UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

For the quarterly period ended September 30, 2015 OR TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT 1934 For the transition period from to	OF
☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT 1934	OF
1934	OF
For the transition period from to	
-	
Commission file number 000-30171	
SANGAMO BIOSCIENCES, INC. (exact name of registrant as specified in its charter)	
Delaware 68-0359556 (State or other jurisdiction of incorporation or organization) Identification No.)	
501 Canal Blvd Richmond, California 94804 (Address of principal executive offices)	
(510) 970-6000 (Registrant's telephone number, including area code)	
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 Act of 1934 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 required to the past 90 days. Yes \boxtimes No \square	
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data 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 period that the registrant was required to submit and post such files). Yes \boxtimes No \square	
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting consecutive filer, a non-accelerated filer, "accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act.	npany.
Large accelerated filer Accelerated filer	
Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company	
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes \Box No \boxtimes	
As of October 26, 2015, 70,046,841 shares of the issuer's common stock, par value \$0.01 per share, were outstanding.	

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SANGAMO BIOSCIENCES, INC.

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CERTIFICATIONS

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Some statements contained in this report are forward-looking with respect to our operations, research, development and commercialization activities, clinical trials, operating results and financial condition. These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- our strategy;
- · product development and commercialization of our products;
- clinical trials;
- · partnering;
- · revenues from existing and new collaborations;
- · our research and development and other expenses;
- · sufficiency of our cash resources;
- · our operational and legal risks; and
- · our plans, objectives, expectations and intentions and any other statements that are not historical facts.

In some cases, you can identify forward-looking statements by terms such as: "anticipates," "believes," "continues," "could," "estimates," "expects," "intends," "may," "plans," "seeks," "should" and "will." These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Many of these risks are discussed in greater detail under the headings "Risk Factors" and "Management's Discussion and Analysis of Financial Conditions and Results of Operations" in this Form 10-Q. Sangamo undertakes no obligation to publicly release any revisions to forward-looking statements to reflect events or circumstances arising after the date of this report. Readers are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this Quarterly Report on Form 10-Q.

ZFP Therapeutic® is a registered trademark of Sangamo BioSciences, Inc.

ITEM 1. FINANCIAL STATEMENTS

SANGAMO BIOSCIENCES, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited; in thousands, except share and per share amounts)

	Sep	September 30, 2015		December 31, 2014
ASSETS				_
Current assets:				
Cash and cash equivalents	\$	34,287	\$	6,030
Marketable securities		185,042		172,932
Interest receivable		399		423
Accounts receivable		7,004		10,368
Prepaid expenses		951		623
Restricted cash		_		320
Other current assets	<u> </u>	<u> </u>		183
Total current assets		227,683		190,879
Marketable securities, non-current		_		47,260
Property and equipment, net		3,063		1,479
Intangible assets, in-process research and development		_		1,870
Goodwill		1,585		1,585
Other assets		185		139
Total assets	\$	232,516	\$	243,212
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities:				
Accounts payable and accrued liabilities	\$	8,888	\$	8,704
Accrued compensation and employee benefits		2,779		2,853
Escrow liability		_		275
Deferred revenues		10,461		9,050
Total current liabilities		22,128		20,882
Deferred revenues, non-current		6,830		13,149
Contingent consideration liability		_		1,800
Deferred tax liability		_		748
Total liabilities		28,958		36,579
Commitments and contingencies				
Stockholders' equity:				
Common stock, \$0.01 par value; 160,000,000 shares authorized, 70,042,758 and 69,062,394 shares issued and outstanding at September 30, 2015, and				
December 31, 2014, respectively		700		690
Additional paid-in capital		558,044		534,518
Accumulated deficit		(355,240)		(328,550)
Accumulated other comprehensive income (loss)		54		(25)
Total stockholders' equity		203,558		206,633
Total liabilities and stockholders' equity	\$	232,516	\$	243,212

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited; in thousands, except per share amounts)

	 Three mon Septem		Nine mon Septem			
	 2015	2014		2015		2014
Revenues:						
Collaboration agreements	\$ 8,406	\$ 12,045	\$	28,878	\$	29,334
Research grants	163	372		1,540		1,584
Total revenues	 8,569	12,417		30,418		30,918
Operating expenses:						
Research and development	16,694	16,340		47,292		41,883
General and administrative	4,560	3,731		14,309		11,347
Total operating expenses	21,254	20,071		61,601		53,230
Loss from operations	(12,685)	(7,654)		(31,183)		(22,312)
Interest and other income, net	101	109		406		214
Loss before income taxes	 (12,584)	(7,545)		(30,777)	'	(22,098)
Benefit from income taxes	3,339	_		4,087		_
Net loss	\$ (9,245)	\$ (7,545)	\$	(26,690)	\$	(22,098)
Basic and diluted net loss per share	\$ (0.13)	\$ (0.11)	\$	(0.38)	\$	(0.33)
Shares used in computing basic and diluted net loss per share	69,892	68,230		69,622		66,488
	 		_			

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS (Unaudited; in thousands)

	Three months ended September 30,					Nine mon Septem	
		2015		2014		2015	2014
Net loss	\$	(9,245)	\$	(7,545)	\$	(26,690)	\$ (22,098)
Change in unrealized gain on available-for-sale securities		57		20		79	41
Comprehensive loss	\$	(9,188)	\$	(7,525)	\$	(26,611)	\$ (22,057)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited: in thousands)

		Nine months ended September 30,					
	2	2015		2014			
Operating Activities:							
Net loss	\$	(26,690)	\$	(22,098)			
Adjustments to reconcile net loss to net cash used in operating activities:							
Depreciation and amortization		745		400			
Amortization of premium on marketable securities		681		843			
Stock-based compensation		8,664		6,165			
Change in fair value of contingent consideration liability		(1,800)		130			
Intangible impairment		1,870		_			
Benefit from income taxes		(4,087)		_			
Net changes in operating assets and liabilities:							
Interest receivable		24		25			
Accounts receivable		3,364		(5,319)			
Prepaid expenses and other assets		129		(1,059)			
Accounts payable and accrued liabilities		(2,534)		3,619			
Accrued compensation and employee benefits		(74)		(530)			
Deferred revenues		(4,908)		14,861			
Net cash used in operating activities		(24,616)		(2,963)			
Investing Activities:							
Purchases of marketable securities		(168,627)		(176,385)			
Maturities of marketable securities		203,175		76,605			
Purchases of property and equipment		(2,327)		(559)			
Net cash provided by / (used in) investing activities		32,221		(100,339)			
Financing Activities:				_			
Proceeds from public offering of common stock, net of issuance costs		_		93,796			
Taxes paid related to net share settlement of equity awards		(48)		_			
Proceeds from issuance of common stock		6,248		10,525			
Claims settlement under Section 16(b)		14,452		_			
Net cash provided by financing activities		20,652		104,321			
Net increase in cash and cash equivalents		28,257		1,019			
Cash and cash equivalents, beginning of period		6,030		10,186			
Cash and cash equivalents, end of period	\$	34,287	\$	11,205			

