\*\* written notice to Amicus; provided further that (i) Amicus shall not be obligated to promote the sale of such Terminated Products in the Affected Area during the Amicus Wind-Down Period; and (ii) if the Terminated Product is a Co-Formulation Product, then GSK shall continue to supply Amicus with its (and its Affiliates' and sublicensees') reasonable requirements of such Terminated Product(s) remaining in Amicus' or its Affiliates' inventory and GSK shall have the option, upon notice to Amicus, to repurchase any such quantities of the Terminated Product(s) from Amicus at a price equal to Amicus' Manufacturing Costs. If GSK so elects to purchase any remaining quantities of the Terminated Product(s) from Amicus as set forth herein, Amicus will transfer to GSK such quantities of inventory of the Terminated Product(s).

14.2.10 <u>Regulatory Filings</u>. Following termination of this Agreement by GSK pursuant to Section 13.2, or the date of the Co-Development Opt-Out Notice, as applicable, and at GSK's written election, Amicus will assign and transfer (or cause to be assigned and transferred) to GSK or its designee (or to the extent not so assignable, Amicus shall take all reasonable action to make available to GSK or its designee the benefits of) all regulatory submissions and filings and

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

marketing approvals (including all INDs, MAAs and Marketing Approvals) Controlled by Amicus pertaining solely to the Terminated Product(s) in the Affected Area. In each case, unless otherwise required by any applicable Law, Amicus shall use all reasonable efforts to make such foregoing assignment (or availability), within \*\*\*\*\*\* after the effective date of any such termination or the Co-Development Opt-Out Effective Date, , as applicable, (or, with respect to any such regulatory filings pertaining to an Ongoing Trial that Amicus is continuing to conduct pursuant to Section 14.2.4 above, within \*\*\*\*\* after the completion of such Ongoing Trial), <u>provided</u>, <u>however</u>, that in the event that Amicus is unable to make such assignment or to make such regulatory filings available to GSK within \*\*\*\*\*\* after the effective date of any such termination (or the completion of such Ongoing Trial, as applicable) or the Co-Development Opt-Out Effective Date, as applicable, due to factors beyond Amicus' reasonable control, then Amicus shall so notify GSK (including the reason for any such delay) prior to the expiration of such \*\*\*\*\*\* period and the Parties shall mutually agree (such agreement not to be unreasonably withheld by either Party) an appropriate extension to such \*\*\*\*\*\* period.

14.3 <u>Rights upon Termination by Amicus for GSK Breach; or Termination by GSK for Convenience</u>. If (a) Amicus terminates this Agreement in its entirety, or terminates with Agreement with respect to a particular Product(s) or with respect to a particular Product in one or more Expanded Major Market Country(ies), in each case, pursuant to Section 13.2 or (b) if GSK terminates this Agreement in its entirety or terminates this Agreement with respect to a particular Product(s), or terminates an Expanded Major Market Country, in each case pursuant to Section 13.3, then the provisions of this Section 14.3 shall apply. As used in this Section 14.3 below: <u>"Terminated Product(s)</u>" shall mean the Compound and all Products in the case of termination of this Agreement in its entirety, or the terminated Product(s) in the case of termination of this Agreement with respect to such Product(s); and <u>"Affected Area</u>" shall mean all countries within the GSK Territory if this Agreement is terminated in its entirety or with respect to a particular Product(s), or the specific terminated Expanded Major Market Country(ies) in the case of termination of this Agreement with respect to such Expanded Major Market Country(ies).

#### 14.3.1 Licenses

(a) The licenses granted by GSK to Amicus pursuant to Sections 2.4 and 2.5 above shall survive such termination, except that from and after such termination such licenses and rights shall also be expanded as follows: (i) if this Agreement is terminated in its entirety for all Products or with respect to a particular Product, the license and rights in clause (i) of Section 2.4.1 and, if applicable, clause (i) of Section 2.4.2 shall convert to an exclusive license, with the right to grant sublicenses, to Develop the Terminated Product(s) in the Field in the Territory; (ii) the license and rights granted by GSK to Amicus in clause (ii) of Section 2.4.1 shall expand to include the right to make and have made and otherwise Manufacture a Terminated Product (other than a Co-Formulation Product) for the purpose of use, sale and/or other Commercialization in the Amicus Territory and/or the Affected Area and (ii) the license and rights granted by GSK to Amicus in clause (iii) of Section 2.4.1 and, if applicable, clause (ii) of Section 2.4.2 shall convert to an

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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exclusive (even as to GSK) license, with the right to grant sublicenses, to use, sell, offer for sale, import and otherwise Commercialize the relevant Termination Product(s) in the Field in the Amicus Territory and/or the Affected Area. Further, Section 2.4.2(b) shall survive and shall be deemed to be amended as follows: the words "and/or the Affected Area" shall be deemed to be added after each reference to "the Amicus Territory" in Section 2.4.2(b).

(b) Following the effective date of termination, the License granted by Amicus to GSK under the Licensed Amicus Technology, solely with respect to the Terminated Product(s) in the Affected Area, shall convert to a non-exclusive license and shall be limited to the use of the Licensed Amicus Technology: (i) for the purposes of permitting GSK to comply with its obligations under this Section 14.3 for the applicable periods described under this Section 14.3 below; and (ii) to make and/or have made the Terminated Product(s) in the Affected Area solely for use and sale (A) by GSK, its Affiliates or Sublicensees within the GSK Territory, excluding the Affected Area, or (B) if the Terminated Product is a Co-Formulation Product, for supply to Amicus pursuant to Section 6.5.4 and/or, if applicable, Section 6.5.5 and the Supply Agreement, unless or until this Agreement is terminated in its entirety. Except as provided in the preceding sentence for the applicable periods described in such sentence, the License, and all of GSK's rights, under the Licensed Amicus Technology with respect to the Terminated Product(s) in the Affected Area shall terminate and shall automatically revert to Amicus upon any such termination of this Agreement.

14.3.2 <u>Assumption of Development and Commercialization Activities for Terminated Product(s) in the relevant terminated Expanded</u> <u>Major Market Country(ies)</u>. With respect to each of the Terminated Product(s) in the Affected Area, following the effective date of any such termination and in each case, in accordance with this Section 14.3, \*\*\*\*\*.

14.3.3 <u>Payment Obligations</u>. Subject to Sections 14.1 and 14.3.4, all of GSK's payment obligations under Section 5.1 with respect to the Terminated Product(s) shall terminate effective as of the effective date of any such termination by Amicus, and thereafter, Amicus shall make the following payments to GSK with respect to the Terminated Product(s)

(a) <u>Milestones Payments:</u> Following the effective date of any such termination by Amicus pursuant to Section 13.2 or by GSK pursuant to Section 13.3, Amicus will make milestone payments to GSK with respect to each Terminated Product and the Affected Area, as set forth in this Section 14.3.3(a). Amicus will pay to GSK the milestone payments set out below following the first achievement by Amicus, its Affiliate or Sublicensee of each of the corresponding milestone events that are achieved after the effective date of such termination, such milestone payment to be made by Amicus to GSK no later than \*\*\*\*\*\* following the receipt of an invoice from GSK therefor. Amicus shall notify GSK in writing promptly, but in no event later than \*\*\*\*\*\* after the first achievement of each of the following milestone events, and no invoice for payment of a milestone shall be sent by GSK to Amicus as provided herein prior to GSK's reasonable determination that the corresponding milestone event has been achieved. Each of the following milestone payments shall be payable only once with respect to the first Terminated Product (other

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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than a Co-Formulation Product) to achieve such milestone event, regardless of the number of times such Terminated Product or any other Terminated Product(s) achieves the milestone event, and no milestones shall be paid or payable by Amicus for milestone events that are not achieved after the effective date of such termination. For clarity, no milestone payments shall be made with respect to a Terminated Product that is a Co-Formulation Product.

Filing and Approval Milestone Event	Milestone Payment
1.****	*****
2.****	*****
3.*****	*****
Sales Performance Milestones	Milestone Payment
4.****	*****
5.****	*****

For purposes of Milestone 4 and Milestone 5 in the table set forth above and the calculation of the royalty tiers in the table set forth in Sections 14.3.3 (b)(i)(a) below, if the Terminated Product(s) is a Product(s) other than a Co-Formulation Product, the Net Sales of all such Terminated Products in the applicable Expanded Major Market Country \*\*\*\*\*\*.

#### (b) Royalties.

Following the effective date of any such termination by Amicus pursuant to Section 13.2, and subject to Section (i) 14.3.3(b)(ii), (iii), (iv) and (v) below, from and after the effective date of such termination or the date of Launch of the applicable Terminated Product in the Affected Area, whichever is later, Amicus shall pay to GSK royalties as set forth in clause a) or b) of this Section 14.3.3(b)(i), as applicable, based on the Net Sales of the applicable Terminated Product(s) in the relevant Affected Area during a particular calendar year, on a Terminated Product-by-Terminated Product basis, and country-by-country basis, for the longer of (x) \*\*\*\*\*\*, (y) \*\*\*\*\*\*, or (z) \*\*\*\*\*\* (the "Amicus Terminated Product Royalty Term"). Upon the expiration of the Amicus Terminated Product Royalty Term for a particular Terminated Product, and subject to Section 14.3.3(b)(iv)(b) below if the Terminated Product is a Royalty-Bearing Co-Formulation Product, Amicus' license with respect to such Terminated Product as set forth in Section 14.3.1 shall become a royalty-free, fully paid-up license.

> a) With respect to a Terminated Product other than a Co-Formulation Product:

- Material has been omitted and filed separately with the Commission.

Net Sales of Terminated Product in an Expa Country in the Affected Area in a particula *****		rket	Royalty *****
*****			*****
*****			*****
*****			*****
*****			*****
	b)	With respect to a Terminated Product that is a Co-Formulation Product:	

Net Sales of Terminated Product in an Expanded Major Market Country in the Affected Area in a particular calendar year	Royalty
****	*****
****	*****
****	*****
****	*****

If, at any time during the applicable Amicus Terminated Product Royalty Term, the only Valid Claim covering (ii) the relevant Terminated Product in the applicable country of the Affected Area is a Valid Claim of a Joint Program Patent, then the royalty rate for such Terminated Product during the applicable period shall be reduced by \*\*\*\*\*\* of the applicable royalty rates set forth in the table above; it being understood that if during such Amicus Terminated Product Royalty Term, such Terminated Product becomes covered by any other Valid Claim in the Affected Area, the applicable royalty rate shall be the full rate set forth in the table above.

Generic Equivalent. During the Amicus Terminated Product Royalty Term, on a Terminated Product-by-(iii) Terminated Product and country-by-country basis, if the cumulative unit volume of Generic Equivalent(s) sold by Third Parties in the applicable country of the Affected Area are equal to or greater than \*\*\*\*\* of the combined unit volume of the applicable Terminated Product and such Generic Equivalent(s) for all indications in the aggregate in such country in the Affected Area in any calendar quarter determined by the number of prescriptions given for the Terminated Product and such Generic Equivalent(s), in the aggregate during such calendar quarter in such country in the Affected Area (as measured by a Scott Levin Associates audit

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or other mechanism mutually agreed by the Parties), then the royalty rates applicable to Net Sales of the Terminated Product in such country in the Affected Area shall be \*\*\*\*\*\* of the royalty rates specified above in clause a) or b) of Section 14.3.3(b)(i), as applicable, with respect to the Net Sales of such Terminated Product in such country in the Affected Area for so long as such competition exists, and such reduced royalty shall be paid by Amicus for the shorter of \*\*\*\*\*\* from the date upon which Amicus' royalty obligations were reduced pursuant to this Section 14.3.3(b)(iii) as a result of the sales of such Generic Equivalent(s) in such country in the Affected Area, or \*\*\*\*\*\* from the date of the first Launch of the Terminated Product in such country in the Affected Area, after which time, and subject to Section 14.3.3(b)(iv)b) if the Terminated Product is a Royalty Bearing Co-Formulation Product, Amicus' license rights with respect to such Terminated Product as set forth in Section 14.3.1 shall become a fully paid-up and royalty-free.

#### Third Party Payments. (iv)

a) During the Amicus Terminated Product Royalty Term for a particular Terminated Product, any milestones, royalties and/or other license payments actually paid to a Third Party by Amicus, its Affiliates, or Sublicensees under a written license agreement covering intellectual property in the Affected Area which, following a reasonable evaluation in accordance with normal business practice, Amicus determines is necessary to enable Amicus to Develop, Manufacture or, use, import, offer for sale, sell or otherwise Commercialize such Terminated Product in the Affected Area in accordance with this Agreement such that, absent such Third Party license the Development, Manufacture or Commercialization of such Terminated Product in the Affected Area would infringe such Third Party intellectual property, then such payments shall be creditable by Amicus against royalties payable to GSK under this Section 14.3; provided that the royalties due by Amicus to GSK with respect to such Terminated Product in any Quarter shall not be so reduced by more than \*\*\*\*\* of the royalties that would otherwise be payable by Amicus to GSK with respect to such Terminated Product for such Quarter; provided further that Amicus can credit the remainder of such amounts paid to such Third Party against future royalties payable to GSK by Amicus.

b) The obligations of GSK under Section 3.4.3(a)(ii) shall terminate solely with respect to the Terminated Product(s) in the Affected Area upon the effective date of termination and thereafter Amicus shall be responsible for any payments owed by Amicus pursuant to the Mount Sinai Agreement as a result of the Manufacture or Commercialization of such Terminated Product(s) in the Affected Area. Only if the Terminated Product is a Royalty-Bearing Co-Formulation Product, the obligations of Amicus, and the rights of GSK, under Section 3.4.1 shall survive any such terminated Product constituting a Royalty-Bearing Co-Formulation Product as owed by GSK pursuant to the GSK/JCR Master Agreement as a result of Net Sales of such Terminated Product constituting a Royalty-Bearing Co-Formulation Product in the Affected Area.

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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(v) Amicus may off-set GSK's share (determined in accordance with Section 5.1.5) of any documented Development Costs (calculated in the same manner as specified in <u>Schedule 5.1.5</u>) that Amicus incurs directly as a result of the assumption, and the conduct of any Development activities in the Affected Area allocated to GSK under the relevant Development Plan for the Terminated Product(s) in effect as of the date of any such termination that are assumed by Amicus following such effective date of termination against any milestone or royalty payments owed by Amicus to GSK pursuant to Section 14.3.3(a) or (b).

(vi) Commencing with the first Quarter in which Net Sales of a Terminated Product(s) for which Amicus owes a royalty to GSK in accordance with Section 14.3.3(b) and for each Quarter thereafter during the Term, Amicus shall, within \*\*\*\*\* after the end of the applicable Quarter, submit to GSK, together with Amicus' payment for the royalties due for each Quarter, a written report showing the Net Sales of Terminated Products and any royalties payable by Amicus pursuant to Section 14.3.3(b). Such reports shall be in the format reasonably requested by GSK and shall include such information regarding the Net Sales of Products and calculation of such royalties as may be reasonably requested by GSK.

(vii) For purposes of this Section 14.3, "<u>Valid Claim</u>" shall have the meaning given to such term in Section 1.199 above, it being understood that for purposes of this Section 14.3, references to a "Product" in Section 1.199 shall be deemed to refer to the applicable Terminated Product.

14.3.4 <u>Development</u>. In the event that, on the date of notice of such termination, there are any ongoing clinical trials of any Terminated Product(s) in the Affected Area (or, if the Affected Area is less than the entire world, any ongoing clinical trials of any Terminated Product(s) that are specifically directed to the requirements of an Expanded Major Market Country or other country within the Affected Area), to the extent and as requested by Amicus, following the effective date of termination, GSK will promptly transition to Amicus or its designee such ongoing clinical trials. During the shorter of (a) the period in which GSK is performing transition activities in accordance with this Section 14.3.4, or (b) for \*\*\*\*\*\* following the effective date of such termination, GSK will remain responsible for GSK's share under Sections 5.1.4 and 5.1.5 of (i) any Development Costs incurred in the continued conduct of such ongoing clinical trials and (ii) any Out-of-Pocket Expenses incurred by GSK or Amicus to transition any such ongoing clinical trials (or portion thereof) to Amicus or its designee, as requested by Amicus.

14.3.5 <u>Committees</u>. For the avoidance of doubt, upon termination of this Agreement in its entirety by Amicus pursuant to Section 13.2 or by GSK pursuant to Section 13.3, as applicable, the Joint Steering Committee and all Subcommittees (other than the Joint Patent Subcommittee) shall cease to exist and, subject to this Section 14.3.5 below, all obligations of the Joint Steering Committee and such Subcommittees shall vest exclusively in Amicus, including the right to make a final decision on matters originally within the scope of responsibilities of the Joint Steering Committee or the relevant Subcommittee, as applicable, subject to Section 4.4. Notwithstanding the

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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foregoing, Amicus shall not have the right to terminate and dissolve the Joint Patent Subcommittee, and the Joint Patent Subcommittee shall continue in effect with the responsibilities described in, and decisions made in accordance with, Section 4.2.1 until the last Patent application included within the Licensed Amicus Technology or Program Patents or Co-Formulation Product IP Controlled by GSK has been granted or rejected in a final, unappealable decision by the relevant governmental authority after which Amicus may terminate and dissolve the Joint Patent Subcommittee, and all obligations of the Joint Patent Subcommittee shall vest exclusively in Amicus, including the right to make a final decision on matters originally within the scope of responsibilities of the Joint Patent Subcommittee. For the avoidance of doubt, in the event that this Agreement is terminated with respect to a particular Product and/or with respect to a particular Expanded Major Market Country(ies), but the Agreement is not terminated in its entirety, then the JSC and all Subcommittees (other than the Joint Patent Subcommittee) shall continue solely with respect to the Products and countries with respect to which this Agreement has not been terminated and the Joint Patent Subcommittee shall continue with respect to both the Terminated Product(s) and any Product(s) with respect to which this Agreement has not been terminated.

# 14.3.6 Additional Matters.

(a) Subject to Section 14.3.5, from and after any termination of this Agreement by Amicus pursuant to Section 13.2, all of the Parties rights and obligations under Articles VII and VIII with respect to the Licensed Amicus Technology, Program Patents, Program Improvements, and Co-Formulation Product IP shall survive .

(b) From and after any termination of this Agreement by Amicus pursuant to Section 13.2 with respect to one or more Product(s) or one or more Expanded Major Market Country(ies), but not this Agreement in its entirety, all of the Parties' rights and obligations with respect to the Development and Commercialization activities for any and all non-terminated Products and non-terminated Expanded Major Market Countries and other countries within the Territory shall survive unchanged and in full force and effect.