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS September 30, 2015 (Unaudited)

NOTE 1—BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of Sangamo BioSciences, Inc. ("Sangamo" or the "Company") have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information and pursuant to the rules and regulations of the Securities and Exchange Commission (SEC). Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the three and nine months ended September 30, 2015 are not necessarily indicative of the results that may be expected for the year ending December 31, 2015. The condensed consolidated balance sheet data at December 31, 2014 were derived from the audited consolidated financial statements included in Sangamo's Form 10-K for the year ended December 31, 2014, as filed with the SEC. The accompanying condensed consolidated financial statements and related financial information should be read in conjunction with the audited financial statements and footnotes thereto for the year ended December 31, 2014, included in Sangamo's Form 10-K, as filed with the SEC.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the accompanying notes. On an ongoing basis, management evaluates its estimates, including critical accounting policies or estimates related to revenue recognition, clinical trial accruals, fair value measurements, business combinations including the fair value of the contingent consideration liability for payments to former Ceregene, Inc. (Ceregene) stockholders and intangible assets related to the acquisition of Ceregene, and stock-based compensation. Estimates are based on historical experience and on various other market specific and other relevant assumptions that the Company believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates.

Revenue Recognition

Revenues from research activities made under strategic partnering agreements and collaborations are recognized as the services are provided when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed or determinable, and collectability is reasonably assured. Revenue generated from research and licensing agreements typically includes upfront signing or license fees, cost reimbursements, research services, minimum sublicense fees, milestone payments and royalties on future licensee's product sales.

Multiple Element Arrangements prior to the adoption of ASU No. 2009-13, Revenue Recognition—Multiple Deliverable Revenue Arrangements (ASU 2009-13). For revenue arrangements entered into before January 1, 2011, that include multiple deliverables, the elements of such agreements were divided into separate units of accounting if the deliverables met certain criteria, including whether the fair value of the delivered items could be determined and whether there was evidence of fair value of the undelivered items. In addition, the consideration was allocated among the separate units of accounting based on their fair values, and the applicable revenue recognition criteria are considered separately for each of the separate units of accounting. Prior to the adoption of ASU 2009-13, the Company recognized nonrefundable signing, license or non-exclusive option fees as revenue when rights to use the intellectual property related to the license were delivered and over the period of performance obligations if the Company had continuing performance obligations. The Company estimated the performance period at the inception of the arrangement and reevaluated it each reporting period. Changes to these estimates were recorded on a prospective basis.

Multiple Element Arrangements after the adoption of ASU 2009-13. ASU 2009-13 amended the accounting standards for certain multiple element revenue arrangements to:

- provide updated guidance on whether multiple elements exist, how the elements in an arrangement should be separated, and how the arrangement consideration should be allocated to the separate elements;
- · require an entity to allocate arrangement consideration to each element based on a selling price hierarchy where the selling price for an element is based on vendor-specific objective evidence (VSOE), if available; third-party evidence (TPE), if available and VSOE is not available; or the best estimate of selling price (ESP), if neither VSOE nor TPE is available; and
- eliminate the use of the residual method and require an entity to allocate arrangement consideration using the relative selling price method.

For revenue agreements with multiple element arrangements, such as license and development agreements, entered into on or after January 1, 2011, the Company allocates revenue to each non-contingent element based on the relative selling price of each element. When applying the relative selling price method, the Company determines the selling price for each deliverable using VSOE of selling price or TPE of selling price. If neither exists, the Company uses ESP for that deliverable. Revenue allocated is then recognized when the basic four revenue recognition criteria are met for each element. The collaboration and license agreements entered into with Shire International GmbH, formerly Shire AG (Shire), in January 2012 and Biogen Inc., formerly Biogen Idec Inc. (Biogen) in January 2014 were evaluated under these amended accounting standards.

Additionally, the Company may be entitled to receive certain milestone payments which are contingent upon reaching specified objectives. These milestone payments are recognized as revenue in full upon achievement of the milestone if there is substantive uncertainty at the date the arrangement is entered into that the objectives will be achieved and if the achievement is based on the Company's performance.

Minimum annual sublicense fees are also recognized as revenue in the period in which such fees are due. Royalty revenues are generally recognized when earned and collectability of the related royalty payment is reasonably assured. The Company recognizes cost reimbursement revenue under collaborative agreements as the related research and development costs for services are rendered. Deferred revenue represents the portion of research or license payments received which have not been earned.

Sangamo's research grants are typically multi-year agreements and provide for the reimbursement of qualified expenses for research and development as defined under the terms of the grant agreement. Revenue under grant agreements is recognized when the related qualified research expenses are incurred to the extent such amounts have been agreed to with the respective collaboration partner.

Recent Accounting Standards

In May 2014 the Financial Accounting Standards Board issued ASU 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09). This standard outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. The main principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration that is expected to be received for those goods or services. ASU 2014-09 provides companies with two implementation methods: (i) apply the standard retrospectively to each prior reporting period presented (full retrospective application); or (ii) apply the standard retrospectively with the cumulative effect of initially applying the standard as an adjustment to the opening balance of retained earnings of the annual reporting period that includes the date of initial application (modified retrospective application). This guidance is effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period. The Company is currently in the process of evaluating the impact of the pending adoption of ASU 2014-09 on its consolidated financial statements.

NOTE 2—FAIR VALUE MEASUREMENT

The Company measures certain financial assets and liabilities at fair value on a recurring basis, including cash equivalents, available-for sale-securities and the contingent consideration liability. The fair value of these assets and contingent liability was determined based on a three-tier hierarchy under the authoritative guidance for fair value measurements and disclosures that prioritizes the inputs used in measuring fair value as follows:

- Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;
- Level 2: Quoted prices in markets that are not active or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability; and
- Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

The fair value measurements of the Company's cash equivalents, available-for-sale marketable securities and contingent consideration liability are identified at the following levels within the fair value hierarchy (in thousands):

		September 30, 2015 Fair Value Measurements									
	_	Total		Total		Level 1		Level 2		Level 3	
Assets:											
Cash equivalents:											
Money market funds	\$	12,747	\$	12,747	\$		\$				
Total		12,747		12,747							
Marketable securities:											
Commercial paper securities		15,399				15,399		_			
Corporate debt securities		29,217		_		29,217		_			
U.S. government sponsored entity debt securities		140,426		<u> </u>		140,426		<u> </u>			
Total		185,042				185,042					
Total cash equivalents and marketable securities	\$	197,789	\$	12,747	\$	185,042	\$	_			
	_	Total		Decembe Fair Value M Level 1				Level 3			
Assets:											
Cash equivalents:											
Money market funds	\$	3,182	\$	3,182	\$		\$				
Total		3,182		3,182		_					
Marketable securities:											
Commercial paper securities		33,748		_		33,748		_			
Corporate debt securities		22,813		_		22,813		_			
U.S. government sponsored entity debt securities		163,631				163,631					
Total		220,192				220,192					
Total cash equivalents and marketable securities	\$	223,374	\$	3,182	\$	220,192	\$				
Liabilities:											
Contingent consideration liability	\$	1,800	\$	_	\$	_	\$	1,800			
Total	\$	1,800	\$		\$		\$	1,800			

Investments

The Company generally classifies its marketable securities as Level 2. Instruments can be classified as Level 2 when observable market prices for identical securities that are traded in less active markets are used. When observable market prices for identical securities are not available, such instruments are priced using benchmark curves, benchmarking of like securities, sector groupings, matrix pricing and valuation models. These valuation models are proprietary to the pricing providers or brokers and incorporate a number of inputs, including, listed in approximate order of priority: benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers and reference data including market research publications. For certain security types, additional inputs may be used, or some of the standard inputs may not be applicable. Evaluators may prioritize inputs differently on any given day for any security based on market conditions, and not all inputs listed are available for use in the evaluation process for each security evaluation on any given day.

Contingent Consideration Liability

In October 2013, the Company acquired Ceregene and recorded a liability for the estimated fair value of contingent consideration payments to former Ceregene stockholders, as outlined under the terms of the merger agreement with Ceregene. These contingent payments are owed if the Company grants a third-party license to develop and commercialize certain product candidates acquired from Ceregene, or if the Company commercializes any of such product candidates itself. The fair value of this liability is estimated using a probability-weighted discounted cash flow analysis. Such valuations require significant estimates and assumptions including but not limited to: determining the timing and estimated costs to complete the in-process projects, projecting regulatory approvals, estimating future cash flows and developing appropriate discount rates. The Company has classified this liability as Level 3.

Subsequent changes in the fair value of this contingent consideration liability are recorded to the research and development (R&D) expense line item in the Condensed Consolidated Statements of Operations as operating expenses. During the nine months ended September 30, 2015, the recognized amount of the liability for contingent consideration decreased by \$1.8 million due to the decrease in the probability of incurring potential future royalty payments associated with the impairment of the in-process research and development (IPR&D) assets acquired from Ceregene (see Note 6).

Fair value as of December 31, 2014	\$ 1,800
Change in fair value	(1,800)
Fair value as of September 30, 2015	\$ _

NOTE 3-MARKETABLE SECURITIES

Sangamo generally classifies its marketable securities as available-for-sale and records its investments at fair value. Available-for-sale securities are carried at estimated fair value, with the unrealized holding gains and losses included in accumulated other comprehensive income (loss). Investments that have maturities beyond one year as of the end of the reporting period are classified as non-current. The Company's investments are subject to a periodic impairment review, and the Company recognizes an impairment charge when a decline in the fair value of its investments below the cost basis is judged to be other-than-temporary. The Company considers various factors in determining whether to recognize an impairment charge, including the length of time and extent to which the fair value has been less than the Company's cost basis, the financial condition and near-term prospects of the investee, and the Company's intent and ability to hold the investment for a period of time sufficient to allow for any anticipated recovery in the market value.

The table below summarizes the Company's investments (in thousands):

	Amortized Cost		Gross Unrealized Gains		Gross Unrealized (Losses)		Estimated Fair Value	
September 30, 2015								
Cash equivalents:								
Money market funds	\$	12,747	\$	<u> </u>	\$	<u> </u>	\$	12,747
Total		12,747				_		12,747
Available-for-sale securities:								
Commercial paper securities	\$	15,371	\$	28	\$	_	\$	15,399
Corporate debt securities		29,215		2		_		29,217
U.S. government sponsored entity debt securities		140,402		24		_		140,426
Total		184,988		54		_		185,042
Total cash equivalents and available-for-sale securities	\$	197,735	\$	54	\$		\$	197,789
December 31, 2014								
Cash equivalents:								
Money market funds	\$	3,182	\$	_	\$	_	\$	3,182
Total		3,182		_				3,182
Available-for-sale securities:		,						
Commercial paper securities	\$	33,715	\$	33	\$	_	\$	33,748
Corporate debt securities		22,831		_		(18)		22,813
U.S. government sponsored entity debt securities		163,671		_		(40)		163,631
Total		220,217		33		(58)		220,192
Total cash equivalents and available-for-sale securities	\$	223,399	\$	33	\$	(58)	\$	223,374

The Company had no other-than-temporary impairments of its investments for the nine months ended September 30, 2015 or the twelve months ended December 31, 2014.

NOTE 4—BASIC AND DILUTED NET LOSS PER SHARE

Basic net loss per share has been computed by dividing the net loss by the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per share is calculated by dividing net loss by the weighted-average number of shares of common stock and potential dilutive securities outstanding during the period.

Because Sangamo is in a net loss position, diluted net loss per share excludes the effects of common stock equivalents consisting of stock options and unvested restricted stock units, which are anti-dilutive. The total number of shares subject to stock

options outstanding excluded from consideration in the calculation of diluted net loss per share for the three and nine months ended September 30, 2015 and 2014 were 7,868,033 and 8,263,998, respectively.

NOTE 5-MAJOR CUSTOMERS, PARTNERSHIPS AND STRATEGIC ALLIANCES

Collaboration Agreements

Collaboration and License Agreement with Biogen Inc. in Human Therapeutics

In January 2014 the Company entered into a Global Research, Development and Commercialization Collaboration and License Agreement (the "Biogen Agreement") with Biogen, pursuant to which Sangamo and Biogen collaborate to discover, develop, seek regulatory approval for and commercialize therapeutics based on Sangamo's zinc finger DNA-binding protein (ZFP) technology for hemoglobinopathies, including beta-thalassemia and sickle cell disease (SCD).

Under the Biogen Agreement, Sangamo and Biogen jointly conduct two research programs: the beta-thalassemia program and the SCD program. For the beta-thalassemia program, Sangamo is responsible for all discovery, research and development activities through the first human clinical trial for the first ZFP Therapeutic developed under the Biogen Agreement for the treatment of beta-thalassemia. For the SCD program, both parties are responsible for research and development activities through the submission of an Investigational New Drug (IND) application for ZFP Therapeutics intended to treat SCD. For both programs, Biogen is responsible for subsequent world-wide clinical development, manufacturing and commercialization of licensed products developed under the Biogen Agreement. At the end of specified research terms for each program or under certain specified circumstances, Biogen retains the right to step in and take over any remaining activities of Sangamo. Furthermore, Sangamo has an option to co-promote in the United States any licensed product to treat beta-thalassemia and SCD developed under the Biogen Agreement, and Biogen agrees to compensate Sangamo for such co-promotion activities.