14.3.7 <u>Non-Compete</u>. From and after any termination of this Agreement by Amicus pursuant to Section 13.2 or by GSK pursuant to Section 13.3, \*\*\*\*\*\*.

14.3.8 <u>Transition</u>. Without limiting the foregoing, following such termination of this Agreement, GSK shall use Commercially Reasonable Efforts to cooperate with Amicus and/or its designee to effect a smooth and orderly transition of the Development activities with respect to the Terminated Product(s) in the Affected Area that were, prior to such termination, allocated to GSK under the applicable Development Plan, and to effect a smooth and orderly transition of all Commercialization activities with respect to such Terminated Product(s) for the Affected Area conducted by or under the authority of GSK prior to such termination.

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14.3.9 <u>Commercialization</u>. To avoid disruption of supply of any Terminated Product(s) to patients if termination occurs after the Launch of a Terminated Product(s) in the relevant Affected Area, GSK, its Affiliates and Sublicensees shall continue to sell the Terminated Product(s) in the relevant Affected Area, in accordance with the terms and conditions of this Agreement, for up to \*\*\*\*\*\* or such shorter period of time as requested by Amicus as provided below, after the effective date of any such termination of any such Terminated Product(s) ("<u>GSK Wind-Down Period</u>"); provided that Amicus may terminate the GSK Wind-Down Period in any country of the relevant Affected Area upon \*\*\*\*\* written notice to GSK; provided further that GSK shall not be obligated to promote the sale of Terminated Products in the Affected Area during the GSK Wind-Down Period. Subject to the foregoing obligations of GSK, during the GSK Wind-Down Period, GSK may transfer any remaining inventory of Terminated Product(s) from the Affected Area to a country within the GSK Territory for which GSK's rights with respect to such Product(s) have not been terminated. Within \*\*\*\*\*\* following the expiration of the GSK Wind-Down Period, GSK shall notify Amicus of any quantities of Terminated Product(s) for the Affected Area remaining in GSK's or its Affiliates' inventory and Amicus shall have the option, upon notice to GSK, to repurchase any such quantities of the Terminated Product(s) from GSK as set forth herein, GSK will transfer to Amicus such quantities of inventory of Terminated Product(s) to a country within the GSK Territory for which GSK's may transfer any such remaining inventory of terminated Product(s) to a country within the GSK remaining quantities of inventory of Terminated Product(s) to a country within the GSK as set forth herein, GSK will transfer to Amicus such quantities of inventory of Terminated Product(s) to a country within the GSK Territory for which GSK's rights with respect to such Product(s) have not been terminated.

14.3.10 <u>Regulatory Filings</u>. Following termination of this Agreement by Amicus pursuant to Section 13.2 or by GSK pursuant to Section 13.3, at Amicus' written election, which shall be exercised by written notice to GSK, GSK will assign and transfer (or cause to be assigned and transferred) to Amicus or its designee (or to the extent not so assignable, GSK shall take all reasonable action to make available to Amicus or its designee) the benefits of all regulatory submissions and filings and marketing approvals (including all INDs, MAAs and Marketing Approvals) related to the Compound or the Terminated Product(s) in the Affected Area, including such regulatory submissions and registrations made or owned by GSK's Affiliates and Sublicensees; provided that GSK may retain a copy of all such regulatory submissions and filing and marketing approvals and shall retain a right of reference to all such regulatory submissions, filings, and marketing approvals, for use in connection with the non-Terminated Product(s) and in the non-terminated countries of the GSK Territory. In each case, unless otherwise required by any applicable Law, GSK shall use all reasonable efforts to make such foregoing assignment (or availability), within \*\*\*\*\*\* after the effective date of any such termination (or, with respect to any such regulatory filings pertaining to an Ongoing Trial that GSK is continuing to conduct pursuant to Section 14.3.4 above, within \*\*\*\*\*\* after the completion of such Ongoing Trial), provided, however, that in the event that GSK is unable to make such assignment or to make such regulatory filings available to Amicus within \*\*\*\*\*\* after the effective date of any such termination (or the completion of such Ongoing Trial, as applicable) due to factors beyond GSK's reasonable control,

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then GSK shall so notify Amicus and (including the reason for any such delay) prior to the expiration of such \*\*\*\*\* period and the Parties shall mutually agree (such agreement not to be unreasonably withheld by either Party) an appropriate extension to such \*\*\*\*\* period.

14.3.11 <u>Supply</u>. \*\*\*\*\*.

14.3.12 <u>Sublicensees</u>. Any contracts with Sublicensees with respect to a Terminated Product in the Affected Area engaged by GSK, other than GSK's Affiliates and JCR, shall be assigned to Amicus, solely to the extent such contracts related to the Terminated Product in the Affected Area and to the extent GSK has the right to do so and Amicus so requests. In the event such assignment is not requested by Amicus or GSK does not have the right to do so, then the rights of such Sublicensees with respect to the Terminated Product in the Affected Area shall terminate upon termination of GSK's rights with respect to the applicable Terminated Product(s) in the Affected Area. GSK shall ensure that its Affiliates and such Sublicensees (if not assigned to Amicus pursuant to this Section 14.3.12) shall transition all Terminated Products in the Affected Area back to Amicus in the manner set forth in this Section 14.3 as if such Affiliate or Sublicensee were named herein.

14.4 <u>Termination solely with respect to a Product(s) or country(ies)</u>. Upon termination of this Agreement by GSK pursuant to Section 13.2 or 13.3 or by Amicus pursuant to Section 13.2 with respect to a Terminated Product(s) and/or the Affected Area only or if Amicus exercises its Co-Development Opt-Out Right pursuant to Section 5.4 with respect to a particular Product(s), the Parties' rights and obligations under the Agreement shall terminate with respect such Terminated Product(s) and/or the Affected Area and shall survive with respect to all other Products in the Parties' respective territories, subject to the following provisions:

(a) Each country of the Affected Area shall cease to be a country within the Territory and the definition of "Territory" in Section 1.184 shall be deemed to be amended accordingly and all references to a Major Market shall be deemed to be references to a "Major Market within the Territory"; similarly, each country of the Affected Area shall cease to be a country within the GSK Territory and the definition of "GSK Territory" in Section 1.96 shall be deemed amended accordingly; similarly, each Terminated Product shall cease to be a Product covered by this Agreement and the definition of "Product" in Section 1.153 shall be deemed amended accordingly;

(b) Notwithstanding any other provision of this Agreement, including the definition of "Amicus Know-How" in Section 1.18 and Sections 2.1, 5.1.7 and 5.2.3, in the event of termination by Amicus pursuant to Section 13.2 or by GSK pursuant to Section 13.3, Amicus shall not have

any obligation to make available to GSK any data or other Know-How with respect to a Terminated Product generated by or on behalf of Amicus, its Affiliates and/or (sub)licensees solely for the Affected Area following any such termination of such Product and GSK shall have no rights to, and neither the License, nor the license granted by Amicus to GSK pursuant to Section 2.1.2, shall include, any such data or Know-How. Notwithstanding any other provision of this Agreement,

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including the Sections 2.4, 5.1.7 and 5.2.3, in the event of termination by GSK pursuant to Section 13.2 or exercise by Amicus of its Co-Development Opt-Out Right pursuant to Section 5.4, GSK shall not have any obligation to make available to Amicus any data or other Know-How with respect to a Terminated Product, in each case that is generated by or on behalf of GSK, its Affiliates and/or (sub)licensees solely for the Affected Area following any such termination of this Agreement with respect to such Product or the Co-Development Opt-Out Effective Date, and Amicus shall have no rights to, and the licenses set forth in Section 2.4 shall not include, any such data or Know-How.

(c) As between the Parties, Parties shall promptly negotiate and implement any appropriate amendments to the safety data exchange agreement described in Section 5.2.6(a) as customary and necessary under such circumstances to clearly define each Party's role with respect to pharmacovigilance and adverse event reporting in the Territory following such termination; and

(d) The Parties rights and obligations under Section 7.1 shall survive; and, upon termination of this Agreement by Amicus pursuant to Section 13.2 or by GSK pursuant to 13.3, in each case in its entirety or only with respect to the Co-Formulation Product, as applicable, GSK's rights and obligations under Article VII regarding the prosecution and maintenance of all GSK Prosecuted Amicus Patents and Program Patents and Patents within the Co-Formulation Product IP in the Affected Area to the extent pertaining to the Terminated Products shall terminate from and after the date of any such termination and all such Patents shall be deemed to be Amicus Prosecuted Patents; <u>provided</u>, <u>however</u>, that Amicus will, in a timely manner, solicit GSK's comments regarding the prosecution and maintenance of such Amicus Patents and Program Patents within the Co-Formulation Product IP and review of the nature and text of any such Patent application and prosecution matters related thereto, including any correspondence between Amicus and any government intellectual property or Patent authorities, agencies or other government bodies, in reasonably sufficient time prior to filing thereof, and Amicus will give due consideration to GSK's reasonable comments and amendments.

14.5 <u>Rights upon Termination for Bankruptcy</u>. Notwithstanding the bankruptcy of Amicus, or the impairment of performance by Amicus of its obligations under this Agreement as a result of bankruptcy or insolvency of Amicus as described in Section 13.4, upon the termination of this Agreement by GSK pursuant to Section 13.4, GSK will be entitled to retain all rights and licenses granted to GSK by Amicus under this Agreement. All rights and licenses granted under or pursuant to this Agreement by Amicus to GSK are, and will otherwise be deemed to be, for purposes of Article 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined under Article 101(52) of the Bankruptcy Code. The Parties agree that GSK, as a licensee of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against Amicus under the Bankruptcy Code, GSK will be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, and same, if not already in its possession, will be

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promptly delivered to GSK (i) upon any such commencement of a bankruptcy proceeding upon written request therefore by GSK, unless Amicus elects to continue to perform all of its obligations under this Agreement, or (ii) if not delivered under (i) above, upon the rejection of this Agreement by or on behalf of Amicus upon written request therefore by GSK. The provisions of this Section 14.5 shall apply *mutatis mutandis* to Amicus in the event of any bankruptcy or insolvency of GSK as described in Section 13.4.

14.6 <u>Return of Materials</u>. No later than \*\*\*\*\*\* after the expiration or termination of this Agreement in its entirety, each Party shall return or cause to be returned to the other Party (or, at such other Party's request, destroy and certify such destruction) all Confidential Information received from the other Party and all copies thereof that are in such Party's possession, as well as all biological or chemical materials delivered or provided by the other Party; <u>provided</u>, <u>however</u>, that each Party may retain one (1) copy of such Confidential Information received from the other Party for record purposes. Notwithstanding the foregoing, to the extent that a Party has a continuing license pursuant to Section 14.2 or Section 14.3 above, as applicable, after such termination of this Agreement, such Party may retain the Confidential Information of the other Party and use such Confidential Information solely to the extent necessary and for the purpose of the continued practice of such license and in such event, notwithstanding Section 11.1 above, such Party's obligations under Article XI above, shall continue for so long as such Party continues to practice such license.

14.7 <u>Survival</u>. Upon the expiration or termination of this Agreement in its entirety, all rights and obligations of the Parties under this Agreement shall terminate except as expressly set forth under this Article XIV and those described in the following provisions (which such provisions shall survive for the term specified therein and, if no such term is specified, then indefinitely): Article XVI and Sections 3.5, 3.6, 3.7 (except as otherwise expressly set forth under this Article XIV), 3.8, 3.9, 3.10, 6.4, 10.2.2 (only with respect to either (i) a termination of this Agreement in its entirety by GSK for Amicus's breach pursuant to Section 13.2 or (ii) if Amicus exercises its Co-Development Opt-Out Right pursuant to Section 5.4 with respect to all Products), 11.1, 11.3, 15.1, 15.2, 15.3, 15.4, 15.6.

# XV. INDEMNIFICATION AND LIMITATION OF LIABILITY

# 15.1 <u>Indemnification of Amicus</u>.

15.1.1 GSK shall indemnify and hold harmless each of Amicus, its Affiliates and the directors, officers, stockholders and employees of such entities and the successors and assigns of any of the foregoing (the "<u>Amicus Indemnitees</u>"), from and against any and all (i) liabilities, damages, penalties, fines, costs, expenses (including, reasonable attorneys' fees and other expenses of litigation) ("<u>Liabilities</u>") from any claims, actions, suits or proceedings brought by a Third Party (a "<u>Third Party Claim</u>") incurred by any Amicus Indemnitee, to the extent arising from, or occurring as a result of: (a)

activities relating to the Development or use of any Compound and Products by GSK, its Affiliates, Sublicensees, or subcontractors in the Territory, and relating to the

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Commercialization of any Compound and Products by GSK, its Affiliates, Sublicensees, or subcontractors in the GSK Territory; (b) any material breach of any representations, warranties or covenants by GSK in Articles 8.1 and X above; (c) activities relating to the Manufacture of any Compound or Products by GSK, its Affiliates, Sublicensees, or subcontractors for distribution in the GSK Territory or the Amicus Territory; and/or (d) \*\*\*\*\*; in each case except to the extent such Third Party Claims fall within the scope of Amicus' indemnification obligations set forth in Section 15.2 below or result from the gross negligence or intentional misconduct of a Amicus Indemnitee. For the avoidance of doubt, Product Liability Claims are not subject to this Section 15.1 and are governed by the provisions of Section 15.4 below.

15.2 Indemnification of GSK. Amicus shall indemnify and hold harmless each of GSK, its Affiliates and Sublicensees and the directors, officers and employees of GSK, its Affiliates and Sublicensees and the successors and assigns of any of the foregoing (the "<u>GSK Indemnitees</u>"), from and against any and all Liabilities from any Third Party Claims incurred by any GSK Indemnitee, to the extent arising from, or occurring as a result of (a) activities relating to the Development or use of any Compound and Products by Amicus, its Affiliates, sublicensees or subcontractors in the Territory, and relating to Commercialization of any Compound and Products by Amicus, its Affiliates, sublicensees or subcontractors in the Amicus Territory; (b) any material breach of any representations, warranties or covenants by Amicus in Article 8.1 and X above; or (c) activities relating to the Manufacture of any Compound or Products (other than the Co-Formulation Product) by Amicus, its Affiliates, sublicensees, or subcontractors; in each case except to the extent such Third Party Claims (i) fall within the scope of GSK's indemnification obligations set forth in Section 15.1 above or (ii) result from the gross negligence or intentional misconduct of an GSK Indemnitee. For the avoidance of doubt, Product Liability Claims are not subject to this Section 15.2 and are governed by the provisions of Section 15.4 below.

15.3 <u>Procedure</u>. A Party that intends to claim indemnification under this Article XV (the "<u>Indemnitee</u>") shall promptly notify the other Party (the "<u>Indemnitor</u>") in writing of the assertion or the commencement of Third Party Claim and will provide the Indemnitor such information with respect thereto that the Indemnitor may reasonably request. The Indemnitor shall be entitled to control and appoint lead counsel for such defense, in each case at its expense. If the Indemnitor shall assume the control of the defense of any Third Party Claim in accordance with the provisions of this Section 15.3, the Indemnitor shall obtain the prior consent of the Indemnitor within a reasonable time after the commencement of any action with respect to a Third Party Claim shall not relieve the Indemnitor of its obligations under this Article XV unless the delay or failure is prejudicial to its ability to defend such action. The Indemnitee under this Section 15.3 shall cooperate fully with the Indemnitor and its legal representatives in the investigation of any action with respect to a Third Party Claim Claim covered by this indemnification.

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### 15.4 Product Liability.

15.4.1 Each Party shall notify the other Party as promptly as practicable if any Third Party Claim is commenced or threatened against such Party alleging product liability, product defect, design, packaging or labeling defect, failure to warn or any similar action relating to the use or safety of Compound and Products (a "<u>Product Liability Claim</u>"). For clarity, a Product Liability Claim will not be deemed to include any Third Party Claims relating to a Manufacturing defect of Compound and Products and Sections 15.1 and 15.2 shall apply to any such Third Party Claims.

15.4.2 To the extent that either the GSK Indemnitees or the Amicus Indemnitees incur, suffer, or are faced with any Product Liability Claims with respect to a Product, then \*\*\*\*\*.

15.4.3 GSK shall have the right to control and appoint lead counsel for the defense of any such Product Liability Claims in the GSK Territory and to settle any such Product Liability Claims, in its discretion, <u>provided</u> that GSK shall reasonably consult with and consider the input of Amicus with respect to such matters. Amicus shall have the right to control and appoint lead counsel for the defense of any such Product Liability Claims in the Amicus Territory and to settle any such Product Liability Claims, in its discretion, <u>provided</u> that Amicus shall reasonably consult with and consider the input of GSK with respect to such matters

15.5 <u>Insurance</u>. In addition to its duty to indemnify, each Party will procure product liability insurance in commercially reasonable amounts in view of its activities. Alternatively, either Party may establish a program of self insurance for the same risks. In either event, as reasonably requested in writing by the other Party not more than once every twelve (12) months, each Party will supply the other Party with evidence of such coverage during the time any Product is being Developed, Manufactured or Commercialized by such Party or any of its Affiliates, sublicensees, designees or agents.

15.6 <u>Disclaimer of Consequential Damages</u>. IN NO EVENT WILL EITHER AMICUS OR GSK BE LIABLE TO THE OTHER FOR ANY SPECIAL, INDIRECT, CONSEQUENTIAL, INCIDENTAL, OR PUNITIVE DAMAGES ARISING UNDER OR AS A RESULT OF THIS AGREEMENT (OR THE TERMINATION HEREOF) INCLUDING, BUT NOT LIMITED TO, THE LOSS OF PROSPECTIVE PROFITS OR ANTICIPATED SALES.

# 15.7 Anti-Bribery and Anti-Corruption.

15.7.1 Amicus acknowledges that it has received and read GSK's 'Prevention of Corruption — Third Party Guidelines' (attached at <u>Exhibit D</u> and incorporated herein by reference). Each Party agrees to perform its obligations under the Agreement in accordance with the applicable anticorruption laws of the territory in which such Party conducts business with the other Party as set forth therein.