Sangamo received an upfront license fee of \$20.0 million upon entering into the Biogen Agreement. In addition, the Company will also be eligible to receive \$126.3 million in payments upon the achievement of specified research, regulatory, clinical development milestones, as well as \$167.5 million in payments upon the achievement of specified commercialization and sales milestones. Biogen reimburses Sangamo for agreed upon costs incurred in connection with research and development activities conducted by Sangamo. In addition, Sangamo is eligible to receive contingent payments upon the achievement of specified regulatory, clinical development, commercialization and sales contingent payments, assuming the achievement of all specified milestone events in the Biogen Agreement, is \$293.8 million, including Phase 1 contingent payments of \$7.5 million for each of the beta-thalassemia and SCD programs. In addition, if products are commercialized under the Biogen Agreement, Biogen will pay Sangamo incremental royalties for each licensed product that are a tiered double-digit percentage of annual net sales of such product. To date, no milestone payments have been received and no products have been approved and therefore no royalty fees have been earned under the Biogen Agreement.

All contingent payments under the Biogen Agreement, when earned, will be non-refundable and non-creditable. The Company has evaluated the contingent payments under the Biogen Agreement based on the authoritative guidance for research and development milestones and determined that certain of these payments meet the definition of a milestone and that all such milestones are evaluated to determine if they are considered substantive milestones. Milestones are considered substantive if they are related to events (i) that can be achieved based in whole or in part on either the Company's performance or on the occurrence of a specific outcome resulting from the Company's performance, (ii) for which there was substantive uncertainty at the date the agreement was entered into that the event would be achieved and (iii) that would result in additional payments being due to the Company. Accordingly, consideration received for the achievement of milestones that are determined to be substantive will be recognized as revenue in their entirety in the period when the milestones are achieved and collectability is reasonably assured. Revenue for the achievement of milestones that are not substantive will be recognized over the remaining period of the Biogen Agreement, assuming all other applicable revenue recognition criteria have been met.

Subject to the terms of the Biogen Agreement, Sangamo grants Biogen an exclusive, royalty-bearing license, with the right to grant sublicenses, to use certain ZFP and other technology controlled by Sangamo for the purpose of researching, developing, manufacturing and commercializing licensed products developed under the Biogen Agreement. Sangamo also grants Biogen a non-exclusive, world-wide, royalty free, fully paid license, with the right to grant sublicenses, of Sangamo's interest in certain other intellectual property developed pursuant to the Biogen Agreement.

The Company has identified the deliverables within the arrangement as a license to the technology and on-going research services activities. The Company has concluded that the license is not a separate unit of accounting as it does not have stand-alone value to Biogen apart from the research services to be performed pursuant to the Biogen Agreement. As a result, the Company will recognize revenue from the upfront payment on a straight-line basis over a forty-month estimated initial research term during which the Company will perform research services. As of September 30, 2015, the Company has deferred revenue of \$10.2 million related to the Biogen Agreement.

Revenues recognized under the agreement with Biogen for the three and nine months ended September 30, 2015 and 2014 are as follows (in thousands):

	Three months ended September 30,					Nine mon Septen	
	2015			2014	2015		2014
Revenue related to Biogen Collaboration:						_	
Recognition of upfront fee	\$	1,556	\$	1,557	\$	4,619	\$ 3,756
Research services		2,594		3,508		5,827	5,270
Total	\$	4,150	\$	5,065	\$	10,446	\$ 9,026

Related costs and expenses incurred under the Biogen agreement related to the beta-thalassemia project, which was co-funded with California Institute for Regenerative Medicine (CIRM), were \$2.3 million and \$2.0 million during the three months ended September 30, 2015 and, 2014, respectively and \$4.7 million and \$4.5 million during the nine months ended September 30, 2015 and, 2014, respectively. Related costs and expenses for other projects including sickle cell disease under the Biogen agreement were \$0.7 million and \$0.5 million during the three months ended September 30, 2015 and, 2014, respectively and \$2.7 million and \$0.8 million during the nine months ended September 30, 2015 and 2014, respectively.

Collaboration and License Agreement with Shire International GmbH in Human Therapeutics and Diagnostics

In January 2012 the Company entered into a collaboration and license agreement (the "Shire Agreement") with Shire, pursuant to which the Company and Shire collaborate to research, develop and commercialize human therapeutics and diagnostics for monogenic diseases based on Sangamo's novel ZFP technology. This agreement was amended on September 1, 2015.

Under the original Shire Agreement, the Company and Shire agreed to develop potential human therapeutic or diagnostic products for seven gene targets. The initial four gene targets selected were blood clotting Factors VII, VIII, IX and X, and products developed for such initial gene targets will be used for treating or diagnosing hemophilia A and B. In June 2012, Shire selected a fifth gene target for the development of a ZFP Therapeutic for Huntington's disease. Shire had the right, subject to certain limitations, to designate two additional gene targets. Pursuant to the Shire Agreement, the Company granted Shire an exclusive, world-wide, royalty-bearing license, with the right to grant sublicenses, to use Sangamo's ZFP technology for the purpose of developing and commercializing human therapeutic and diagnostic products for the gene targets.

Under the terms of the Shire Agreement, the Company was responsible for all research activities through the submission of an IND or European Clinical Trial Application (CTA), while Shire was responsible for clinical development and commercialization of products generated from the research program from and after the acceptance of an IND or CTA for the product. Shire reimbursed Sangamo for agreed upon internal and external program-related research costs. The Company received an upfront license fee of \$13.0 million upon entering into the Shire Agreement in 2012. In 2014 Sangamo recognized a \$1.0 million milestone payment related to the hemophilia program.

On September 1, 2015, the Shire Agreement was amended such that Shire agreed to return to Sangamo the exclusive, world-wide rights to gene targets for the development and commercialization of ZFP Therapeutics for hemophilia A and B. Shire retains the rights and will continue to develop a ZFP Therapeutic for Huntington's disease and a ZFP Therapeutic for one additional gene target yet to be named. Sangamo will provide certain target feasibility services, and upon Shire's request, certain research activities according to a research plan as agreed upon by both companies. Such research activities performed by Sangamo will be reimbursed by Shire. Shire's rights with respect to other targets contemplated in the original agreement revert to Sangamo. Under the revised agreement, each company is responsible for expenses associated with its own programs and will reimburse the other for any ongoing services provided. Shire is responsible for reimbursement of \$4.0 million related to obligations prior to the amendment date which will be recognized in revenue as expenses are incurred. During the 3 months ended September 30, 2015, \$2.3 million was incurred and recognized related to prior obligations. Sangamo has granted Shire a right of first negotiation to license the hemophilia A and B programs. Under the amended agreement, Shire does not have any milestone payment obligations to us with respect to the retained programs, but it is required to pay single digit percentage royalties to us, up to a specified maximum cap, on the commercial sales of ZFP therapeutic products from such programs. Under the Agreement, Sangamo has full control over, and full responsibility for the costs of, the hemophilia programs returned to us, subject to certain diligence obligations and Shire's right of first negotiation to obtain a license to such programs under certain circumstances. The Company is required to pay single digit percentage royalties to Shire, up to a specified maximum cap, on commercial sales of ZFP therapeutic products from such

The Company has identified the deliverables within the amended arrangement as a license to the technology and on-going research services activities. The Company has concluded that the license is not a separate unit of accounting as it does not have stand-alone value to Shire apart from the research services to be performed pursuant to the Shire amendment. Sangamo continues to be responsible for research activities related to our licensed technology with Shire under the amendment. As a result, the Company will continue to recognize revenue from the upfront payment received upon entering into the original Shire agreement in 2012 on a

straight-line basis over the six-year initial research term during which the Company expects to perform research services. As of September 30, 2015, the Company has deferred revenue of \$7.1 million related to the Shire Agreement.

Revenues recognized under the agreement with Shire for the three and nine months ended September 30, 2015 and 2014, were as follows (in thousands):

	Three months ended September 30,						nths ended mber 30,		
	2015		2015 2014		2015			2014	
Revenue related to Shire Collaboration:								_	
Recognition of upfront fee	\$	542	\$	542	\$	1,625	\$	1,625	
Recognition of milestone		_		1,000		_		1,000	
Research services		3,313		5,002		11,729		15,912	
Total	\$	3,855	\$	6,544	\$	13,354	\$	18,537	

Related costs and expenses incurred under the Shire agreement were \$3.2 million and \$5.1 million during the three months ended September 30, 2015 and 2014, respectively and \$11.9 million and \$15.5 million during the nine months ended September 30, 2015 and 2014, respectively.

Agreement with Sigma-Aldrich Corporation in Laboratory Research Reagents, Transgenic Animal and Commercial Protein Production Cell-line Engineering

In July 2007 the Company entered into a license agreement (the "Sigma Agreement") with Sigma-Aldrich Corporation (Sigma). Under the Sigma Agreement, Sangamo agreed to provide Sigma with access to Sangamo's proprietary ZFP technology and the exclusive right to use the technology to develop and commercialize research reagent products and services in the research field, excluding certain agricultural research uses that Sangamo previously licensed to Dow AgroSciences LLC (DAS). Under the Sigma Agreement, Sangamo and Sigma agreed to conduct a three-year research program to develop laboratory research reagents using Sangamo's ZFP technology during which time Sangamo agreed to assist Sigma in connection with its efforts to market and sell services employing the Company's ZFP technology in the research field. Sangamo has transferred its ZFP manufacturing technology to Sigma.

In October 2009 the Company expanded the Sigma Agreement. In addition to the original terms of the Sigma Agreement, Sigma received exclusive rights to develop and distribute ZFP-modified cell lines for commercial production of protein pharmaceuticals and certain ZFP-engineered transgenic animals for commercial applications. Under the terms of the Sigma Agreement as expanded in 2009, Sigma made an upfront cash payment of \$20.0 million consisting of a \$4.9 million purchase of 636,133 shares of Sangamo common stock and a \$15.1 million upfront license fee. The upfront license fee was recognized on a straight-line basis from the effective date of the expanded license through July 2010, which represents the period over which Sangamo was obligated to perform research services for Sigma. Sangamo is also eligible to receive commercial license fees of \$5.0 million based upon a percentage of net sales. As of September 30, 2015 Sangamo has received the entire \$5.0 million of commercial license fees and is eligible to receive royalty payments of 5.25% of net sales and sublicensing revenue. In addition, upon the achievement of certain cumulative commercial milestones Sigma will make milestone payments to Sangamo up to an aggregate of \$25.0 million.

Revenues recognized under the agreement with Sigma for the three and nine months ended September 30, 2015 and 2014, were as follows (in thousands):

	Three months ended September 30,					Nine mon Septen		
	2015			2014		2015		2014
Revenue related to Sigma Collaboration:						_		
Royalty revenues	\$	97	\$	67	\$	390	\$	270
License fee revenues		172		269		4,449		447
Total	\$	269	\$	336	\$	4,839	\$	717

Related costs and expenses incurred under the Sigma agreement were both \$0.0 million during the three months ended September 30, 2015 and 2014, respectively. Related costs and expenses incurred under the Sigma agreement were \$0.3 million and \$0.1 million during the nine months ended September 30, 2015 and 2014, respectively.

Agreement with Dow AgroSciences in Plant Agriculture

In October 2005 the Company entered into an exclusive commercial license agreement with DAS (the "DAS Agreement"). Under the DAS Agreement, Sangamo provides DAS with access to Sangamo's proprietary ZFP technology and the exclusive right to

use the technology to modify the genomes or alter the nucleic acid or protein expression of plant cells, plants, or plant cell cultures. Sangamo has retained rights to use plants or plant-derived products to deliver ZFP transcription factors (ZFP TFs) or ZFP nucleases (ZFNs) into humans or animals for diagnostic, therapeutic or prophylactic purposes. The DAS Agreement provided for an initial three-year research term. In June 2008, DAS exercised its option under the agreement to obtain a commercial license to sell products incorporating or derived from plant cells generated using the Company's ZFP technology, including agricultural crops, industrial products and plant-derived biopharmaceuticals. The exercise of the option triggered a one-time commercial license fee of \$6.0 million, payment of the remaining \$2.3 million of the previously agreed \$4.0 million in research milestones, development and commercialization milestone payments for each product, and royalties on sales of products. Furthermore, DAS has the right to sublicense Sangamo's ZFP technology to third parties for use in plant cells, plants or plant cell cultures. Sangamo will be entitled to 25% of any cash consideration received by DAS under such sublicenses. In December 2010, the Company amended the DAS Agreement to extend the period of reagent manufacturing services and research services through December 31, 2012.

The DAS Agreement also provides for minimum license fees each year due to Sangamo every October, provided the Agreement is not terminated by DAS. Annual fees range from \$250,000 to \$3.0 million and total \$25.3 million over 11 years. The Company does not have any ongoing performance obligations under the agreement with DAS. DAS has the right to terminate the agreement at any time; accordingly, the Company's actual license fees over the term of the DAS Agreement could be lower than \$25.3 million. In addition, each party may terminate the DAS Agreement upon an uncured material breach by the other party. In the event of any termination of the DAS Agreement, all rights to use the Company's ZFP technology will revert to Sangamo, and DAS will no longer be permitted access to Sangamo's ZFP technology or to develop or, except in limited circumstances, commercialize any products derived from the Company's ZFP technology.

There were no revenues or related costs and expenses recognized under the DAS Agreement during the three and nine months ended September 30, 2015 and 2014, respectively.