15.7.2 Each Party shall be entitled to exercise its termination right under and in accordance with the terms of Section 13.2 to terminate this Agreement pursuant to Section 13.2 above immediately on written notice to the other Party, if the other Party fails to perform its

obligations in accordance with Section 15.7.1 or 10.1.1 (to the extent such failure to perform solely relates to a violation of applicable anti-bribery and anticorruption laws as set forth therein). Neither Party shall have a claim against the other Party for compensation for any loss of whatever nature by virtue of the termination of this Agreement in accordance with this Section 15.7. To the extent (and only to the extent) that the laws of the territory provide for any such compensation to be paid to a Party upon the termination of this Agreement, each Party hereby expressly agrees (to the extent possible under the laws of the territory) to waive or to repay to the other Party any such compensation or indemnity. For the avoidance of doubt, it is understood that nothing in this Section 15.7.2 shall be deemed to limit a Party's obligations to pay the applicable milestones, royalties and other amounts set forth in Article XIV following any termination of this agreement in accordance with this Section 15.7.

### XVI. MISCELLANEOUS

16.1 <u>Governing Law</u>. For all matters other than the scope and validity of Patents, this Agreement shall be deemed to have been made in the State of Delaware and its form, execution, validity, construction and effect shall be determined in accordance with the laws of the State of Delaware, without giving effect to the principles of conflicts of law thereof and the Parties agree to the personal jurisdiction of and venue in any federal or state court located in Delaware. The application of the United Nations Convention for Contracts for the International Sales of Goods is hereby expressly excluded.

### 16.2 Dispute Resolution.

16.2.1 The Parties agree that with respect to any disputes arising with respect to the interpretation, breach, enforcement, termination or validity of this Agreement (for the purposes of this Section 16.2, each a "Dispute"), the Dispute shall first be presented to the Chief Executive Officer of Amicus and the GSK Chairman of Research and Development, or their respective designees for resolution. If the Amicus Chief Executive Officer and GSK Chairman or Research and Development, or their respective designees, cannot resolve the Dispute within \*\*\*\*\*\* of the request to do so, either Party may initiate arbitration proceedings with respect thereto as provided in Section 16.2.2 below. Prior to the establishment of an arbitration tribunal, Amicus and GSK shall each have the right to apply to any court of competent jurisdiction for appropriate interim or provisional relief, as necessary to protect the rights or property of that Party.

16.2.2 Any Dispute shall be finally resolved by arbitration in accordance with the Commercial Arbitration Rules of the American Arbitration Association ("<u>AAA</u>") then in effect (the "<u>Rules</u>"), except as modified herein. The place of arbitration shall be Wilmington, Delaware. If the amount in controversy \*\*\*\*\*\*, there shall be one (1) neutral and impartial arbitrator who shall be agreed upon by the Parties within twenty (20) days of receipt by respondent of a copy of the demand for arbitration. If the amount in controversy \*\*\*\*\*\*, there shall be three (3) arbitrators, of whom each Party shall appoint one (1) within thirty (30) days of the receipt by the respondent of the

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demand for arbitration. The two (2) arbitrators so appointed shall select a third (3<sup>rd</sup>) arbitrator as the chair of the arbitral tribunal within thirty (30) days of the appointment of the second arbitrator. If any arbitrator is not appointed within the time limit provided herein, such arbitrator shall be appointed by the AAA in accordance with the listing, striking, and ranking procedures in the Rules. Any arbitrator appointed by the AAA shall be an attorney with no less than fifteen (15) years of experience with commercial cases and an experienced arbitrator, who shall, if practicable, have substantial experience with transactions or disputes related to the field of pharmaceutical products and/or, if applicable, intellectual property.

16.2.3 In the case of any Dispute which may be submitted to arbitration hereunder, the procedures of this Section 16.2.3 shall apply. Arbitration with respect to all such Disputes shall be a "baseball" type arbitration, meaning that, following all permitted discovery and in accordance with procedures otherwise determined by the arbitrator, each Party shall prepare and submit to the arbitrator and the other Party a written report setting forth its final position with respect to the substance of the dispute, and each party may submit a revised report and position within 15 (fifteen) days of receiving the other party's report. The arbitrator shall then select one of the Party's positions as his or her final decision and shall not have authority to render any substantive decision other than to so select the position of either GSK or Amicus. The Parties and the arbitrator shall use all reasonable efforts to complete any such arbitration with respect to a Dispute within ninety (90) days.

16.2.4 The arbitral tribunal is not empowered to award damages in excess of compensatory damages, and each Party hereby irrevocably waives any right to recover punitive, exemplary, multiple or similar damages with respect to any Dispute. Any arbitration proceedings, decision, or award rendered hereunder and the validity, effect, and interpretation of this arbitration provision shall be governed by the Federal Arbitration Act, 9 U.S.C. §1 et seq. The decision of the arbitral tribunal shall be in writing and, if applicable, shall state the findings of fact and conclusions of law on which it is based. The decision of the arbitral tribunal shall be final and binding upon the Parties regarding the applicable Dispute presented to the arbitral tribunal. Judgment upon the decision of the arbitral tribunal may be entered in any court having jurisdiction. The arbitration proceedings and the decision of the arbitral tribunal shall not be made public without the joint consent of the Parties and each Party shall maintain the confidentiality of such proceedings and decision unless each Party otherwise agrees in writing; provided that either Party may make such disclosures as are permitted for Confidential Information of the other Party under Article XI above. The Parties agree that they shall share equally the cost of the arbitration filing and hearing fees, and the cost of the arbitral tribunal and administrative fees of the AAA. Each Party shall bear its own costs and attorneys' and witnesses' fees and associated costs and expenses. The arbitral tribunal shall have full authority to grant provisional remedies and to direct the Parties to request that any court modify or vacate any temporary or preliminary relief issued by such court.

16.2.5 The Parties hereby submit to the exclusive jurisdiction of the federal and state courts located in Delaware for the purpose of an order to compel arbitration, for preliminary relief in aid of arbitration, or for a preliminary injunction to maintain the status quo or prevent irreparable

harm prior to the appointment of the arbitrators, and to the non-exclusive jurisdiction of such courts for the enforcement of any award issued hereunder. The Parties hereby agree to accept service of process pursuant to the notice provisions of this Agreement.

# 16.3 <u>Assignment and Binding Effect</u>.

16.3.1 This Agreement may not be assigned, by operation of law or otherwise, by either Party without the prior written consent of the other, except as otherwise permitted under this Section 16.3:

(a) Amicus may assign this Agreement to an Affiliate or to a Third Party without such prior written consent as part of a merger, consolidation, sale, or transfer of all or substantially all its assets, but only if the assignee has or simultaneously acquires all of the necessary rights and other assets to perform Amicus's obligations under this Agreement; <u>provided</u>, <u>however</u>, a Change of Control event of Amicus shall be subject to the terms set forth in Article XII.

(b) GSK may assign this Agreement to any Affiliate without the prior written consent of Amicus. GSK may also assign this Agreement to a Third Party as part of a merger, consolidation, sale, or transfer of all or substantially all its assets, without the prior written consent of Amicus, but only if the assignee has or simultaneously acquires all of the necessary rights and other assets to perform GSK's obligations under this Agreement.

16.3.2 No assignment under this Section 16.3 shall be effective unless the intended assignee executes and delivers to the Party which is not the assignor a writing whereby the assignee expressly undertakes to perform and comply with all of its assignor's obligations hereunder. Notwithstanding such undertaking, such assignor shall continue to be primarily liable for such assignee's performance hereof and compliance herewith.

16.3.3 Any assignment in violation of this Section 16.3 shall be void and of no effect.

16.3.4 This Agreement, and the rights and obligations of the Parties herein contained, shall be binding upon, and shall inure to the benefit of, the Parties and their respective legal representatives, successors and permitted assigns.

16.4 <u>Independent Contractor Status</u>. The relationship of the Parties is that of independent contractors. Nothing in this Agreement will be construed to constitute, create, give effect or otherwise imply a joint venture, agency, partnership or other formal business organization or any employee relationship of any kind between the Parties.

16.5 <u>Notices</u>. All notices, requests and other communications required or permitted to be given hereunder or with respect hereto will be in writing and in English, and may be given by (i) personal service, (ii) registered first-class mail, postage prepaid, return receipt requested,

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(iii) express delivery service, charges prepaid, or (iv) facsimile (complete transmission verified and a copy promptly sent by another permissible method of providing notice described in clauses (i), (ii) or (iii) above) and in each case addressed to the other Party at the address for such Party as set forth below, and shall be effective upon receipt in the case of clauses (i), (iii) or (iv) above, and five days after mailing in the case of clause (ii) above.

If to GSK:	Glaxo Group Limited Great West Road Brentford, Middlesex United Kingdom TW8 9GS Facsimile: +44 (020) 804 76904 Attention: Company Secretary
With a copy to:	GlaxoSmithKline 980 Great West Road Brentford, Middlesex, TW8 9GS Facsimile: +44 (0) (208) 046-0641 Attention: Marc Dunoyer President, GSK Rare Diseases And GlaxoSmithKline 2301 Renaissance Boulevard
	Mail Code RN0220 King of Prussia, PA 19406 Facsimile: (610) 787-7084 Attention: Vice President and Associate General Counsel, Legal Operations — Business Development Transactions
If to Amicus:	Amicus Therapeutics, Inc. 1 Cedar Brook Drive Cranbury, New Jersey 08512 Attention: John F. Crowley

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With a copy to:

Wilson Sonsini Goodrich & Rosati 650 Page Mill Road Palo Alto CA 94304-1050 Attention: Kenneth A. Clark, Esq. Facsimile: +1 (650) 493-6811

The address of either Party set forth above may be changed from time to time by written notice in the manner prescribed herein from the Party requesting the change.

16.6 <u>Further Assurances</u>. The Parties will execute and deliver any further or additional instruments or documents and perform any acts which may be reasonably necessary in order to effectuate and carry out the purposes of this Agreement.

16.7 <u>Waivers</u>. The waiver by either Party of a default or a breach of any provision of this Agreement by the other Party will not operate or be construed to operate as a waiver of any subsequent default or breach. The continued performance by either Party with knowledge of the existence of a default or breach will not operate or be construed to operate as a waiver of any default or breach. Any waiver by a Party of a particular provision or right will be in writing, will be as to a particular matter and, if applicable, for a particular period of time and will be signed by such Party.

16.8 Effect of Restatement; Entire Agreement. From and after the Restatement Effective Date, this Agreement (including the Exhibits and Schedules hereto), the Prior Equity Agreement, the Equity Agreement, the Trademark License Agreement (to be entered into in accordance with Section 2.5) and the Pharmacovigilance Agreement (including as amended or replaced in accordance with Section 5.2.6(c)) (in each case, if and when executed by the Parties) constitute the entire agreement between the Parties with respect to the subject matter hereof, and supersede and replace all prior agreements and negotiations with respect to such subject matter from and after the Restatement Effective Date, including the Original Agreement (other than with respect to the Equity Agreement attached as Exhibit A to the Original Agreement which such agreement shall continue in effect in accordance with its terms following the Restatement Effective Date).

16.9 <u>Severability</u>. If any provision in this Agreement is deemed to be, or becomes, invalid, illegal, void or unenforceable under applicable Laws, then: (i) it will be deleted with respect to the applicable jurisdiction(s) to which such Law pertains and the validity, legality and enforceability of the remaining provisions of this Agreement shall not be impaired or affected in any way, and (ii) the Parties will use Commercially Reasonable Efforts to substitute for the invalid, illegal or unenforceable provision a valid, legal and enforceable provision which conforms as nearly as possible with the original intent of the Parties. In the event a Party seeks to avoid a provision of this Agreement by asserting that such provision is invalid, illegal or otherwise unenforceable, the other Party shall have the right to terminate this Agreement upon sixty (60) days' prior written notice to the asserting Party, unless such assertion is eliminated and the effect of such assertion cured within such sixty (60) day period. Any termination in accordance with the foregoing shall be deemed a

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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termination of this Agreement in its entirety pursuant to Section 13.3 if the Party who made the assertion was GSK, and shall be deemed a termination of this Agreement in its entirety under Section 13.2 by reason of a breach by Amicus, if Amicus is the Party who made such assertion.

16.10 <u>Counterparts</u>. This Agreement may be executed in more than one counterpart, each of which shall be deemed to be an original but all of which taken together shall be deemed a single instrument. A facsimile transmission of the signed Agreement will be legal and binding on both Parties.

16.11 <u>Force Majeure</u>. Neither Party to this Agreement will be liable for failure or delay in the performance of any of its obligations hereunder (other than the failure to pay monies owed), if such failure or delay is due to acts of God, earthquakes, fires, strikes, acts of war (whether declared or not), terrorism, civil unrest, or intervention of any governmental authority or any other event or occurrence beyond the reasonable control of such Party (a "<u>Force Majeure Event</u>"), but any such delay or failure will be remedied by such Party as soon as practicable after the removal of the cause of such failure or delay. Upon the occurrence of Force Majeure Event, the Party failing or delaying performance will promptly notify the other Party in writing, setting forth the nature of the occurrence, its expected duration and how such Party's performance is affected, and the Party failing or delaying performance will use its Commercially Reasonable Efforts to avoid or remove the causes of non-performance and shall continue performance with the utmost dispatch whenever such causes are removed.

16.12 <u>Interest on Late Payments</u>. If any Party fails to pay in full on or before the date due any royalty, fee or other amount that is required to be paid to the other Party under this Agreement, the paying Party will also pay to the other Party (or its designee) interest at a rate equal to: (i) the prime rate as reported by Citibank N.A., plus \*\*\*\*\*; or (ii) if lower, the maximum rate permitted by law; calculated on the number of days such payment is delinquent, compounded annually and computed on the basis of a three hundred sixty five (365) day year.

16.13 <u>Cumulative Remedies</u>. Unless otherwise set forth in this Agreement, all rights and remedies of the Parties, including all rights to payment, rights of termination, rights to injunctive relief, and other rights provided under this Agreement, shall be cumulative and in addition to all other remedies provided for in this Agreement, in law, and in equity.

16.14 <u>Amendment</u>. This Agreement may not be amended, supplemented or otherwise modified except by an instrument in writing signed by both Parties that specifically refers to this Agreement.

16.15 <u>Headings and References</u>. All section headings contained in this Agreement are for convenience of reference only and will not affect the meaning or interpretation of this Agreement.

16.16 <u>No Strict Construction</u>. This Agreement has been prepared jointly and will not be strictly construed against either Party.

- Material has been omitted and filed separately with the Commission.

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\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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IN WITNESS WHEREOF, the Parties hereto, intending to be legally bound hereby, have caused this Amended and Restated License and Expanded Collaboration Agreement to be executed by their duly authorized representatives.

AMICU	S THERAPEUTICS, INC.	GLAXO	) GROUP LIMITED
By:	/s/ John F. Crowley	By:	/s/ Paul Williamson
Name:	John F. Crowley	Name:	Paul Williamson
Title:	Chairman and CEO	Title:	Corporate Director
Date:	July 17, 2012	Date:	July 17, 2012

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

### EXHIBIT A

# STOCK PURCHASE AGREEMENT

(See Exhibit 10.2 to Quarterly Report on Form 10-Q filed on November 5, 2012)

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

### EXHIBIT B

# INITIAL PRESS RELEASE

(See attached.)

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.





Amicus Therapeutics and GlaxoSmithKline Expand Fabry Disease Collaboration

Companies Jointly to Develop Proprietary Enzyme Replacement Therapy (ERT) for Fabry Disease Co-Formulated with Migalastat HCl Chaperone

# Fabry Products to be Commercialized by Amicus in U.S. and by GSK ex-U.S.

### GSK to Increase Ownership in Amicus to 19.9% with \$18.6 Million Investment in Common Stock Priced at \$6.30 per share

**CRANBURY, NJ, US & LONDON, UK, July 17, 2012** — Amicus Therapeutics (Nasdaq: FOLD) and Glaxo Group Limited (GSK) today announced an expansion of their collaboration to develop and commercialize the investigational pharmacological chaperone migalastat HCl for Fabry disease.

The expanded alliance comprises three components:

- Co-development of all current and future formulations of migalastat HCl for Fabry disease, including a co-formulation of migalastat HCl with GSK/JCR Pharmaceutical's investigational enzyme replacement therapy (ERT) for Fabry disease;
- Commercialization arrangements for all future Fabry products. Amicus will have commercial rights to all Fabry products in the United States and GSK will commercialize all products in the rest of world; and
- Increased GSK ownership in Amicus with \$18.6 million investment in common stock priced at \$6.30 per share, bringing GSK's total ownership stake in Amicus to 19.9%.

"We have strengthened our relationship with Amicus through the expanded Fabry collaboration and additional equity investment in the Company," said Marc Dunoyer, Global Head of GSK Rare Diseases and a member of the GSK Corporate Executive Team. "Amicus has a very successful track record as our development partner, long-standing relationships with the Fabry community and we look forward to their leadership in the U.S. commercialization of now several potential new medicines for patients with Fabry disease. This is an important step in our strategic vision, allowing us to undertake and fund an enlarged scientific program with a view to turning molecules into medicines for rare diseases faster and more effectively than ever before."

The global Fabry collaboration combines Amicus' U.S. presence, pharmacological chaperone development expertise, and established relationships in the rare and orphan disease community with GSK's global rare disease unit and worldwide regulatory, commercial, and manufacturing capabilities. Amicus and GSK are now committed to the parallel development of three different uses of migalastat HCl for Fabry disease:

•\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

- Migalastat HCl monotherapy in Phase 3: Phase 3 global registration studies (Study 011 and Study 012) are currently underway in patients with genetic mutations that are amenable to chaperone monotherapy. Results from Study 011 are anticipated in the third quarter of 2012 to support a New Drug Application submission to the U.S. Food and Drug Administration (FDA). If approved, Amicus will be responsible for the U.S. commercial launch.
- **Migalastat HCl co-administered with ERT in Phase 2:** A Phase 2 study of migalastat HCl co-administered with ERT for Fabry disease (Study 013) is currently ongoing. In January 2012, Amicus announced positive preliminary results from Study 013.
- Migalastat HCl co-formulated with a proprietary preclinical ERT: Amicus and GSK, in collaboration with Japan-based JCR Pharmaceuticals, are developing migalastat HCl co-formulated with a proprietary recombinant human alpha-Gal A enzyme (JR-051). This ERT was developed by JCR and licensed to GSK for all markets outside Japan. Preclinical studies conducted by Amicus, GSK and JCR suggest that this chaperone-ERT co-formulation may provide greater alpha-Gal A enzyme uptake into tissue uptake and markedly reduced levels of GL-3 in Fabry disease-relevant tissues compared to recombinant enzyme alone. Amicus and GSK believe that this co-formulated chaperone-ERT for Fabry disease has the potential to enter clinical studies in 2013. Further details of this program and preclinical results will be presented on today's conference call and webcast.