Funding from Research Foundations

California Institute for Regenerative Medicine - HIV

In May 2014 CIRM agreed to fund a \$5.6 million Strategic Partnership Award to fund the clinical studies of this potentially curative ZFP Therapeutic for HIV/AIDS based on the application of its ZFN genome editing technology in hematopoietic stem and progenitor cells (HSPCs). The four year grant provides matching funds to support evaluation of the Company's stem cell-based ZFP Therapeutic in a clinical trial in HIV-infected individuals conducted at City of Hope.

There were no revenues attributable to research and development performed under the Strategic Partnership Award during the three and nine months ended September 30, 2015 and 2014, respectively. Related costs and expenses incurred under the CIRM Strategic Partnership Award were \$0.6 million and \$0.0 million during the three months ended September 30, 2015 and 2014, respectively and \$1.3 million and \$0.0 million during the nine months ended September 30, 2015 and 2014, respectively.

California Institute for Regenerative Medicine - Beta-Thalassemia

In May 2013 CIRM granted Sangamo a \$6.4 million Strategic Partnership Award to develop a potentially curative ZFP Therapeutic for beta-thalassemia based on the application of its ZFN gene editing technology in HSCs. The four-year grant was intended to provide matching funds for preclinical work to support an IND application and a Phase 1 clinical trial in transfusion-dependent beta-thalassemia patients using the BCL11A knockout strategy. In May 2015 Sangamo announced a consolidated development path for its beta-thalassemia and SCD programs using the "BCL11A Enhancer" target. Due to the switch to the BCL11A Enhancer strategy, CIRM and Sangamo terminated the Strategic Partnership Award as of June 30, 2015. Sangamo returned \$3.0 million in unused funds received from CIRM under the award during the three months ended September 30, 2015.

Revenue attributable to research and development performed under the CIRM grant agreement for beta-thalassemia was \$0.0 million and \$0.4 million during the three months ended September 30, 2015 and 2014, respectively and \$1.2 million and \$1.1 million during the nine months ended September 30, 2015 and 2014, respectively. Related costs and expenses incurred under the CIRM grant agreement were \$0.0 million and \$0.4 million during the three months ended September 30, 2015 and 2014, respectively and \$1.2 million and \$1.1 million during the nine months ended September 30, 2015 and 2014, respectively.

NOTE 6—INTANGIBLE ASSETS

Intangible assets for IPR&D consisted of two clinical product candidates from our 2013 acquisition of Ceregene. IPR&D is an intangible asset classified as indefinite-lived until the completion or abandonment of the associated research and development effort, and is amortized over an estimated useful life to be determined at the date the project is completed.

The carrying values of these intangibles assets are as follows (in thousands):

	As of September 30, 2015	As of December 31, 2014		
CERE-110 for the treatment of Alzheimer's disease	\$ —	\$ 1,640		
CERE-120 for the treatment of Parkinson's disease	_	230		
Total identifiable intangible assets	<u> </u>	\$ 1,870		

In the first quarter of 2015, the Company decided to discontinue the CERE-110 and CERE-120 clinical trial programs. As such, the probability of achieving projected revenues and cash flows associated with these programs were adversely affected. The Company does not believe the programs have an alternative future use for itself or other market participants. Accordingly, during the nine months ended September 30, 2015, the Company recognized a \$1.9 million impairment charge related to these assets. The impairment is recorded in research and development expense in the accompanying condensed consolidated statements of operations.

NOTE 7—INCOME TAXES

The Company maintains deferred tax assets that reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. These deferred tax assets include net operating loss carryforwards, research credits and capitalized research and development costs. Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain based on Sangamo's history of losses. Accordingly, the Company's net deferred tax assets have been fully offset by a valuation allowance. Utilization of operating losses and credits may be subject to substantial annual limitation due to ownership change provisions of the Internal Revenue Code of 1986, as amended and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization.

During the nine months ended September 30, 2015, the Company received a \$14.5 million disgorgement settlement that was recognized as additional paid-in capital. The disgorgement settlement was recognized net of taxes of \$5.8 million, which under the intraperiod tax allocation rules resulted in an income tax benefit of \$3.4 being recognized in the accompanying condensed consolidated statements of operations for the three and nine months ended September 30, 2015.

NOTE 8—STOCK-BASED COMPENSATION

The following table shows total stock-based compensation expense included in the condensed consolidated statements of operations for the three and nine months ended September 30, 2015 and 2014 (in thousands):

	Three months ended September 30,					Nine months ended September 30,			
		2015		2014		2015		2014	
Research and development	\$	1,595	\$	1,182	\$	5,020	\$	3,418	
General and administrative		1,233		947		3,644		2,747	
Total stock-based compensation expense	\$	2,828	\$	2,129	\$	8,664	\$	6,165	

NOTE 9—CLAIMS SETTLEMENT

In September 2015, the Company received \$14.5 million as a settlement with certain investors who were beneficial owners of our common stock related to the disgorgement of short-swing profits pursuant to Section 16 of the Securities Exchange Act of 1934, as amended. The settlement of \$8.7 million, net of a \$5.8 million income tax benefit and certain expenses, was recognized as additional paid-in capital.

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

The discussion in "Management's Discussion and Analysis of Financial Condition and Results of Operations" contains trend analysis, estimates and other forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements include, without limitation, statements containing the words "believes," "anticipates," "expects," "continue," and other words of similar import or the negative of those terms or expressions. Such forward-looking statements are subject to known and unknown risks, uncertainties, estimates and other factors that may cause the actual results, performance or achievements of the Company, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. You should read the following discussion and analysis along with the financial statements and notes attached to those statements included elsewhere in this report and in our annual report on Form 10-K for the year ended December 31, 2014 as filed with the SEC.

Overview

We are a clinical stage biopharmaceutical company focused on the research, development and commercialization of engineered DNA-binding proteins for the development of novel therapeutic strategies for unmet medical needs. Our current mission is to develop ZFP Therapeutics®, or human therapeutics based on our proprietary zinc finger DNA-binding protein (ZFP) technology, through early stage clinical testing, strategically partner with biopharmaceutical companies at points of value inflection and have the partners execute late-stage clinical trials and commercial development. In the long-term, our goal is to integrate marketing and development operations and to capture the value of late-stage and commercial ZFP Therapeutic products for ourselves.

We and our licensed partners are the leaders in the research, development and commercialization of ZFPs, a naturally occurring class of proteins. We have used our knowledge and expertise to develop a proprietary technology platform. ZFPs can be engineered to make ZFP nucleases (ZFNs), proteins that can be used to modify DNA sequences in a variety of ways and ZFP transcription factors (ZFP TFs), proteins that can be used to turn genes on or off. As ZFPs act at the DNA level, they have broad potential applications in several areas, including human therapeutics, plant agriculture and research reagents, as well as production of transgenic animals and cell-line engineering.

The main focus for our company is the development of novel human therapeutics and we are building a pipeline of ZFP Therapeutics. Our lead ZFP Therapeutic, SB-728-T, a ZFN-modified autologous T-cell product for the treatment of HIV/AIDS, is the first therapeutic application of our ZFN technology and is being evaluated in a Phase 2 clinical trial in HIV-infected subjects. We also have a Phase 1 clinical trial of this same approach in hematopoietic stem cells.

In January 2014 we entered into a collaborative partnership with Biogen Inc., formerly Biogen Idec Inc. (Biogen) to research, develop and commercialize our preclinical ZFP Therapeutic development program in hemoglobinopathies, targeting sickle cell disease (SCD) and beta-thalassemia. In January 2012 we entered into a collaborative partnership with Shire International GmbH, formerly Shire AG (Shire), to research, develop and commercialize certain of our preclinical ZFP Therapeutic development programs, including programs in hemophilia A and B, Huntington's disease (HD) and other monogenic diseases. On September 1, 2015, the agreement with Shire was amended such that Shire agreed to return to us the exclusive world-wide rights to gene targets for the development, clinical testing and commercialization of ZFP Therapeutics for hemophilia A and B. Shire will retain rights and will continue to develop ZFP Therapeutic clinical leads for HD disease and a ZFP Therapeutic for one additional gene target yet to be named. Sangamo will provide certain target feasibility services, and upon Shire's request, certain research activities according to a research plan as agreed upon by both companies. Such research activities performed by Sangamo will be reimbursed by Shire. Shire's rights with respect to other targets contemplated in the original agreement revert to Sangamo. Under the revised agreement, each company is responsible for expenses associated with its own programs and will reimburse the other for any ongoing services provided. We also have proprietary preclinical programs in several lysosomal storage disorders (LSDs). In addition, we have research stage programs in other monogenic diseases, including certain immunodeficiencies, as well as central nervous system (CNS) disorders and cancer immunotherapy.

We believe the potential commercial applications of ZFPs are broad-based and we have entered into strategic partnerships in fields outside human therapeutics to facilitate the sale or licensing of our ZFP platform as follows:

- · We have a license agreement with the research reagent company Sigma-Aldrich Corporation (Sigma). Sigma has the exclusive rights to develop and market high value laboratory research reagents based upon our ZFP technology as well as ZFP-modified cell lines for commercial production of protein pharmaceuticals and ZFP-engineered transgenic animals. Sigma is marketing ZFN-derived gene editing tools under the trademark CompoZr[®].
- · We have a license agreement with Dow AgroSciences, LLC (DAS), a wholly owned subsidiary of Dow Chemical Corporation. Under the agreement, we have provided DAS with access to our ZFP technology and the exclusive rights to use it to modify the genomes or alter protein expression of plant cells, plants or plant cell cultures. DAS markets our ZFN

technology under the trademark EXZACTTM Precision Technology. We have retained rights to use plants or plant-derived products to deliver ZFP TFs or ZFNs into human or animals for diagnostic, therapeutic or prophylactic purposes.

We have incurred net losses since inception and expect to incur losses in the future as we continue our research and development activities. To date, we have funded our operations primarily through the issuance of equity securities, payments from corporate collaborations and research grants.

For the three months ended September 30, 2015, we incurred a consolidated net loss of \$9.2 million, or \$0.13 per share, compared to a net loss of \$7.5 million, or \$0.11 per share, for the same period in 2014. For the nine months ended September 30, 2015, we incurred a consolidated net loss of \$26.7 million, or \$0.38 per share, compared to a net loss of \$22.1 million, or \$0.33 per share, for the same period in 2014. As of September 30, 2015, we had cash, cash equivalents, marketable securities and interest receivable totaling \$219.7 million compared to \$226.6 million as of December 31, 2014. As of September 30, 2015, we had an accumulated deficit of \$355.2 million.

Our revenues have consisted primarily of revenues from partnerships of our ZFP technology platform in both therapeutic and non-therapeutic applications, including license fees, research reimbursement and milestones, royalties, as well as revenues from research grant funding. We expect revenues will continue to fluctuate from period to period, and there can be no assurance that new collaborations or partner funding will continue beyond their current terms.

In the development of our ZFP technology platform, we are focusing our resources on higher-value ZFP Therapeutic product development and less on our non-therapeutic applications. Development of novel therapeutic products is costly and is subject to a lengthy and uncertain regulatory process at the FDA. Our future products will be gene-based therapeutics. Adverse events in both our own clinical program and other programs may have a negative impact on regulatory approval, the willingness of potential commercial partners to enter into agreements and public perception.

Critical Accounting Estimates

The accompanying discussion and analysis of our financial condition and results of operations are based upon our condensed consolidated financial statements and the related disclosures, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts in our consolidated financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that there have been no significant changes in our critical accounting policies and estimates disclosed in our Annual Report on Form 10-K for the year ended December 31, 2014, as filed with the SEC.

Results of Operations

Three and nine months ended September 30, 2015 and 2014

Revenues

	Th	ree months end	ded September 3	0,	Nine months ended September 30,					
	(in th	ousands, excep	ot percentage val	ues)	(in thousands, except percentage values)					
	2015	2014	Change	%	2015	2014	Change	%		
Revenues:										
Collaboration agreements	\$ 8,406	\$ 12,045	\$ (3,639)	(30%)	\$ 28,878	\$ 29,334	\$ (456)	(2%)		
Research Grants	163	372	(209)	(56%)	1,540	1,584	(44)	(3%)		
Total revenues	\$ 8,569	\$ 12,417	\$ (3,848)	(31%)	\$ 30,418	\$ 30,918	\$ (500)	(2%)		

Total revenues consist of revenues from collaboration agreements and research grants. We anticipate revenues over the next several years will be derived primarily from our collaboration agreements with Biogen, DAS and Sigma.

Revenues from our corporate collaboration agreements were \$8.4 million for the three months ended September 30, 2015, compared to \$12.0 million in the corresponding period in 2014. The \$3.6 million decrease in collaboration agreements revenues was primarily due to a decrease of \$2.7 million in revenues related to the amendment of our collaboration and license agreement with Shire and a \$0.9 million decrease in revenues related to our collaboration and license agreement with Biogen. The revenues from Shire included \$3.3 million from research services and \$0.5 million related to partial recognition of an upfront license fee of \$13.0 million. The revenues from Biogen included \$2.6 million from research services and \$1.6 million related to partial recognition of an upfront

payment of \$20.0 million. Research grant revenues were approximately \$0.2 million for the three months ended September 30, 2015, compared to \$0.4 million in the corresponding period in 2014.