John F. Crowley, Chairman and Chief Executive Officer of Amicus said, "GSK has added significant value to the Fabry program through its global scale and capabilities as well as the dedicated focus of GSK Rare Diseases. Through our expanded agreement, GSK is increasing its investment in the Fabry development program and Amicus is transforming into a commercial-stage biopharmaceutical company within the U.S. Amicus is leveraging this chaperone-ERT platform to advance migalastat HCl in multiple potential uses for patients with Fabry disease."

### Expanded Amicus-GSK Collaboration for Fabry Disease: Key Highlights

- · Amicus will commercialize all formulations of migalastat HCl in the U.S., while GSK will commercialize in the rest of the world.
- Amicus and GSK will continue to share research and development costs for all formulations of migalastat HCl, with Amicus funding 25% and GSK funding 75% of these costs for monotherapy and co-administration during the remainder of 2012. Amicus and GSK will be responsible for 40% and 60% of these costs, respectively, for co-formulation immediately and for all formulations in 2013 and beyond.
- GSK will make an \$18.6 million equity investment in Amicus by purchasing 2,949,581 shares common stock at \$6.30 per share, a 7% premium over the 15 day average closing sale price of Amicus's common stock as reported by Nasdaq, bringing GSK's total ownership stake in Amicus to 19.9%.
- Amicus will receive a \$3.5 million cash payment from GSK this quarter to reflect Amicus' achievement of a clinical development milestone during the second quarter 2012.
- GSK will be eligible to receive U.S. regulatory approval and product launch milestones totaling \$20 million for migalastat HCl monotherapy and chaperone-ERT co-administration.
- GSK will be eligible to receive additional regulatory and time-based milestone payments totaling up to \$35 million within 7 years following the launch of a co-formulation product. Amicus will also be
- \*\*\*\*\*\* Material has been omitted and filed separately with the Commission.

responsible for certain additional pass-through milestone payments and single-digit royalties on the net U.S. sales of the co-formulated chaperone-ERT product that GSK must pay to a Third Party.

# **Conference Call and Webcast**

Amicus Therapeutics will host a conference call and webcast today, July 17, 2012 at 5:00 P.M. ET to discuss the expanded agreement with GSK and provide additional details surrounding the new chaperone-ERT co-formulation. Interested participants and investors may access the live conference call by dialing 877-303-5859 (U.S./Canada) or 678-224-7784 (international).

An audio webcast can also be accessed via the Investors section of the Amicus Therapeutics corporate web site at http://www.amicustherapeutics.com, and will be archived for 30 days. Web participants are encouraged to go to the Web site 15 minutes prior to the start of the call to register, download and install any necessary software.

A telephonic replay of the call will be available for seven days beginning at 8 p.m. ET today. Access numbers for this replay are 855-859-2056 (U.S./Canada) and 404-537-3406 (international); participant code 11288561.

# About Fabry Disease

Fabry disease is an inherited lysosomal storage disease that is currently estimated to affect approximately 5,000 to 10,000 people worldwide. Fabry Disease is caused by deficiency of an enzyme called alpha-galactosidase A (alpha-Gal A). The role of alpha-Gal A within the body is to break down a complex lipid called globotriaosylceramide (GL-3). Reduced or absent levels of alpha-Gal A activity leads to the accumulation of GL-3 in the affected tissues, including the central nervous system, heart, kidneys, and skin. This accumulation of GL-3 is believed to cause the various symptoms of Fabry disease, including pain, kidney failure, and increased risk of heart disorders and stroke.

# **About Amicus Therapeutics**

Amicus Therapeutics (Nasdaq:FOLD) is a biopharmaceutical company at the forefront of developing therapies for rare diseases. The Company is developing orally-administered, small molecule drugs called pharmacological chaperones, a novel, first-in-class approach to treating a broad range of human genetic diseases. Amicus' late-stage programs for lysosomal storage disorders include migalastat HCl monotherapy in Phase 3 for Fabry disease; migalastat HCl co-administered with enzyme replacement therapy (ERT) in Phase 2 for Fabry disease; and AT2220 co-administered with ERT in Phase 2 for Pompe disease.

# About GlaxoSmithKline

GlaxoSmithKline - one of the world's leading research-based pharmaceutical and healthcare companies - is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For further information please visit www.gsk.com

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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# **Amicus Forward-Looking Statements**

This press release contains, and the accompanying conference call will contain, "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 relating to preclinical and clinical development of Amicus' candidate drug products, the timing and reporting of results from preclinical studies and clinical trials evaluating Amicus' candidate drug products, the projected cash position for the Company, and business development and other transactional opportunities. Words such as, but not limited to, "look forward to," "believe," "expect," "anticipate," "estimate," "intend," "plan," "targets," "likely," "will," "would," "should" and "could," and similar expressions or words identify forward-looking statements. Such forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. The inclusion of forward-looking statements should not be regarded as a representation by Amicus that any of its plans will be achieved. Any or all of the forward-looking statements in this press release may turn out to be wrong. They can be affected by inaccurate assumptions Amicus might make or by known or unknown risks and uncertainties. For example, with respect to statements regarding the goals, progress, timing and outcomes of discussions with regulatory authorities and the potential goals, progress, timing and results of preclinical studies and clinical trials, actual results may differ materially from those set forth in this release due to the risks and uncertainties inherent in the business of Amicus, including, without limitation: the potential that results of clinical or pre-clinical studies indicate that the product candidates are unsafe or ineffective; the potential that it may be difficult to enroll patients in our clinical trials; the potential that regulatory authorities may not grant or may delay approval for our product candidates; the potential that preclinical and clinical studies could be delayed because we identify serious side effects or other safety issues; the potential that we will need additional funding to complete all of our studies and, our dependence on third parties in the conduct of our clinical studies. Further, the results of earlier preclinical studies and/or clinical trials may not be predictive of future results. With respect to statements regarding projections of the Company's cash position, actual results may differ based on market factors and the Company's ability to execute its operational and budget plans. In addition, all forward looking statements are subject to other risks detailed in our Annual Report on Form 10-K for the year ended December 31, 2011. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, and Amicus undertakes no obligation to revise or update this news release to reflect events or circumstances after the date hereof. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

# GlaxoSmithKline cautionary statement regarding forward-looking statements

Under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Factors that may affect GSK's operations are described under 'Risk Factors' in the 'Financial review & risk section' in the company's Annual Report 2011 included as exhibit 15.2 to the company's Annual Report on Form 20-F for 2011.

# **Amicus Contact:**

Investors/Media: Sara Pellegrino (609) 662-5044 / spellegrino@amicusrx.com

Media: Dan Budwick (973) 271-6085 / dan@purecommunicationsinc.com

# GlaxoSmithKline Contacts:

UK Media enquiries:	David Mawdsley	(020) 8047 5502
	Stephen Rea	(020) 8047 5502
	Alexandra Harrison	(020) 8047 5502
	Janet Morgan	(020) 8047 5502
	David Daley	(020) 8047 5502

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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US Media enquiries:	Nancy Pekarek Mary Anne Rhyne Kevin Colgan Sarah Alspach	(919) 483 2839 (919) 483 2839 (919) 483 2839 (919) 483 2839 (919) 483 2839
European Analyst/Investor enquiries:	Sally Ferguson Gary Davies Ziba Shamsi	(020) 8047 5543 (020) 8047 5503 (020) 8047 3289
US Analyst/ Investor enquiries:	Tom Curry Jeff McLaughlin	(215) 751 5419 (215) 751 7002

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\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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# EXHIBIT C

# TRADEMARK LICENSE AGREEMENT

THIS **TRADEMARK LICENSE AGREEMENT** ("<u>Agreement</u>") is made as of the day of , 20 (the "<u>Effective Date</u>") by and between Glaxo Group Limited, a company organized under the laws of England and Wales with its registered office at Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex, UB6 0NN, England ("<u>Licensor</u>"), as licensor, and Amicus Therapeutics, Inc., a Delaware corporation having a place of business at 6 Cedar Brook Drive, Cranbury, New Jersey, 08512 ("<u>Licensee</u>"), as licensee. Licensee and Licensor are sometimes collectively referred to herein as the "<u>Parties</u>" and separately as a "<u>Party</u>."

**WHEREAS**, pursuant to that certain Amended and Restated License and Expanded Collaboration Agreement by and between Licensee and Licensor, dated as of the 17<sup>th</sup> day of July, 2012 (the "License and Collaboration Agreement"), Licensor agreed to license to Licensee certain trademarks in the Territory as set forth on Exhibit A attached hereto, including all common law rights to such trademarks (the "Licensed Marks") in the United States (the "Territory");

**WHEREAS**, Licensor is willing to grant, and Licensee is willing to receive, a license to use the Licensed Marks in connection with Licensee's right to Develop Compound and Products in the Territory, and to Manufacture Compound and Products and Commercialize Products (as those terms are defined in the License and Collaboration Agreement) in the Amicus Territory pursuant to the terms and conditions set forth in this Agreement.

**NOW, THEREFORE**, in consideration of the mutual covenants, agreements and stipulations set forth herein and in the License and Collaboration Agreement, the receipt and legal sufficiency of which are hereby mutually acknowledged, Licensor and Licensee hereby agree as follows:

1. <u>DEFINITIONS</u>. Capitalized terms not otherwise defined in this Agreement shall have the meaning set forth in the License and Collaboration Agreement.

# 2. GRANT OF LICENSE.

- 2.1. During the Term of this Agreement, and pursuant to the terms and conditions contained herein, Licensor hereby grants to Licensee and its Affiliates, and Licensee and its Affiliates hereby accept, a non-exclusive, royalty-free license, including the right to grant sublicenses as provided in Section 2.3 below, to use the Licensed Marks in the Territory solely in connection with Licensee's right to:
  - 2.1.1. Develop Compound and Product in the Field in the Territory as provided in Article V of the License and Collaboration Agreement;
  - 2.1.2. Manufacture Compound or Product in the Field in the Territory accordance with Section 6.5 of the License and Collaboration Agreement; and
- \*\*\*\*\*\* Material has been omitted and filed separately with the Commission.

- 2.1.3. use, sell, offer for sale, distribute, promote and otherwise Commercialize Products in the Field in the Amicus Territory in accordance with the terms of the License and Collaboration Agreement.
- 2.2. Licensee shall have the right to use the Licensed Marks (excluding GSK House Marks) as part of a domain name, subject to Licensor's prior written approval and provided that Licensee remains responsible for all costs associated with development and operation of the associated website.
- 2.3. Licensee shall have the right to grant sublicenses under this Agreement solely as and to the extent Licensee is permitted to grant sublicenses to any of its Affiliates (solely for so long as such entity remains an Affiliate) and to Third Parties, in each case, under and in accordance with Section 2.4.1 of the License and Collaboration Agreement. In any event, Licensee shall ensure that each of its Third Party Sublicensees is bound by a written agreement containing provisions at least as protective of the Licensed Marks and Licensor as this Agreement; and Licensee shall remain responsible to Licensor for all activities of its Affiliates and Sublicensees in connection with the Licensed Marks to the same extent as if such activities had been undertaken by Licensee itself.

# 3. USE OF THE LICENSED MARKS

3.1. Upon reasonable advance written request, Licensee agrees to submit to Licensor samples of the Product (to the extent Manufactured by Licensee or its designee) and samples of packaging of the Product displaying the Licensed Marks for Licensor's inspection. If Licensor reasonably determines that Licensee has failed to maintain a level of quality consistent with those normally employed by the Licensor in the use of the Licensor's Trademarks, then Licensor may request that Licensee take reasonable steps to remedy any such deficiencies and Licensee agrees to take commercially reasonable actions to comply with such requests, and in any event, Licensee shall not use or distribute Product or any packaging for the Product displaying the Licensed Marks until it has complied with such requests.

3.2. Licensee and its Affiliates and Sublicensees shall comply with all applicable laws and regulations pertaining to the Commercialization of Products bearing the Licensed Marks, to the extent that Licensee shall perform any such Commercialization activities under the License and Collaboration Agreement.

# 4. MAINTENANCE OF LICENSED MARKS.

4.1. Licensor shall prepare, file, prosecute and maintain trademark applications and registrations for the Licensed Marks used on or in connection with Product in the Territory. All costs and expenses (including but not limited to attorneys' fees and expenses and official fees) of preparing, filing, prosecuting and maintaining the Licensed Marks shall be borne by Licensor.

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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4.2. Licensor shall not (i) abandon any rights in the Licensed Marks in the Territory, (ii) abandon or allow any pending application for the Licensed Marks to lapse in the Territory, or (iii) permit any active registration for the Licensed Marks to lapse, expire or be cancelled in the Territory, without first notifying Licensee.

5. <u>TERM</u>. This Agreement shall be effective commencing on the Effective Date and shall continue perpetually unless terminated as set forth in Section 6 below.

# 6. <u>TERMINATION</u>.

6.1. This Agreement shall terminate automatically, without notice or any further action hereunder by either Party: (a) in its entirety upon the expiration of the License and Collaboration Agreement in its entirety or upon the expiration of the Amicus Wind-Down Period, following a termination of the License and Collaboration Agreement in its entirety by GSK pursuant to Section 13.2 thereof, or by either Party pursuant to Section 13.4 of the License and Collaboration Agreement; or (b) if the License and Collaboration Agreement is terminated by GSK pursuant to Section 13.2 with respect to a Product (but not terminated in its entirety, i.e. with respect to all Products), then this Agreement shall terminate with respect to the particular Licensed Mark and particular country(ies) licensed for use in connection with the Terminated Product in the relevant Affected Area upon the expiration of the applicable Amicus Wind-Down Period following the termination of the License and Collaboration Agreement by GSK pursuant to Section 13.2 with respect to the Product with which such Licensed Mark is used in the Territory.

6.2. The Parties may terminate this Agreement in its entirety or on a Licensed Mark-by-Licensed Mark basis at any time and for any reason during the Term upon their mutual written agreement; provided that the Parties shall agree to terminate this Agreement, in its entirety, or on a Licensed Mark-by-Licensed Mark basis, as applicable, if the JSC determines that such Licensed Mark(s) shall no longer be used with respect to a Product in the Territory.

6.3. Subject to and in accordance with Section 14.2 of the License and Collaboration Agreement, Licensee agrees, with respect to all Licensed Marks upon termination or expiration of this Agreement in its entirety, or, if the License and Collaboration Agreement is terminated with respect to a Terminated Product and/or a particular country(ies), but not in its entirety, then solely with respect to such Licensed Marks that are licensed with respect to the Terminated Product(s) in such country(ies): (i) to discontinue immediately following the expiration of the Amicus Wind-Down Period, and to cause all of Licensee's Affiliates and any Sublicensees of Licensee thereof to discontinue immediately, the use of such Licensed Marks; (ii) to return to Licensor, upon Licensor's request, or to destroy all tangible embodiments (other than packaging containing Product) of any such Licensed Marks; (iii) to

furnish Licensor with certification and evidence of destruction of such items or materials bearing the Licensed Marks, if such items or materials are destroyed by Licensee at Licensor's request; and (iv) to reasonably work with Licensor to facilitate the proper possession, transfer and/or destruction of packaging containing Product and such Licensed Marks in accordance with the License and Collaboration Agreement.

7. <u>OWNERSHIP</u>. Licensor represents and warrants, and Licensee acknowledges, that the Licensed Marks are the sole and exclusive property of Licensor or its Affiliates in the Territory and all goodwill accrued through use of the Licensed Marks shall be deemed to be the absolute property of Licensor or its Affiliates. Licensee further acknowledges that nothing in this Agreement confers upon Licensee any right of ownership in and to the Licensed Marks. Licensee agrees to reasonably cooperate with Licensor to execute, deliver, and otherwise provide to Licensor all information and documents reasonably requested for the purpose of establishing, registering, evidencing or defending Licensor's complete and exclusive ownership of all rights, titles, and interests of every kind and nature whatsoever in and to the Licensed Marks. Licensee agrees not to register, use or authorize the use of any trademark or designation confusingly similar to the Licensed Marks, and Licensee agrees not to challenge Licensor's or its Affiliates' ownership of the Licensed Marks.

8. <u>ASSIGNMENTS</u>. Neither this Agreement, nor any of the rights or obligations of a Party may be directly or indirectly assigned, sold, delegated or otherwise disposed of by a Party except in connection with such Party's assignment of, and to the same assignee as, the License and Collaboration Agreement in accordance with Section 16.3 of the License and Collaboration Agreement.

8.1. No assignment under this Section 8 shall be effective unless the intended assignee executes and delivers to the Party which is not the assignor a writing whereby the assignee expressly undertakes to perform and comply with all of its assignor's obligations hereunder. Notwithstanding such undertaking, such assignor shall continue to be primarily liable for such assignee's performance hereof and compliance herewith.

8.2. Any assignment in violation of this Section 8 shall be void and of no effect.

8.3. This Agreement, and the rights and obligations of the Parties herein contained, shall be binding upon, and shall inure to the benefit of, the Parties and their respective legal representatives, successors and permitted assigns.

9. <u>AMENDMENTS</u>. No waiver, amendment or modification of any provision hereof or of any right or remedy hereunder shall be effective unless in writing and signed by the Party against whom such waiver, amendment or modification is sought to be enforced.

10. <u>COUNTERPARTS</u>. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, but all of which together shall constitute but one and the

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\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

same instrument. Delivery of an executed counterpart signature page of this Agreement by facsimile or other electronic transmission shall be as effective as delivery of a manually executed signature page.

11. <u>APPLICABLE LAW AND DISPUTE RESOLUTION</u>. This Agreement shall be governed by, interpreted and construed, and all claims and disputes, whether in tort, contract or otherwise be resolved in accordance with the substantive laws of the State of Delaware without reference to any rules of conflict of laws. Any and all disputes under this Agreement shall be resolved in accordance with Section 16.2 of the License and Collaboration Agreement.

12. <u>FURTHER ASSURANCES</u>. Each of Party shall, at any time or from time to time after the Effective Date, at the request and expense of the other Party, execute and deliver to the other Party all such instruments and documents or further assurances as the other Party may reasonably request in order to give effect to the transactions contemplated by this Agreement, including but not limited to Licensee's request for Licensor's cooperation to record or register this Agreement with any applicable governmental entity.

13. <u>REPRESENTATIONS AND WARRANTIES</u>. Each Party represents and warrants that (i) this Agreement has been duly and validly executed and delivered by such Party and constitutes a legal and binding obligation of such Party, enforceable against it in accordance with its terms, and (ii) it has all necessary right, power and authority to execute and perform its obligations under this Agreement and to grant the rights granted herein. Licensor further represents and warrants that it is the owner of all right, title, and interest in and to the Licensed Marks and that the execution, delivery, and performance of its obligations under this Agreement or other obligation of Licensor or binding upon Licensor's assets, including but not limited to the Licensed Marks.

14. <u>SEVERABILITY</u>. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future law, and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (a) such provision will be fully severable, (b) this Agreement will be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement will remain in full force and effect and will not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom, and (d) in lieu of such illegal, invalid or unenforceable provision, there will be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties.

15. <u>WAIVER</u>. No waiver by any Party in one or more instances of any of the provisions of this Agreement or the breach thereof shall establish a precedent for any other instance with respect to that or any other provision. Furthermore, in case of waiver of a particular provision, all other provisions of this Agreement will continue in full force and effect.

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

16. <u>INTEGRATION</u>. This Agreement (including Exhibits hereto), and the License and Collaboration Agreement, embodies the entire agreement of the Parties hereto with respect to the subject matter hereof and supersedes any and all prior agreements with respect thereto.

### [Remainder of page intentionally left blank]

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed as of the Effective Date by their duly authorized representatives.

# AMICUS THERAPEUTICS, INC.

By:

Name:

Title:

### GLAXO GROUP LIMITED

By:

Name:

Title:

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

### EXHIBIT A

### TO TRADEMARK LICENSE AGREEMENT

### LICENSED MARKS

Mark	<b>Registration/Application No.</b>	Territory/Country
CONECTRIC	Reg. No. 3961746	US

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

### EXHIBIT D

### PREVENTION OF CORRUPTION - THIRD PARTY GUIDELINES

The GSK Anti-Bribery and Corruption Policy (POL-GSK-007) requires compliance with the highest ethical standards and all anti-corruption laws applicable in the countries in which GSK (whether through a third party or otherwise) conducts business. POL-GSK-007 requires all GSK employees and any third party acting for or on behalf of GSK to ensure that all dealings with third parties, both in the private and government sectors, are carried out in compliance with all relevant laws and regulations and with the standards of integrity required for all GSK business. GSK values integrity and transparency and has zero tolerance for corrupt activities of any kind, whether committed by GSK employees, officers, or third-parties acting for or on behalf of the GSK.

**Corrupt Payments** — GSK employees and any third party acting for or on behalf of GSK, shall not, directly or indirectly, promise, authorise, ratify or offer to make or make any "payments" of "anything of value" (as defined in the glossary section) to any individual (or at the request of any individual) including a "government official" (as defined in the glossary section) for the improper purpose of influencing or inducing or as a reward for any act, omission or decision to secure an improper advantage or to improperly assist the company in obtaining or retaining business.

**Government Officials** — Although GSK's policy prohibits payments by GSK or third parties acting for or on its behalf to any individual, private or public, as a "quid pro quo" for business, due to the existence of specific anticorruption laws in the countries where we operate, this policy is particularly applicable to "payments" of "anything of value" (as defined in the glossary section), or at the request of, "government officials" (as defined in the glossary section).

**Facilitating Payments** — For the avoidance of doubt, facilitating payments (otherwise known as "greasing payments" and defined as payments to an individual to secure or expedite the performance of a routine government action by government officials) are no exception to the general rule and therefore prohibited.

### GLOSSARY

The terms defined herein should be construed broadly to give effect to the letter and spirit of the ABAC Policy. GSK is committed to the highest ethical standards of business dealings and any acts that create the appearance of promising, offering, giving or authorising payments prohibited by this policy will not be tolerated.

Anything of Value: this term includes cash or cash equivalents, gifts, services, employment offers, loans, travel expenses, entertainment, political contributions, charitable donations, subsidies, per diem payments, sponsorships, honoraria or provision of any other asset, even if nominal in value.

Payments: this term refers to and includes any direct or indirect offers to pay, promises to pay, authorisations of or payments of anything of value.

### Government Official shall mean:

- · Any officer or employee of a government or any department, agency or instrument of a government;
- Any person acting in an official capacity for or on behalf of a government or any department, agency, or instrument of a government;
- · Any officer or employee of a company or business owned in whole or part by a government;
- · Any officer or employee of a public international organisation such as the World Bank or United Nations;
- · Any officer or employee of a political party or any person acting in an official capacity on behalf of a political party; and/or
- · Any candidate for political office.

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

# EXHIBIT E

\*\*\*\*\*

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

# Schedule 1.29

# BACKGROUND LICENSE AGREEMENTS

1) \*\*\*\*\*

2) \*\*\*\*\*

3) Amended and Restated Agreement between Mount Sinai School of Medicine of New York University and Amicus Therapeutics, Inc., dated October 31, 2008.

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

# Schedule 1.48

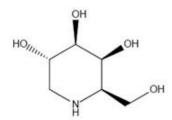
# **DESCRIPTION OF COMPOUND**

United States Adopted Name: migalastat

Other Chemical Names:

- 1) 1-deoxygalactonojirimycin
- 2) (2R,3S,4R,5S)-2-(hydroxymethyl)piperidine-3,4,5-triol

Chemical Structure:



MOLECULAR FORMULA: C<sub>6</sub>H<sub>13</sub>NO<sub>4</sub>

MOLECULAR WEIGHT: 163.17

CAS REGISTRY NUMBER: 108147-54-2

\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

### Schedule 1.116

**JR051** 

\*\*\*\*\*

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

### Schedule 3.4.3

### THIRD PARTY PAYMENTS OWED

As of the Effective Date, pursuant to Amended and Restated Agreement between Mount Sinai School of Medicine of New York University ("<u>MSSM</u>") and Amicus Therapeutics, Inc., dated October 31, 2008 ("<u>MSSM License</u>") royalties are payable by Amicus to MSSM at the rates specified below and otherwise in accordance with the terms of the MSSM License:

\*\*\*\*\*\* and

### \*\*\*\*\*\*

Capitalized terms used in this <u>Schedule</u> 3.4.3 and not defined in the Amended and Restated License and Collaboration Agreement to which this <u>Schedule</u> 3.4.3 is attached have the meanings given to such terms in the MSSM License, a copy of which has been provided by Amicus to GSK prior to the Effective Date.

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

### Schedule 5.1A

### EXISTING DEVELOPMENT PLAN

\*\*\*\*\*

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

# Schedule 5.1B

### **CO-FORMULATION DEVELOPMENT PLAN**

\*\*\*\*\*

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

### DEVELOPMENT COST SHARING

#### \*\*\*\*\*

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

### Schedule 6.1

### GLOBAL COMMERCIAL PLAN

### \*\*\*\*\*

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

### Schedule 6.5.1

# TECHNOLOGY TRANSFER REQUIREMENTS

# Technology Transfer Requirements

Note: GSK's responsibility with regard to items in this document are restricted to materials and data generated by GSK since the execution of the Original Agreement.

Contacts

1. Name, address, phone, FAX, and e-mail address of key technical contacts for each Party and all third parties involved in process development, manufacture, analysis, or release.

### Materials

2. Allocated portion of drug substance inventory of, and intermediates, along with their batch histories, batch records and analytical results (to the extent such histories, records and analytical results can be reproduced and transferred from the site of the contract manufacturer).

3. Drug substance primary reference standard and any reports describing its characterization and assignment of purity.

4. Working references standards for drug substance, intermediates and impurities along with any report on their comparability, characterization, or assignment of purity.

5. Allocation of drug product inventory, with CoA, shelf life, input drug substance and other details

API (chemical synthesis)

6. An updated schematic of the chemical synthesis, including typical yields for each stage.

7. Copies of detailed complete manufacturing instructions for all stages and operations of the API chemical synthesis processes on the largest scale to date, including all in-process analytical tests and methods. To be transferred upon completion of DS validation work and analytical test method/validation work and reporting of the same.

8. Available documented process knowledge established through development and commercial supply. To be transferred upon completion of DS validation work and analytical test method/validation work and reporting of the same.

9. Process validation protocols and reports when available

10. Cleaning method and validation reports for each stage of the chemical processes.

\*\*\*\* - Material has been omitted and filed separately with the Commission.

11. For all key raw materials, a table of suppliers, ordering lead times, and buying specifications, including detailed specifications of any components to the extent access to such information is provided to Amicus or GSK by the contract manufacturer.

12. A summary report describing the history of chemical synthesis process development, changes and their reason, and optimization of the processes.

13. Report on the Genotoxic Risk Assessment of the manufacturing process

- 14. A report summarizing available data describing the physical properties of the drug substance, including MW, solubility, pKa, etc as applicable.
- 15. The Drug Substance Stability Report, including all data and methods.

16. Current specifications for drug substance and starting materials, including justification for the specifications.

17. All analytical methods and validation reports employed for analysis of the starting and key raw materials

18. A complete drug substance batch history table, including lot number, amount, Certificates of Analyses, and use or intended use (particularly for safety assessment or clinical studies).

19. A statement or certificate of available API inventory is free from TSEs/BSEs.

20. All analytical methods employed for analysis of the drug substance used in safety assessment and clinical trial supplies. This should include methods/limits of detection/limits of quantification for heavy metals and low level potential genotoxic impurities if such analysis is performed.

21. A table listing all impurities (by Retention Time of the major, Relative Retention Time and {% (a/a) or (w/w)} of all impurities present in the drug substance used in safety assessment studies and in the clinical trial supplies.

22. A table or report describing drug substance impurities including critical and typical levels, probable origins, and methods for control, particularly for any known or potential highly-toxic or mutagenic impurities or degradants.

23. A report summarizing effort to characterize drug substance impurities.

24. A report summarizing the history of analytical methods development.

25. A table of isolated intermediate acceptance criteria or buying specifications, and their analytical methods (including purity profile), including limits for any potentially mutagenic or highly toxic impurities.

26. Recommended storage conditions for the drug substance and intermediates suitable for international shipping.

27. Any shipping studies data for drug substance and intermediates including container specifications used for storage and shipping.

\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

### Drug Product: Formulation and Manufacturing

- 28. Full analytical data on all batches of drug substance that have been converted to drug product.
- 29. Reports on and details of pre-formulation studies
- 30. Reports on and details of development pharmaceutics, including all formulation approaches considered and evaluated
- 31. Any analytical methods developed or modified subsequent to formulation development, method validation and drug product specifications.
- 32. Results of any drug-excipient compatibility studies that have been conducted if applicable.
- 33. The Drug Product Stability Report, including all data and methods
- 34. Details of the manufacturing process
- 35. Full manufacturing records to the extent access to such information is provided to Amicus or GSK by the contract manufacturer \*\*\*\*\*
- 36. Process validation protocols and reports when available
- 37. Statement or certificate that the drug product capsules do not contain TSEs/BSEs.
- 38. Formulation and process details of toxicology formulations and approaches including crystal form of input drug substance
- 39. Any shipping studies or data for drug product, including container specifications used for storage and shipping.
- 40. Details on commercial pack development

# Regulatory

41. All CMC regulatory documentation including the NDA and IND, including agency questions and responses, especially those related to any aspect of primary drug substance manufacture, analysis, batch histories, impurity profiles, or stability.

- 42. Any regulatory data to support international shipment or shaking of drug substance or process materials.
- 43. Any drug substance process data or reports needed to support regulatory filings.

44. Any new GSK audit reports of \*\*\*\*\*\*

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

### Environmental, Health and Safety

45. Any worker safety information on the drug substance, formulation, reagents/excipients, including toxicity (including exposure limits, where known), thermal, gaseous or other hazards.

- MSDS (where applicable)
- · Occupational exposure limits or exposure guidelines (where defined).
- · Occupational Hygiene monitoring and analytical methods (where available)
- 46. A report summarizing any environmental process safety assessment for the API process, including
  - Environmental fate and effects data (e.g., aquatic toxicity, biodegradability, bioaccumulation potential) for API/materials/excipients.
  - Chemical hazard data for the process used to manufacture drug substance (e.g., material stability, hazardous incompatibilities, etc.)

### Intellectual Property

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• Reference to any Amicus intellectual property (e.g. patents, patent applications) covering the drug substance, intermediates, or synthetic processes.

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

### Schedule 6.5.4

# API AND DRUG PRODUCT SPECIFICATIONS

#### \*\*\*\*\*

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

# Schedule 6.6

# COMMERCIAL TRANSITION PLAN

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\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

# Schedule 7.2.1

# **GSK PROSECUTED AMICUS PATENTS**

\*\*\*\*\*

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

# Schedule 7.2.2

### AMICUS PROSECUTED PATENTS

# Schedule 7.2.3

### PATENT APPLICATIONS TO BE SEGREGATED PER SECTION 7.2.3

### \*\*\*\*\*

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

### Schedule 10.2

### BACKGROUND LICENSE AGREEMENT PROVISIONS

### 1. MSSM LICENSE

Pursuant to Section 2.d. of the MSSM License, GSK agrees: (i) to be bound by, and comply with, Sections 6 (Confidential Information), 9 (Liability and Indemnification) and 10 (Security for Indemnification) of the MSSM License (substituting "GSK" for "AMICUS" in such provisions), the text of which is included below and incorporated herein by reference, to the extent applicable to GSK in its capacity as sublicensee; and (ii) that MSSM is an intended third party beneficiary of the Agreement for purposes of enforcing such indemnification and insurance provisions.

Pursuant to Section 2.c. of the MSSM License, GSK agrees: (a) the sublicense granted by Amicus to GSK under the MSSM License shall be subject and subordinate to the terms and conditions of the MSSM License; (b) such sublicense shall expire automatically on the termination of the MSSM License; (c) such sublicense shall not be assignable, in whole or in part; provided, however, that GSK may, with written notice to MSSM, assign the sublicense in connection with a merger or acquisition of GSK or the sale by the sublicensee of substantially all of its assets; (d) GSK shall be entitled to grant further sublicenses, provided that GSK complies with the obligations of Amicus under Section 2.c., Section 2.d. and all other provisions of MSSM License relating to the grant of sublicenses by Amicus under the MSSM License; and (e) both during the term of such sublicense and thereafter GSK shall be bound by a secrecy obligation similar to that imposed on Amicus in Section 6 of the MSSM License, and that GSK shall bind its employees and agents, both during the terms of their employment and thereafter, with a similar undertaking of secrecy. In addition, GSK, in its capacity as a sublicensee under the determination of the amounts payable by Amicus, as a result of the activities of GSK in its capacity as a sublicensee.

### Provisions Extracted from MSSM License:

Capitalized terms in the following provisions of the MSSM License, but not defined therein, shall have the meanings given to such terms in the MSSM License.

# "6. Confidential Information.

a. In the course of research to be performed under this Agreement, it will be necessary for each party to disclose "Confidential Information" to the other. For purposes of this Agreement, "Confidential Information" is defined as all information, data and know-how disclosed by one party (the "Disclosing Party") to the other (the "Receiving Party"), either embodied in tangible materials (including writings, drawings, graphs, charts, photographs, recordings, structures, technical and other information) marked "Confidential" or, if initially disclosed orally, which is reduced to writing marked "Confidential" within 21 days after initial oral disclosure, other than that information which is,

i) known by the Receiving Party at the time of its receipt, and not through a prior disclosure by

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

the Disclosing Party, as documented by the Receiving Party's business records; or

ii) at the time of disclosure, or thereafter becomes, published or otherwise part of the public domain without breach of this Agreement by the Receiving Party; or

iii) obtained from a third party who has the legal right to make such disclosure and without any confidentiality obligation to the Disclosing Party; or

iv) independently developed by the Receiving Party without the use of Confidential Information received from the Disclosing Party and such independent development can be documented by the Receiving Party; or

v) disclosed to governmental or other regulatory agencies in order to obtain patents, provided that such disclosure may be made only to the extent reasonably necessary to obtain such patents or authorizations, and further provided that any such patent applications shall be filed in accordance with the terms of this Agreement; or

vi) required by law, regulation, rule, act or order of any governmental authority to be disclosed.

b. The Receiving Party agrees that at all times and notwithstanding any termination, expiration, or cancellation hereunder, it will hold the Confidential Information of the Disclosing Party in strict confidence, will use all reasonable safeguards to prevent unauthorized disclosure by its employees and agents. Notwithstanding the foregoing, the parties recognize that industry standards with respect to the treatment of Confidential Information may not be appropriate

in an academic setting. However, MSSM agrees to retain Confidential Information of AMICUS in the same manner and with the same level of confidentiality as MSSM retains its own Confidential Information.

c. The Receiving Party will maintain reasonable procedures to prevent accidental or other loss, including unauthorized publication of any Confidential Information of the Disclosing Party. The Receiving Party will promptly notify the Disclosing Party in the event of any loss or unauthorized disclosure of the Confidential Information.

d. Upon termination or expiration of this Agreement, and upon written request, the Receiving Party will promptly return to the Disclosing Party all documents or other tangible materials representing Confidential Information and all copies thereof.

e. The Receiving Party will immediately notify the Disclosing Party in writing, if it is requested by a court order, a governmental agency, or any other entity to disclose Confidential Information in the Receiving Party's possession. The Disclosing Party will have an opportunity to intervene by seeking a protective order or other similar order, in order to limit or prevent disclosure of the Confidential Information. The Receiving Party will disclose only the minimum Confidential Information required to be disclosed in order to comply, whether or not a protective order or other similar order is obtained by the Disclosing Party."

"9. Liability and Indemnification.

a. AMICUS shall indemnify, defend and hold harmless MSSM and its trustees, officers, directors, medical and professional staff, employees, students and agents and their respective

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

successors, heirs and assigns (the "Indemnitees"), against any liability, damage, loss or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon the Indemnitees or any one of them in connection with any claims, suits, actions, demands or judgments: (i) arising out of the production, manufacture, sale, use in commerce or in human clinical trials, lease, or promotion by AMICUS or by a licensee, Affiliate or agent of AMICUS of any Licensed Product, process or service relating to, or developed pursuant to, this Agreement, or (ii) arising out of any other activities to be carried out pursuant to this Agreement.

b. AMICUS' indemnification under subsection a(i), above, shall apply to any liability, damage, loss or expense whether or not it is attributable to the negligent activities of the Indemnitees. AMICUS' indemnification under subsection a(ii) above, shall not apply to any liability, damage, toss or expense to the extent that it is attributable to the negligence, gross negligence or intentional misconduct of the Indemnitees.

c. AMICUS shall, at its own expense, provide attorneys reasonably acceptable to MSSM to defend against any actions brought or filed against any party indemnified hereunder with respect to the subject of indemnity contained herein, whether or not such actions are rightfully brought.

d. EXCEPT AS PROVIDED IN THIS SECTION 9, NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR INCIDENTAL, CONSEQUENTIAL, SPECIAL, EXEMPLARY OR PUNITIVE DAMAGES.

10. Security for Indemnification.

a. At such time as any Licensed Product is being commercially distributed or sold (other than for the purpose of obtaining regulatory approvals) by AMICUS or by a sub-licensee, Affiliate or agent of AMICUS and to the extent that it is available on commercially reasonable terms, AMICUS shall at its sole cost and expense, procure and maintain policies of comprehensive general liability insurance in amounts not less than \*\*\*\*\* per incident and \*\*\*\*\* annual aggregate and naming the indemnitees as additional insureds. Such comprehensive general liability insurance shall provide (i) product liability coverage and (ii) broad form contractual liability coverage for AMICUS' indemnification under Section 9 of this Agreement. The minimum amounts of insurance coverage required under this Section 10 shall not be construed as a limit of AMICUS' liability with respect to its indemnification under Section 9 of this Agreement.

b. AMICUS shall provide MSSM with written evidence of such insurance upon request of MSSM. AMICUS shall provide MSSM with written notice at least 60 days prior to the cancellation, non-renewal or material change in such insurance; if AMICUS does not obtain replacement insurance providing comparable coverage within such 60 day period effective immediately upon notice to AMICUS, MSSM shall have the right to terminate this Agreement effective at the end of such 60 day period without notice or any additional waiting periods.

c. AMICUS shall maintain such comprehensive general liability insurance beyond the expiration or termination of this Agreement during: (i) the period that any product, process or service, relating to, or developed pursuant to, this Agreement is being commercially distributed or sold (other than for the purpose of obtaining regulatory approvals) by AMICUS or by a licensee, Affiliate or agent of AMICUS and (ii) a reasonable period after the period referred to in (c)(i) above

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

which in no event shall be less than seven years."

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

# Schedule 12.1B

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\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

# Schedule 14.2.3

CALCULATION OF ROYALTY RATE REDUCTION

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\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

Portions of this exhibit have been omitted and filed separately with the Secretary of the Securities and Exchange Commission (the "Commission") pursuant to an application for confidential treatment filed with the Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended. Such portions are marked as indicated below.

### STOCK PURCHASE AGREEMENT

THIS STOCK PURCHASE AGREEMENT (this "<u>Agreement</u>") is made as of the 17<sup>th</sup> day of July, 2012 (the "<u>SPA Effective Date</u>") by and between Amicus Therapeutics, Inc. ("<u>Amicus</u>"), a Delaware corporation with its principal place of business at 1 Cedar Brook Drive, Cranbury, New Jersey 08512, and Glaxo Group Limited, a company organized under the laws of England and Wales with its registered office address at Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex, UB6 0NN, England ("<u>GSK</u>"). Amicus and GSK are each referred to herein by name or as a "<u>Party</u>" or, collectively, as the "<u>Parties</u>".

# **RECITALS**

WHEREAS, Amicus and GSK entered into that certain Amended and Restated License and Expanded Collaboration Agreement dated as of July 17<sup>th</sup>, 2012 (the "<u>Amended License and Collaboration Agreement</u>"); and

WHEREAS, in connection with the execution of the Amended License and Collaboration Agreement, Amicus desires to sell to GSK and GSK desires to purchase from Amicus shares of Common Stock of Amicus on the terms and subject to the conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the foregoing recitals and the mutual covenants and agreements contained herein, the Parties hereto, intending to be legally bound, do hereby agree as follows:

1. **Definitions**. The capitalized terms used herein shall have the meanings ascribed to them below, provided that capitalized terms used herein that are not defined herein shall have the meanings ascribed to them in the Amended License and Collaboration Agreement:

1.1 "<u>Affiliate</u>" means, with respect to any specified Person, at any time, a Person that, directly or indirectly, through one or more intermediaries, controls, or is controlled by, or is under common control with, such specified Person at such time. For purposes of this definition, "control," when used with respect to any specified Person, shall mean (a) the direct or indirect ownership of more than fifty percent (50%) (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the total voting power of securities or other evidences of ownership interest in such Person or (b) the power to direct or cause the direction of the management and policies of such Person, directly or indirectly, whether through ownership of voting securities, by contract or otherwise.

1.2 "<u>Closing</u>" has the meaning ascribed to it in Section 3.1.

1.3 "<u>Closing Date</u>" means the day on which the transaction that is the subject of such Closing is consummated as set forth in Section 3.1.

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

1.4 "Common Stock" means the common stock of Amicus, par value \$0.01 per share.

1.5 "Exchange Act" means the Securities Exchange Act of 1934, as amended, together with the rules and regulations promulgated thereunder.

1.6 "FDA Documents" has the meaning ascribed to such term in Section 4.7.

1.7 "GAAP" means generally accepted accounting principles in the United States.

- 1.8 "<u>GSK Indemnitee</u>" has the meaning ascribed to such term in Section 7.5.
- 1.9 "<u>Holder</u>" means each person owning of record Registrable Securities that have not been sold to the public.

1.10 "Investor Rights Agreement Investor" means any Person, other than Amicus and GSK that owns shares of Common Stock and is party to the Third Amended and Restated Investor Rights Agreement dated as of September 13, 2006 by and among Amicus and the investors named therein.

1.11 "<u>Knowledge</u>" means the knowledge of such Person, assuming that such Person engaged in reasonable inquiry or investigation with respect to the relative subject matter.

1.12 "Lock-Up Period" has the meaning ascribed to such term in Section 8.1.

1.13 "<u>Material Adverse Effect</u>" on or with respect to an entity (or group of entities taken as a whole) means any state of facts, event, change or effect that has had, or that would reasonably expected to have, a material adverse effect on the business, properties, results of operations or financial condition of such entity (or of such group of entities taken as a whole).

- 1.14 "<u>Nasdaq</u>" means the Nasdaq Stock Market, Inc.
- 1.15 "<u>Party</u>" means a party to this Agreement.

1.16 "<u>Per Share Price</u>" has the meaning ascribed to it in Section 2.

1.17 "<u>Purchase Price</u>" has the meaning ascribed to it in Section 2.

1.18 "<u>Person</u>" means any individual, firm, corporation, partnership, limited liability company, trust, incorporated or unincorporated association, joint venture, joint stock company, government (or an agency or political subdivision thereof) or other entity of any kind, and shall include any successor (by merger or otherwise) of such entity.

1.19 "<u>Register</u>," "<u>Registered</u>," and "<u>Registration</u>" refer to a registration effected by preparing and filing a Registration Statement in compliance with the Securities Act, and the declaration or ordering of effectiveness of such Registration Statement or document by the SEC.

1.20 "<u>Registrable Securities</u>" means (a) the Shares, and (b) any shares of Common Stock of Amicus or other securities issued as (or issuable upon the conversion or exercise of any warrant,

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

right or other security which is issued as) a dividend or other distribution with respect to, or in exchange for or in replacement of, the Shares by way of stock dividend, stock split or in connection with a combination of shares, recapitalization or other reorganization or otherwise. Notwithstanding the foregoing, as to any particular Shares or other securities described above, once issued they shall cease to be Registrable Securities when (1) a registration statement with respect to the sale of such securities shall have become effective under the Securities Act and such securities shall have been disposed of in accordance with such registration statement, (2) they shall have been distributed pursuant to Rule 144 (or any successor provision) under the Securities Act, (3) such securities may be sold without volume restrictions pursuant to Rule 144, as determined by the counsel to Amicus pursuant to a written opinion letter to such effect, addressed and acceptable to Amicus's transfer agent, or (4) such securities shall have been otherwise transferred in a private transaction in which the rights under Section 7 hereof have not been assigned in connection with such transfer.

- 1.21 "<u>Registration Statement</u>" means a Registration Statement filed pursuant to the Securities Act.
- 1.22 "Rule 144" means Rule 144 promulgated under the Securities Act, or any successor rule.
- 1.23 "SEC Documents" has the meaning ascribed to such term in Section 4.7.

1.24 "<u>SEC Guidance</u>" means (i) any publicly-available written guidance, or rule of general applicability of the SEC staff, or (ii) written comments, requirements or requests of the SEC staff to Amicus in connection with the review of a Registration Statement.

- 1.25 "SEC" means the U.S. Securities and Exchange Commission.
- 1.26 "Securities Act" means the Securities Act of 1933, as amended, together with the rules and regulations promulgated thereunder.
- 1.27 "Shares" means the shares of Common Stock to be acquired by GSK hereunder as set forth in Section 2.
- 1.28 "Transaction Documents" means this Agreement and the Amended License and Collaboration Agreement.

1.29 "<u>Voting Stock</u>" means securities of any class or series of a corporation or association the holders of which are ordinarily, in the absence of contingencies, entitled to vote generally in matters put before the shareholders or members of such corporation or association, or securities convertible or exchangeable into or exercisable for any such securities.

# 2. <u>Purchase and Sale</u>.

At the Closing, on terms and conditions as set forth herein, Amicus will issue and sell to GSK and GSK will purchase from Amicus, Two Million Nine Hundred Forty Nine Thousand Five Hundred Eighty One (2,949,581) shares of Common Stock of Amicus, which, when added to the shares of Common Stock beneficially owned by GSK (as determined pursuant to Rule 13d-3 under the Exchange Act) immediately prior to the Closing Date, as a percentage of Amicus' total number

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

3

of shares of Common Stock issued and outstanding immediately following the Closing, will equal nineteen and nine tenths percent (19.9%) of the total number of shares of Common Stock issued and outstanding immediately following the Closing (the "<u>Shares</u>"). Such number of Shares shall be subject to appropriate and equitable adjustment for any stock split, stock dividend or reclassification of the Common Stock or similar event between the date hereof and the Closing, for an aggregate consideration equal to the product of the number of Shares times the Per Share Price (the "<u>Purchase Price</u>"). For the purposes of this Section 2, the "Per Share Price" shall be equal to \*\*\*\*\*.

# 3. <u>Closing</u>.

3.1 <u>Closing</u>. Subject to the satisfaction or waiver of the conditions set forth in Article 6, the completion of the sale and purchase of the Shares (the "<u>Closing</u>") shall occur within ten (10) Business Days of the SPA Effective Date; <u>provided</u> that if any conditions have not been so satisfied or waived on such date, the Closing shall occur on the first Business Day after the satisfaction or waiver (by the Party entitled to grant such waiver) of the conditions to the Closing set forth in Article 6 herein (other than those conditions that by their nature are to be satisfied at the Closing, but subject to fulfillment or waiver of those conditions), or on such other date as the parties shall mutually agree (the "<u>Closing Date</u>").

- 3.2 <u>Delivery</u>. At the Closing, subject to the terms and conditions hereof:
  - (a) GSK shall deliver to Amicus:

(i) the Purchase Price by wire transfer within ten (10) Business Days after the Closing to the following account:

Bank: Bank Address:	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
Beneficiary: Beneficiary Address:	Amicus Therapeutics, Inc. 1 Cedar Brook Drive Cranbury, NJ 08512
ABA: Account: SWIFT Code:	XXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXX

Agreement.

together with any other documents as are required to be delivered by GSK to Amicus pursuant to the terms of this

Amicus will deliver to GSK a stock certificate, in the name of GSK, representing the Shares purchased at the Closing, dated as of (b) the Closing Date, against payment of such Purchase Price, and any other documents as are required to be delivered by Amicus to GSK

- Material has been omitted and filed separately with the Commission.

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pursuant to the terms of this Agreement, including resolutions of the Board of Directors of Amicus approving the transactions contemplated by this Agreement.

Location. The Closing shall occur at the offices of Amicus, located at 1 Cedar Brook Drive, Cranbury, New Jersey 08512 (or remotely via 3.3 the exchange of signatures and documents) unless otherwise agreed to by the Parties.

**<u>Representations and Warranties of Amicus</u>**. Amicus hereby represents and warrants to GSK as of the date hereof and as of the Closing Date 4. (except as set forth below), as follows:

Capitalization. As of June 30, 2012, the authorized capital stock of Amicus consisted of (a) 125,000,000 shares of Common Stock, of 4.1 which (i) 46,377,897 shares were issued and outstanding, (ii) up to 1,854,946 shares have been reserved for issuance upon exercise of outstanding common stock warrants, (iii) 9,731,021 shares have been reserved for issuance under Amicus's Amended and Restated 2007 Equity Incentive Plan, (iv) 580,797 shares have been reserved for issuance under Amicus's Amended and Restated 2007 Director Option Plan, (v) 1,203,721 shares have been reserved for issuance under Amicus's 2002 Equity Incentive Plan, and (iv) 200,000 shares have been reserved for issuance under Amicus's 2007 Employee Stock Purchase Plan; and (b) 10,000,000 shares of preferred stock, none of which is outstanding. All issued and outstanding shares of Amicus's capital stock have been duly authorized and validly issued, and are fully paid and nonassessable, and were issued in compliance with all applicable federal and state securities laws. As of the SPA Effective Date, there are no preemptive or similar rights on the part of any holder of any class or securities of Amicus. As of the SPA Effective Date, except as set forth in the SEC Documents or as described or referred to above, there are no securities convertible into or exchangeable for, or options, warrants, calls, subscriptions, rights, contracts, commitments, or understandings of any kind to which Amicus is a party or by which it is bound obligating Amicus to issue, deliver or sell, or cause to be issued, delivered or sold additional shares of its capital stock or other voting securities of Amicus. As of the SPA Effective Date, there are no outstanding agreements of Amicus to repurchase, redeem or otherwise acquire any shares of its capital stock. At the Closing, Amicus shall provide GSK with a certificate of a duly authorized officer of Amicus setting forth: (a) the capitalization of Amicus immediately following the Closing including the number of shares of the following: (i) issued and outstanding Common Stock, including, with respect to restricted Common Stock, vesting schedule and repurchase price; (ii) issued stock options, including vesting schedule and exercise price; (iii) stock options not vet issued but reserved for issuance; (iv) each series of preferred stock; and (v) warrants or stock purchase rights, if any; and (b) that as of the Closing Date (i) except as set forth in the SEC Documents or as described or referred to above, there are no securities convertible into or exchangeable for, or options, warrants, calls, subscriptions, rights, contracts, commitments, or understandings of any kind to which Amicus is a party or by which it is bound obligating Amicus to issue, deliver or sell, or cause to be issued, delivered or sold additional shares of its capital stock or other voting securities of Amicus; and (ii) there are no outstanding agreements of Amicus to repurchase, redeem or otherwise acquire any shares of its capital stock.

4.2 Litigation. There are no actions, suits, proceedings or, to its Knowledge, any investigations, pending or currently threatened against Amicus that questions the validity of this Agreement or the issuance of the Common Stock contemplated hereby, nor to its Knowledge, is

- Material has been omitted and filed separately with the Commission.

there any basis therefor. As of the Closing, there is no other material action, suit, or proceeding pending or, to the Knowledge of Amicus, currently threatened against Amicus. As of the Closing, there are no material outstanding consents, orders, decrees or judgments of any governmental entity naming Amicus.

43 Organization and Good Standing. Amicus is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware and has all requisite corporate power and authority to own, lease and operate its properties and carry on its business as now conducted. Amicus is duly qualified and is in good standing as a foreign corporation in each jurisdiction in which the properties owned, leased or operated, or the business conducted, by it requires such qualification except where the failure to be so qualified or in good standing, individually or in the aggregate, would not have a Material Adverse Effect.

4.4 <u>Authorization</u>. All corporate actions on the part of Amicus, its officers, directors and stockholders necessary for the authorization, execution and delivery of the Transaction Documents and for the issuance of the Shares have been taken. Amicus has the requisite corporate power to enter into the Transaction Documents and to carry out and perform its obligations thereunder. The Transaction Documents have been duly authorized, executed and delivered by Amicus and, upon due execution and delivery by GSK, each Transaction Document will be a valid and binding agreement of Amicus, except as enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally or by equitable principles.

4.5 <u>Subsidiaries.</u> Other than Amicus Therapeutics UK Limited, Amicus does not currently own or control, directly or indirectly, any interest in any other corporation, partnership, trust, joint venture, limited liability company, association, or other business entity. Amicus is not a participant in any joint venture, partnership or similar arrangement other than its relationship with GSK pursuant to the Amended License and Collaboration Agreement .

4.6 <u>No Conflict With Other Instruments</u>. Neither the execution, delivery nor performance of the Transaction Documents, nor the consummation by Amicus of the transactions contemplated hereby will result in any violation of, be in conflict with, cause any acceleration or any increased payments under, or constitute a default under, with or without the passage of time or the giving of notice: (a) any provision of Amicus's Restated Certificate of Incorporation or Bylaws as in effect on the date hereof or at the Closing; (b) any provision of any judgment, decree or order to which Amicus is a party or by which it is bound, (c) any note, mortgage, material contract, material agreement, license, waiver, exemption, order or permit.

# 4.7 <u>Disclosure Documents</u>.

(a) For the two years preceding the SPA Effective Date, Amicus has filed, on a timely basis or has received a valid extension as of such time of filing and has thereafter made such filings prior to the expiration of any such extension, all reports, schedules, forms, statements and other documents required to be filed by Amicus with the SEC under the Securities Act and the Exchange Act, including pursuant to Section 13(a) or 15(d) thereof, (the foregoing materials, including the exhibits thereto and documents incorporated by reference therein, being collectively

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referred to herein as the "<u>SEC Documents</u>") and with the U.S. Food and Drug Administration ("<u>FDA</u>") under its applicable regulations ("<u>FDA Documents</u>"), and Amicus has paid all fees and assessments due and payable in connection with the SEC Documents and the FDA Documents. As of their respective dates, the SEC Documents and the FDA Documents complied in all material respects with all statutes and applicable rules and regulations of the SEC or FDA, as applicable, including the requirements of the Securities Act or the Exchange Act, as applicable, and none of the SEC Documents or FDA Documents, when filed, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(b) The audited financial statements of Amicus included in Amicus's SEC Documents comply in all material respects with the published rules and regulations of the SEC with respect thereto, and such audited financial statements (i) were prepared from the books and records of Amicus, (ii) were prepared in accordance with GAAP applied on a consistent basis (except as may be indicated therein or in the notes or schedules thereto) and (iii) present fairly the financial position of Amicus as of the dates thereof and the results of operations and cash flows for the periods then ended. The unaudited financial statements included in the SEC Documents comply in all material respects with the published rules and regulations of the SEC with respect thereto, and such unaudited financial statements (i) were prepared from the books and records of Amicus, (ii) were prepared in accordance with GAAP, except as otherwise permitted under the Exchange Act and the rules and regulations thereunder, applied on a consistent basis (except as may be indicated therein or in the notes or schedules thereto) and (iii) present fairly the financial position of Amicus as of the periods then ended, subject to normal year-end adjustments and any other adjustments described therein or in the notes or schedules thereto.

4.8 <u>Absence of Certain Events and Changes</u>. Since the date of Amicus's Quarterly Report on Form 10-Q for the quarter ended on March 31, 2012: (i)Amicus has conducted its business in the ordinary course consistent with past practice, (ii) there has not been any event, change or development which, individually or in the aggregate, would have a Material Adverse Effect, taken as a whole, (iii) Amicus has not incurred any material liabilities (contingent or otherwise) other than expenses incurred in the ordinary course of business consistent with past practice, (iv) Amicus has not altered its method of accounting in any material respect, and (v) Amicus has not declared or made any dividend or distribution of cash or other property to its shareholders or purchased, redeemed or made any agreements to purchase or redeem any shares of its capital stock.

4.9 <u>Intellectual Property</u>. Amicus owns, or has an exclusive right pursuant to a valid, written license agreement to use and exploit, all material Intellectual Property used in or necessary for the conduct of the business of Amicus as conducted as of the Closing. No claims have been asserted by a third party in writing (a) alleging that the conduct of the business of Amicus has infringed or misappropriated any Intellectual Property rights of such third party, or (b) challenging or questioning the validity or effectiveness of any Intellectual Property right of Amicus, and, to the Knowledge of Amicus, there is no valid basis for any such claim (a) or (b). To the Knowledge of Amicus, no third party is misappropriating or infringing any Intellectual Property right of Amicus. No loss or expiration of any of Amicus' material Intellectual Property is pending, or, to the

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Knowledge of Amicus, threatened. Amicus has taken reasonable steps in accordance with standard industry practices to protect its rights in its Intellectual Property and at all times has maintained the confidentiality of all information used in connection with the business that constitutes or constituted a trade secret of Amicus.

4.10 <u>Compliance with Applicable Law</u> Amicus has all material permits, licenses, franchises, authorizations, orders and approvals of, and has made all filings, applications and registrations with, governmental entities that are required in order to permit Amicus to own or lease properties and assets and to carry on its business as presently conducted that are material to Amicus. Amicus has complied and is in compliance in all material respects with all statutes, laws, regulations, rules, judgments, orders and decrees of all governmental entities applicable to it that relate to its business, including but not limited

to compliance with the U.S. Foreign Corrupt Practices Act of 1977 (FCPA) (15 U.S.C. §§ 78dd-1, et seq.) and any applicable similar laws in foreign jurisdictions in which Amicus is currently, or has previously, conducted its business or is currently, or has previously, conducted clinical trials. Amicus has not received any notice alleging noncompliance, and, to the Knowledge of Amicus, Amicus is not under investigation with respect to, or threatened to be charged, with any material violation of any applicable statutes, laws, regulations, rules, judgments, orders or decrees of any governmental entities.

4.11 <u>Valid Issuance of Shares</u>. When issued, sold and delivered in accordance with the terms hereof for the consideration expressed herein, the Shares will be duly and validly authorized and issued, fully paid and non-assessable, free and clear of all liens, and, based in part on the representations of GSK in Section 5 of this Agreement, will be issued in compliance with all applicable federal and state securities laws.

4.12 <u>Governmental Consents</u>. No consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any federal, state or local governmental authority on the part of Amicus is required in connection with the consummation of the transactions contemplated by the Transaction Documents, except for notices required or permitted to be filed with certain state and federal securities commissions, which notices will be filed on a timely basis.

4.13 <u>No Brokers</u>. No broker, finder or investment banker is entitled to any brokerage, finder's or other fee or commission in connection with the transactions contemplated by this Agreement based on arrangements made by Amicus.

4.14 <u>No Undisclosed Liabilities</u>. Amicus does not have any liabilities (contingent or otherwise), except for (i) liabilities reflected or reserved against in financial statements of Amicus included in the SEC Documents filed with the SEC prior to the date of this Agreement, and (b) liabilities that have not been and would not reasonably be expected to be material.

4.15 <u>Internal Controls</u>. The records, systems, controls, data and information of Amicus are recorded, stored, maintained and operated under means (including any electronic, mechanical or photographic process, whether computerized or not) that are under the exclusive ownership and direct control of Amicus (including all means of access thereto and therefrom), except for any non-

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exclusive ownership and non-direct control that would not reasonably be expected to have a material adverse effect on the system of internal accounting controls described herein.

5. **<u>Representations And Warranties Of GSK.</u>** GSK hereby represents and warrants to Amicus as of the date hereof and as of the Closing Date as follows:

5.1 <u>Legal Power</u>. GSK has the requisite corporate power to enter into the Transaction Documents, to carry out and perform its obligations under the terms of the Transaction Documents.

5.2 <u>Due Execution</u>. The Transaction Documents have been duly authorized, executed and delivered by GSK, and, upon due execution and delivery by Amicus, each of the Transaction Documents will be a valid and binding agreement of GSK, except as enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally or by equitable principles.

5.3 <u>Ownership</u>. As of the date hereof, GSK and its Affiliates beneficially own (as determined in accordance with Rule 13d-3 under the Exchange Act) 6,866,244 shares of Common Stock. Other than the foregoing shares of Common Stock, neither GSK nor its Affiliates beneficially own (as determined in accordance with Rule 13d-3 under the Exchange Act) any other securities of Amicus.

5.4 <u>Investment Representations</u>. In connection with the offer, purchase and sale of the Shares, GSK makes the following representations:

(a) GSK is acquiring the Shares for its own account, not as nominee or agent, for investment and not with a view to, or for resale in connection with, any distribution or public offering thereof within the meaning of the Securities Act.

(b) GSK understands that:

(i) the Shares have not been registered under the Securities Act by reason of a specific exemption therefrom, that such securities may be required to be held by it indefinitely under applicable securities laws, and that GSK must, therefore, bear the economic risk of such investment indefinitely, unless a subsequent disposition thereof is registered under the Securities Act or is exempt from such registration;

(ii) each certificate representing such Shares will be endorsed with the following legend:

"THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), OR UNDER THE SECURITIES LAWS OF CERTAIN STATES. THESE SECURITIES ARE SUBJECT TO RESTRICTIONS ON TRANSFERABILITY AND RESALE AND MAY NOT BE TRANSFERRED OR RESOLD EXCEPT AS PERMITTED UNDER THE ACT AND ANY APPLICABLE STATE SECURITIES LAWS, PURSUANT TO REGISTRATION OR

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(iii) Amicus will instruct its transfer agent not to register the transfer of the Shares (or any portion thereof) unless the conditions specified in the foregoing legends are satisfied.

GSK has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of the (c) investment in the Shares to be purchased hereunder.

GSK is an "accredited investor" as such term is defined in Rule 501(a) of the rules and regulations promulgated under the (d) Securities Act.

#### **Conditions To Closing.** 6.

Conditions to Obligations of GSK at the Closing. GSK's obligation to purchase the Shares at the Closing is subject to the fulfillment to its 61 reasonable satisfaction, on or prior to the Closing, of all of the following conditions, any of which may be waived by GSK:

Representations and Warranties True. The representations and warranties made by Amicus in Section 4 hereof shall be true and (a) correct in all material respects on the Closing Date (except for the representations and warranties made in the first and fourth sentences of Section 4.1) with the same force and effect as if they had been made on and as of such date, and a certificate duly executed by an officer of Amicus, to the effect of the foregoing, shall be delivered to GSK.

Performance of Obligations. Amicus shall have performed and complied with all obligations and conditions herein required to be (b) performed or complied with by it on or prior to the Closing and a certificate duly executed by an officer of Amicus, to the effect of the foregoing, shall be delivered to GSK.

(c) Proceedings and Documents. All corporate and other proceedings in connection with the transactions contemplated at the Closing and all documents and instruments incident to such transactions shall be reasonably satisfactory in substance and form to GSK, and GSK shall have received all such counterpart originals or certified or other copies of such documents as it may reasonably request.

Qualifications; Legal Investment. All authorizations, approvals, or permits, if any, of any governmental authority or regulatory (d)body of the United States or of any state that are required in connection with the lawful sale and issuance of the Shares shall have been duly obtained and shall be effective on and as of the Closing. No stop order or other order enjoining the sale of the Shares shall have been issued and no proceedings for such purpose shall be pending or, to the Knowledge of Amicus, threatened by the SEC.

Nasdaq Listing. If required by Nasdaq, the Shares shall have been approved for listing on the Nasdaq Stock Market, subject only (e) to official notice of issuance.

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Conditions to Obligations of Amicus at the Closing. Amicus's obligation to issue and sell the Shares at the Closing is subject to the 62 fulfillment to its reasonable satisfaction, on or prior to the Closing, of the following conditions, any of which may be waived by Amicus:

Representations and Warranties True. The representations and warranties made by GSK in Section 5 hereof shall be true and correct in all material respects on the Closing Date with the same force and effect as if they had been made on and as of such date, and a certificate duly executed by an officer of GSK, to the effect of the foregoing, shall be delivered to Amicus.

Performance of Obligations. GSK shall have performed and complied with all agreements and conditions herein required to be (b)performed or complied with by it on or before the Closing, and a certificate duly executed by an officer of GSK, to the effect of the foregoing, shall be delivered to Amicus.

Qualifications; Legal Investment. All authorizations, approvals, or permits, if any, of any governmental authority or regulatory (c) body of the United States or of any state that are required in connection with the lawful sale and issuance of the Shares shall have been duly obtained and shall be effective on and as of the Closing. No stop order or other order enjoining the sale of the Shares shall have been issued and no proceedings for such purpose shall be pending or, to the Knowledge of Amicus, threatened by the SEC.

Condition to Obligations of each Party at the Closing. The obligations of Amicus and GSK to consummate the transactions contemplated to 6.3 occur at the Closing shall be subject to the satisfaction prior to Closing of the following conditions, each of which may be waived by the other party only if it is legally permitted to do so.

HSR and Other Approvals. Any applicable waiting period under the Hart-Scott-Rodino Antitrust Improvement Act of 1976 (the (a) "HSR Act") relating to the transactions contemplated hereby shall have expired or been terminated, and all other material authorizations, consents, orders or approvals of, or regulations, declarations or filings with, or expirations of applicable waiting periods imposed by, any governmental entity (including, without limitation, any foreign antitrust filing) necessary for the consummation of the transactions contemplated hereby, shall have been obtained or filed or shall have occurred.

No Litigation, Injunctions or Restraints. No statute, rule, regulation, executive order, decree, temporary restraining order, (b)preliminary or permanent injunction or other order enacted, entered, promulgated, enforced or issued by any governmental entity or other legal restraint or prohibition preventing the consummation of the transactions contemplated by this Agreement shall be in effect.

(c) Amended License and Collaboration Agreement. The Amended License and Collaboration Agreement shall continue to be in full force and effect.

#### 7. **Registration Rights**.

7.1 Registration. As soon as reasonably practicable, but no event later than sixty (60) days after the Closing, Amicus shall prepare and file with the SEC a Registration Statement covering

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the resale of all, or such portion as permitted by SEC Guidance (provided that, Amicus shall use commercially reasonable efforts to advocate with the SEC for the registration of the maximum number of the Registrable Securities permitted by SEC Guidance), of the Registrable Securities and use commercially reasonable efforts to cause a Registration Statement to be declared effective (including, without limitation, the execution of any required undertaking to file post-effective amendments) as promptly as possible after the filing thereof, but in any event prior to the date which is: (i) one hundred twenty (120) days after the Closing if the Registration Statement is not reviewed by the SEC, or (ii) one-hundred fifty days (150) days after the Closing, if the Registration Statement shall be on Form S-3 (except if Amicus fails to meet one or more of the registrant requirements specified in General Instruction I.A. on Form S-3, such registration shall be on another appropriate form in accordance herewith).

7.2 <u>Expenses Of Registration</u>. Amicus shall pay all fees and expenses incurred in connection with any registration, qualification, exemption or compliance by Amicus in the performance of its obligations pursuant to this Section 7, whether or not any Registrable Securities are sold pursuant to a Registration Statement, and including all registration and filing fees, exchange listing fees, and the fees and expenses of counsel and accountants for Amicus.

7.3 <u>Obligations Of Amicus</u>. In the case of registration, qualification, exemption or compliance effected by Amicus pursuant to this Agreement, Amicus will, upon request of GSK, inform GSK as to the status of such registration, qualification, exemption and compliance. Amicus shall, at its expense and in addition to its obligations under Section 7.1, as expeditiously as reasonably possible:

(a) except for such times as Amicus is permitted hereunder to suspend the use of the prospectus forming part of the Registration Statement, use its commercially reasonable efforts to keep such registration, and any required qualification, exemption or compliance under state securities laws, continuously effective with respect to GSK and its permitted assignees, until the date all Shares held by GSK may be sold during any ninety (90) day period under Rule 144 and any contractual agreements with Amicus. The period of time during which Amicus is required hereunder to keep the Registration Statement effective is referred to herein as the *"Registration Period."* 

(b) advise GSK promptly (and, in any event, within five (5) business days):

(i) when the Registration Statement or any amendment thereto has been filed with the SEC and when the Registration Statement or any post-effective amendment thereto has become effective;

(ii) of the receipt by Amicus of any notification from the SEC of any stop order suspending the effectiveness of the Registration Statement or the initiation of any proceedings for such purpose;

(iii) of the receipt by Amicus of any notification with respect to the suspension of the qualification of the Registrable Securities included therein for sale in any jurisdiction or the initiation or threatening of any proceeding for such purpose; and

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(iv) of the occurrence of any event that requires the making of any changes in the Registration Statement or the prospectus so that, as of such date, the statements therein are not misleading and do not omit to state a material fact required to be stated therein or necessary to make the statements therein (in the case of the prospectus, in the light of the circumstances under which they were made) not misleading;

(c) use its commercially reasonable efforts to obtain the withdrawal of any order suspending the effectiveness of any Registration Statement as soon as reasonably practicable;

(d) if GSK so requests in writing, promptly furnish to GSK, without charge, at least one copy of such Registration Statement and any post-effective amendment thereto, including financial statements and schedules, and, if explicitly requested, all exhibits in the form filed with the SEC;

(e) during the Registration Period, promptly deliver to GSK, without charge, at least one copy of the prospectus included in such Registration Statement and any amendment or supplement thereto and as many additional copies as GSK may reasonably request; and Amicus consents to the use, consistent with the provisions hereof, of the prospectus or any amendment or supplement thereto by GSK in connection with the offering and sale of the Registrable Securities covered by the prospectus or any amendment or supplement thereto;

(f) during the Registration Period, if GSK so requests in writing, deliver to GSK, without charge, (i) one copy of the following documents, other than those documents available via EDGAR (and excluding, in each case, exhibits thereto): (A) its annual report to its stockholders, if any (which annual report will contain financial statements audited in accordance with GAAP by a firm of certified public accountants of recognized standing), (B) if not included in substance in its annual report to stockholders, its annual report on Form 10-K (or similar form), (C) its definitive proxy statement with respect to its annual meeting of stockholders, (D) each of its quarterly reports to its stockholders, and, if not included in substance in its quarterly reports to stockholders, its quarterly report on Form 10-Q (or similar form), and (E) a copy of the Registration Statement; and (ii) if explicitly requested, any exhibits filed with respect to the foregoing;

(g) upon the occurrence of any event contemplated by Section 7.3(b)(iv) above, except for such times as Amicus is permitted hereunder to suspend the use of the prospectus forming part of the Registration Statement, Amicus will use its commercially reasonable efforts to as soon as reasonably practicable prepare a post-effective amendment to the Registration Statement or a supplement to the related prospectus, or file any other required document so that, as thereafter delivered to GSK, the prospectus will not include any untrue statement of a material fact or omit to state any material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading;

Securities;

(h)

comply in all material respects with all applicable rules and regulations of the SEC which could affect the sale of the Registrable

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(i) use its commercially reasonable efforts to cause all Registrable Securities to be listed on each securities exchange or market, if any, on which equity securities issued by Amicus have been listed;

(j) use its commercially reasonable efforts to take all other steps necessary to effect the registration of the Registrable Securities contemplated hereby and to enable GSK to sell Registrable Securities under Rule 144; and

(k) permit counsel for GSK to review the Registration Statement and all amendments and supplements thereto, within two (2) business days prior to the filing thereof with the Commission;

*provided* that, in the case of clause (k) above, Amicus will not be required to delay the filing of the Registration Statement or any amendment or supplement thereto to incorporate any comments to the Registration Statement or any amendment or supplement thereto by or on behalf of GSK if such comments would require a delay in the filing of such Registration Statement, amendment or supplement, as the case may be.

If at any time during the Registration Period there is not an effective Registration Statement covering all of the Registrable Securities and Amicus determines to prepare and file with the SEC a registration statement relating to an offering for its own account or the account of any other stockholder upon demand (a "Demanding Stockholder") under the Securities Act of any of its equity securities, other than on Form S-4 or Form S-8 (each as promulgated under the Securities Act) or their then equivalents (an "Incidental Registration"), then Amicus will send to GSK written notice of such determination and, if within ten (10) business days after receipt of such notice, GSK will so request in writing, Amicus will use commercially reasonable efforts to include in such registration statement or, in the case of an underwritten offering, cause the managing underwriter or underwriters to include, all or any part of such Registrable Securities GSK requests to be registered, on the same terms and conditions as the securities of Amicus or of the Demanding Stockholder included therein. In connection with any Incidental Registration, Amicus shall not be required to include any Registrable Securities in such underwritten offering unless GSK accepts the terms of the underwritten offering as agreed upon between Amicus, the Demanding Stockholder, if any, and the underwritter, and then only in such quantity as the underwriter believes will not have a material adverse effect on the success of such offering. If the underwriter determines that the registration of all or part of the Registrable Securities which GSK has requested to be included would have a material adverse effect on the success of such offering, then Amicus shall be required to include in such Incidental Registration, to the extent of the amount that the underwriter believes may be sold without causing such adverse effect, first, all of the securities to be offered for the account of Amicus or the account of the Demanding Stockholder; second, any securities to be offered for the account of the Investor Rights Agreement Investors, if any, and third, the Registrable Securities; provided, that (i) if at any time after giving written notice of its intention to register any securities and prior to the effective date of the registration statement filed in connection with such registration, Amicus will determine for any reason not to register or to delay registration of such securities, Amicus may, at its election, give written notice of such determination to GSK and, thereupon, (A) in the case of a determination not to register, will be relieved of its obligation to register any Registrable Securities to this paragraph in connection with such registration (but not from its

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obligation to pay expenses in accordance with this Agreement), and (B) in the case of a determination to delay registering, will be permitted to delay registering any Registrable Securities being registered pursuant to this paragraph for the same period as the delay in registering such other securities.

7.4 <u>Furnishing Information</u>.

(a) It shall be a condition precedent to the obligations of Amicus to take any action pursuant to Section 7.1 that the selling Holders shall furnish to Amicus such information regarding themselves, the Registrable Securities held by them and the intended method of disposition of such securities as shall be legally required under the Securities Act or otherwise required by the SEC to effect the registration of their Registrable Securities.

# 7.5 <u>Indemnification; Contribution</u>.

(a) Amicus shall indemnify and hold harmless each Holder (including the employees, agents, representatives, officers and directors of GSK and its Affiliates) (each a "<u>GSK Indemnitee</u>") from and against any and all losses, claims, damages, liabilities and expenses (including reasonable costs of investigation) arising out of or based upon any untrue, or allegedly untrue, statement of a material fact contained in any Registration Statement, prospectus or preliminary prospectus or notification or offering circular prepared by Amicus in connection with the registration and/or offering of the Registrable Securities (as amended or supplemented if Amicus shall have furnished any amendments or supplements thereto) or arising out of or based upon any omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, except insofar as the same are caused by or contained in any information concerning such Holder furnished in writing to Amicus by such Holder expressly for use in such document.

(b) Each Holder shall indemnify and hold harmless Amicus, and its respective directors, officers, employees and each Person who controls Amicus (within the meaning of the Securities Act and the Exchange Act) from and against any and all losses, claims, damages, liabilities and expenses (including reasonable costs of investigation) arising out of or based upon any untrue, or allegedly untrue, statement of a material fact contained in any Registration Statement, prospectus or preliminary prospectus or notification or offering circular prepared by Amicus in connection with the registration and/or offering of the Registrable Securities (as amended or supplemented if Amicus shall have furnished any amendments or supplements thereto) or arising out of or based upon any omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, if such statement or omission was made in reliance upon and in conformity with any information concerning such Holder furnished in writing to Amicus by such Holder specifically for use in the preparation of such document.

(c) Each Person entitled to indemnification hereunder (the "<u>Indemnified Party</u>") agrees to give prompt written notice to the indemnifying party (the "<u>Indemnifying Party</u>") after the receipt by the Indemnified Party of any written notice of the commencement of any action, suit, proceeding or investigation or threat thereof made in writing for which the Indemnified Party intends

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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to claim indemnification or contribution pursuant to this Agreement; provided, however, that the failure to so notify the Indemnifying Party shall not relieve the Indemnifying Party of any liability that it may have to the Indemnified Party hereunder unless, and only to the extent that, such failure results in the Indemnifying Party's forfeiture of substantive rights or defenses. If notice of commencement of any such action is given to the Indemnifying Party as above provided, the Indemnifying Party shall be entitled to participate in and, to the extent it may wish, jointly with any other Indemnifying Party similarly notified, to assume the defense of such action at its own expense, with counsel chosen by it and reasonably satisfactory to such Indemnified Party. The Indemnified Party shall have the right to employ separate counsel in any such action and participate in the defense thereof, but the fees and expenses of such counsel (other than reasonable costs of investigation) shall be paid by the Indemnified Party unless (i) the Indemnifying Party agrees to pay the same, (ii) the Indemnifying Party fails to assume the defense of such action with counsel reasonably satisfactory to the Indemnified Party in its reasonable judgment or (iii) the named parties to any such action (including any impleaded parties) have been advised by such counsel that either (x) representation of such Indemnified Party and the Indemnifying Party by the same counsel would be inappropriate under applicable standards of professional conduct or (y) there may be one or more legal defenses available to it which are different from or additional to those available to the Indemnified Party. No Indemnifying Party shall be liable for any settlement entered into without its written consent (other than in the case where the Indemnifying Party is unconditionally released from liability and its rights are not adversely effected), which consent shall not be unreasonably withheld.

(d) If the indemnification provided for in this Section 7.5 from the Indemnifying Party pursuant to applicable law is unavailable to an Indemnified Party hereunder in respect of any losses, claims, damages, liabilities or expenses referred to therein, then the Indemnifying Party, in lieu of indemnifying such Indemnified Party, shall contribute to the amount paid or payable by such Indemnified Party as a result of such losses, claims, damages, liabilities or expenses in such proportion as is appropriate to reflect the relative fault of the Indemnifying Party and Indemnified Party in connection with the actions which resulted in such losses, claims, damages, liabilities or expenses, as well as any other relevant equitable considerations. The relative faults of such Indemnifying Party and Indemnified Party shall be determined by reference to, among other things, whether any action in question, including any untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact, has been made by, or relates to information supplied by, such Indemnifying Party or Indemnified Party, and the parties' relative intent, Knowledge, access to information and opportunity to correct or prevent such action. The amount paid or payable by a party as a result of the losses, claims, damages, liabilities and expenses referred to above shall be deemed to include, subject to the limitations set forth in Sections 7.5(a), (b) and (c), any legal or other fees, charges or expenses reasonably incurred by such party in connection with any investigation or proceeding. The parties hereto agree that it would not be just and equitable considerations referred to in the immediately preceding paragraph. No Person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any Person.

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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7.6 <u>Rule 144 Reporting</u>. In order to make the benefits of the rules and regulations of the SEC that may permit the sale of the Registrable Securities to the public without registration available to GSK, Amicus agrees to use commercially reasonable efforts to:

(a) make and keep public information available, as those terms are understood and defined in Rule 144(c)(1) or any similar or analogous rule promulgated under the Securities Act, at all times after the SPA Effective Date;

(b) file with the SEC, in a timely manner, all reports and other documents required of Amicus under the Exchange Act; and

(c) so long as GSK owns any Registrable Securities, furnish GSK forthwith upon request: (i) a written statement by Amicus as to its compliance with the reporting requirements of Rule 144 under the Securities Act, and of the Exchange Act; (ii) a copy of the most recent annual or quarterly report of Amicus; and (iii) such other reports and documents as GSK may reasonably request in availing itself of any rule of regulation of the SEC allowing it to sell any such securities without registration.

7.7 <u>Assignment of Registration Rights</u>. The rights and obligations under this Section 7 may only be assigned by GSK to a transferee or assignee of Registrable Securities that is (a) an Affiliate or (b) a successor (by operation of law or otherwise) to substantially all the business or assets of GSK; provided, however, that such attempted assignment shall be void unless (i) GSK, within thirty (30) days after such transfer, furnishes to Amicus written notice of the name and address of such transferee or assignee and the securities with respect to which such registration rights are being assigned, and (ii) such transferee agrees to be subject to all obligations and restrictions with respect to the Registrable Securities set forth in this Agreement.

# 8. <u>Stock Ownership Governance</u>.

8.1 <u>Lock-Up Period</u>. Excluding any transfers or intra-company disposal of Shares between GSK and any of its Affiliates, during the six (6) month period beginning on the Closing Date and ending on the six (6) month anniversary thereof (the "<u>Lock-Up Period</u>"), GSK shall not, and shall cause any other Holder not to, without the prior written consent of Amicus, sell, contract to sell, pledge or otherwise dispose of, directly or indirectly, any Shares or enter into a transaction which would have the same effect.

8.2 <u>Market Stand-Off Agreement</u>. During the Lock-Up Period, GSK agrees that in connection with any registration of Amicus's securities that, upon the request of Amicus or the underwriters managing any underwritten offering of Amicus's securities, not to sell, make any short sale of, loan, grant any option for the purchase of, or otherwise dispose of any Registrable Securities without the prior written consent of Amicus or such underwriters, as the case

may be, for such period of time from the effective date of such registration as Amicus or the underwriters may specify, provided that each executive officer and director of Amicus agrees to a similar lockup.

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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8.3 <u>Remedies</u>. Without prejudice to the rights and remedies otherwise available to the parties, Amicus shall be entitled to equitable relief by way of injunction if GSK or any other Holder breaches or threatens to breach any of the provisions of this Section 8.

### 9. <u>Covenants</u>.

### 9.1 <u>Covenant of Amicus</u>.

(a) Amicus hereby covenants and agrees that it shall take all necessary and appropriate actions to ensure that it shall have available under its Restated Certificate of Incorporation as in effect on the Closing Date sufficient authorized but unissued shares of its Common Stock to issue and sell to GSK all of the Shares.

(b) Amicus will file with Nasdaq all documentation required by Nasdaq, if any, in connection with the issuance of the Shares.

9.2 \*\*\*\*\*.

### 10. <u>Termination</u>.

10.1 <u>Termination</u>. This Agreement may be terminated at any time prior to the Closing:

- (a) by mutual written consent of GSK and Amicus;
- (b) by GSK or Amicus:

(i) if there shall be any statute, law, regulation or rule that makes consummating the transactions contemplated hereby illegal or if any court or other governmental entity of competent jurisdiction shall have issued judgment, order, decree or ruling, or shall have taken such other action restraining, enjoining or otherwise prohibiting the consummation of the transactions contemplated hereby and such judgment, order, decree or ruling shall have become final and non-appealable;

(ii) if the Amended License and Collaboration Agreement shall have terminated; or

(iii) the United States Federal Trade Commission ("<u>FTC</u>") and/or the United States Department of Justice shall seek a preliminary injunction under the HSR Act against Amicus and GSK to enjoin the transactions contemplated by this Agreement or the Amended License and Collaboration Agreement; or

(c) by GSK:

(i) if Amicus shall have (A) failed to perform any of its material obligations contained herein, or (B) breached any of its material representations or warranties contained herein, provided that GSK gives Amicus written notice of such failure to perform or

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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breach and Amicus does not cure such failure to perform or breach within thirty (30) days after its receipt of such written notice;

(ii) if any of the conditions set forth in Section 6 shall become impossible to fulfill (other than as a result of any breach by GSK of the terms of this Agreement) and shall not have been waived in accordance with the terms of this Agreement; or

(iii) if the Common Stock shall no longer be listed for trading on the Nasdaq National Market or other national securities exchange or automated quotation system.

(d) by Amicus:

(i) if GSK shall have (A) failed to perform any of its material obligations contained herein, or (B) breached any of its material representations or warranties contained herein, provided that Amicus gives GSK written notice of such failure to perform or breach and GSK does not cure such failure to perform or breach within thirty (30) days after its receipt of such written notice; or

(ii) if any of the conditions set forth in Section 6 shall become impossible to fulfill (other than as a result of any breach by Amicus of the terms of this Agreement) and shall not have been waived in accordance with the terms of this Agreement.

10.2 <u>Effect of Termination</u>. In the event of termination of this Agreement by either GSK or Amicus as provided in Section 10.1, this Agreement shall forthwith become void and have no effect, without any liability or obligation on the part of GSK or Amicus, other than the provisions of this Section 10.2, and except to the extent that such termination results from a material breach by a party of its representations, warranties, covenants or agreements set forth in this Agreement.

### 11. Miscellaneous.

11.1 <u>Governing Law</u>. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Delaware, without regard to the choice of law provisions thereof, and the federal laws of the United States.

11.2 <u>Public Statements</u>. Any statement to the public regarding this Agreement shall be approved in advance by Amicus and GSK, except as otherwise required by law, regulation or legal process. Notwithstanding the foregoing, GSK acknowledges that Amicus shall file (i) a current report on Form 8-K disclosing this Agreement, and (ii) a mutually-agreed redacted version of this Agreement with the SEC to the extent such redactions are permitted under applicable law; and Amicus acknowledges that GSK shall make a Schedule 13 filing with the SEC.

11.3 <u>Successors and Assigns</u>. Except as otherwise expressly provided herein, the respective rights and obligations of either Party under this Agreement shall not be assignable in whole or in part by a Party without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed. Notwithstanding the preceding sentence, in connection with the merger, acquisition, transfer of all or substantially all of a Party's assets or other change in control of either Party, such Party may assign its rights and obligations under this Agreement in

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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whole or in part to such Party's transferee or successor in interest without the prior written consent of the other Party. This Agreement shall bind and inure to the benefit of Parties and their permitted successors and assigns.

11.4 <u>Entire Agreement</u>. This Agreement, the Amended License and Collaboration Agreement and the exhibits thereto, the Stock Purchase Agreement dated as of October 28, 2010 between Amicus and GSK, and that certain Confidential Disclosure Agreement dated as of March 29, 2006 and amended as of December 28, 2006 between the Amicus and GSK and the other documents delivered pursuant hereto, constitute the full and entire understanding and agreement among the Parties with regard to the subjects hereof and no Party shall be liable or bound to any other Party in any manner by any representations, warranties, covenants, or agreements except as specifically set forth herein or therein. Nothing in this Agreement, express or implied, is intended to confer upon any Party, other than the parties hereto and their respective successors and assigns, any rights, remedies, obligations, or liabilities under or by reason of this Agreement, except as expressly provided herein.

11.5 <u>Separability</u>. In the event any provision of this Agreement shall be invalid, illegal, or unenforceable, it shall to the extent practicable, be modified so as to make it valid, legal and enforceable and to retain as nearly as practicable the intent of the Parties, and the validity, legality, and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.

11.6 <u>Amendment and Waiver</u>. Except as otherwise provided herein, any term of this Agreement may be amended and the observance of any term of this Agreement may be waived (either generally or in a particular instance, either retroactively or prospectively, and either for a specified period of time or indefinitely), with the written consent of Amicus and GSK. Any amendment or waiver effected in accordance with this Section shall be binding upon any holder of any securities purchased under this Agreement (including securities into which such securities have been converted), each future holder of all such securities, and Amicus.

11.7 <u>Notices</u>. All notices, requests, or other communications given hereunder shall be in writing and shall be deemed to have been duly given if (a) delivered by hand; (b) mailed by registered or certified mail; (c) sent by air courier; or (d) sent by cable, telex or facsimile, followed within twenty-four (24) hours by notification pursuant to (a), (b) or (c) above, in each case to the address set forth below or to such other address as a Party may specify for itself by written notice given as aforesaid.

If to GSK:	Glaxo Group Limited
	Great West Road
	Brentford, Middlesex
	United Kingdom
	TW8 9GS
	Facsimile: +44 (020) 804 76904
	Attention: Company Secretary

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With a copy to:

GlaxoSmithKline 980 Great West Road Brentford, Middlesex, TW8 9GS UK Facsimile: +44 (020) 804 70641 Attention : Marc Dunoyer President, GSK Rare Diseases

And

Glaxo Smith Kline 2301 Renaissance Boulevard Mail Code RN0220 King of Prussia, PA 19406 Facsimile: (610) 787-7084 Attention: Vice President and Associate General Counsel, If to Amicus:

Amicus Therapeutics, Inc. 1 Cedar Brook Drive Cranbury, NJ 08512 Facsimile: 609-662-2001 Attention: Chief Business Officer

with a copy to:

Amicus Therapeutics, Inc. 1 Cedar Brook Drive Cranbury, NJ 08512 Facsimile: 609-662-2001 Attention: Secretary

11.8 <u>Fees and Expenses</u>. Amicus and GSK shall each bear their own expenses and legal fees incurred on their behalf with respect to this Agreement and the transactions contemplated hereby.

11.9 <u>Titles and Subtitles</u>. The titles of the Sections and subsections of this Agreement are for convenience of reference only and are not to be considered in construing this Agreement.

11.10 <u>Counterparts; Effectiveness</u>. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one instrument. This Agreement shall become effective when each party hereto shall have received counterparts thereof signed and delivered (by telecopy or other electronic means) by the other party hereto.

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

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IN WITNESS WHEREOF, this Stock Purchase Agreement is hereby executed as of the date first above written.

# AMICUS THERAPEUTICS, INC.

By:	/s/ John F. Crowley	
Name:	John F. Crowley	
Title:	Chairman and CEO	

# **GLAXO GROUP LIMITED**

By: Name: Title:

/s/ Paul Williamson Paul Williamson Corporate Director

\*\*\*\*\*\* - Material has been omitted and filed separately with the Commission.

Signature Page to Stock Purchase Agreement

Schedule	A
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### **Expected Amicus Capitalization Table After Closing Date**

Common shares issued & outstanding	49,327,478
Common shares to be issued on exercise of warrants	1,854,946
Total common shares & equivalents outstanding	51,182,424

Total stock options issued & outstanding	7,235,069(a)
Total stock options reserved for future issuance	4,280 470(b)
Preferred shares issued & outstanding	(C)
Grand total	62,697,963

(a) weighted average exercise price = \$6.74 & standard vesting term = 4 years
(b) 4,946,524 warrants outstanding at exercise rate = 0.375
(c) 10,000,000 preferred shares authorized

- Material has been omitted and filed separately with the Commission. \*\*\*\*\*

# CERTIFICATIONS PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002 CERTIFICATION BY PRINCIPAL EXECUTIVE OFFICER

I, John F. Crowley, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Amicus Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and 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: November 5, 2012

/s/ John F. Crowley John F. Crowley

**Chairman and Chief Executive Officer** 

# CERTIFICATIONS PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002 CERTIFICATION BY PRINCIPAL FINANCIAL OFFICER

I, William D. Baird III, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Amicus Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e)) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and 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: November 5, 2012

/s/ William D. Baird III	
William D. Baird III	
<b>Chief Financial Officer</b>	

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

Each of the undersigned hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, in his capacity as an officer of Amicus Therapeutics, Inc. (the "Company"), that, to his knowledge, the Quarterly Report of the Company on Form 10-Q for the period ended September 30, 2012, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 78o(d)) and that the information contained in such report fairly presents, in all material respects, the financial condition and results of operations of the Company. This written statement is being furnished to the Securities and Exchange Commission as an exhibit to such Form 10-Q. A signed original of this statement has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Date: November 5, 2012	By:	/s/ John F. Crowley
	_	John F. Crowley
		Chairman and Chief Executive Officer
Date: November 5, 2012	By:	/s/ William D. Baird III
	_	William D. Baird III
		Chief Financial Officer