Revenues from our corporate collaboration agreements were \$28.9 million for the nine months ended September 30, 2015, compared to \$29.3 million in the corresponding period in 2014. The decrease of \$0.4 million in collaboration agreement revenues was primarily attributable to a \$5.2 million decrease in revenues related to the amendment of our agreement with Shire and a \$0.8 million decrease under our license agreement with Open Monoclonal Technology, Inc., partially offset by a \$4.0 million increase in revenues related to our agreement with Sigma and a \$1.4 million increase in revenues related to our agreement with Biogen. Research grant revenues were \$1.5 million for the nine months ended September 30, 2015, compared to \$1.6 million in the corresponding period in 2014.

Operating Expenses

	Three months ended September 30,					Nine months ended September 30,				
	(in thousands, except percentage values)					(in thousands, except percentage values)				
	2015	2014	Ch	ange	<u></u> %	2015	2014	Change	%	
Operating expenses:										
Research and development	\$ 16,694	\$ 16,340	\$	354	2%	\$ 47,292	\$ 41,883	\$ 5,409	13%	
General and administrative	4,560	3,731		829	22%	14,309	11,347	2,962	26%	
Total expenses	\$ 21,254	\$ 20,071	\$	1,183	6%	\$ 61,601	\$ 53,230	\$ 8,371	16%	

Research and development

Research and development expenses consist primarily of salaries and personnel related expenses, including stock-based compensation, laboratory supplies, preclinical and clinical studies, manufacturing expenses, allocated facilities expenses, subcontracted research expenses and expenses for technology licenses. In 2015, we established a Technical Operations group to manage the relationships with third-party vendors used in our manufacturing processes as well as to improve our process development and increase our overall manufacturing capabilities. We expect to continue to devote substantial resources to research and development in the future and expect research and development expenses to increase in the next several years if we are successful in advancing our HIV/AIDS program in the clinic and if we are able to move our earlier stage ZFP Therapeutic product candidates into clinical trials. We also expect that expenses related to research performed under our collaboration and license agreement with Biogen will increase our research and development expenses during the terms of the agreements. Pursuant to the terms of the agreement with Biogen, future expenses for research activities under the collaboration will be reimbursed, including internal employee and external research costs related to the programs. The reimbursement for these services will be recognized as revenue as the expenses are incurred and collection is reasonably assured.

Research and development expenses were \$16.7 million for the three months ended September 30, 2015, compared to \$16.3 million in the corresponding period in 2014. The increase of \$0.4 million in research and development expenses was primarily due to increases of \$0.7 million increase in facilities and lab supply expenses, \$0.6 million in salaries and benefits and \$0.4 million in stock-based compensation expense attributable to the establishment of a Technical Operations group in 2015, partially offset by decrease of \$0.6 million in external research expenses and \$0.7 million in clinical trial and manufacturing expenses related to our HIV/AIDs program.

Research and development expenses were \$47.3 million for the nine months ended September 30, 2015, compared to \$41.9 million in the corresponding period in 2014. The increase of \$5.4 million in research and development expenses was primarily due to an increase of \$2.2 million in salaries and benefits, \$2.0 million increase in facilities expense related to increased headcount in the Technical Operations group and \$1.6 million in stock-based compensation expense. The increase was partially offset by a decrease of \$1.1 million in external research expenses.

General and administrative

General and administrative expenses consist primarily of salaries and personnel related expenses, including stock-based compensation, other expenses for executive, finance and administrative personnel, professional fees, allocated facilities expenses, patent prosecution expenses and other general corporate expenses. As we continue to pursue clinical and commercial development of our therapeutic programs, we expect the business aspects of the Company to become more complex. In the future we may be required to add personnel and incur additional expenses related to the maturity of our business.

General and administrative expenses were \$4.6 million for the three months ended September 30, 2015 compared to \$3.7 million for the corresponding period in 2014. The increase was primarily related to an increase of \$0.3 million in salaries and benefits, \$0.3 million in stock-based compensation expense and \$0.2 million in professional fees and consulting expense.

General and administrative expenses were \$14.3 million for the nine month period ended September 30, 2015 and \$11.3 million for the corresponding period in 2014. The increase was primarily related to an increase of \$1.0 million in professional fees and consulting expense, \$0.9 million in stock-based compensation expense and \$0.6 million in salaries and benefits.

Benefit from income taxes

During the nine months ended September 30, 2015, the Company recognized an income tax benefit of \$4.1 million, including a \$3.4 million benefit from income taxes related to the \$14.5 million settlement with certain investors who were beneficial owners. Under the intraperiod tax allocations rules, the income taxes related to the settlement recognized in additional paid-in capital requires an income tax benefit to be recognized.

Liquidity and Capital Resources

Liquidity

Since inception, we have incurred significant net losses and we have funded our operations primarily through the issuance of equity securities, payments from corporate collaborators and strategic partners and research grants.

As of September 30, 2015, we had cash, cash equivalents, marketable securities and interest receivable totaling \$219.7 million compared to \$226.6 million as of December 31, 2014.

Our most significant use of capital pertains to salaries and benefits for our employees and external development expenses, such as manufacturing and clinical trial activities, related to our ZFP Therapeutic programs. Our cash and investment balances are held in a variety of interest bearing instruments, which can include obligations of U.S. government agencies, U.S. treasury debt securities, corporate debt securities, commercial paper securities and money market funds. Cash in excess of immediate requirements is invested in accordance with our investment policy with a view toward capital preservation and liquidity.

Under the agreement with Biogen, we received an upfront license fee of \$20.0 million in 2014. Biogen will reimburse us for agreed upon costs incurred in connection with research and development activities conducted by us. In addition, we are eligible to receive development milestone payments upon the achievement of specified regulatory, clinical development and commercialization milestones. We will also be eligible to receive incremental royalties for each licensed product that are a tiered double-digit percentage of annual net sales of such product, if any.

In January 2012, we entered into a license and collaboration agreement with Shire, under which we received an upfront license fee of \$13.0 million. In addition, Shire agreed to reimburse us for agreed upon costs incurred in connection with research and development activities that we conducted and to pay us certain milestone payments based on our achievement of specified research, regulatory, clinical development, commercialization and sales milestones, which depended upon our ability with Shire to continue to progress our programs under collaboration. We were also eligible to receive royalty payments on net sales of products developed under the collaboration, if any. On September 1, 2015, we amended the Shire agreement such that going forward, each company is responsible for expenses associated with its own programs and will reimburse the other for any ongoing services provided. Under the amended agreement, Shire does not have any milestone payment obligations to us with respect to the retained programs, but it is required to pay single digit percentage royalties to us, up to a specified maximum cap, on the commercial sales of ZFP therapeutic products from such programs. Under the Agreement, we have full control over, and full responsibility for the costs of, the hemophilia programs returned to us, subject to certain diligence obligations and Shire's right of first negotiation to obtain a license to such programs under certain circumstances. We are required to pay single digit percentage royalties to Shire, up to a specified maximum cap, on commercial sales of ZFP therapeutic products from such returned programs.

Cash Flow

Operating activities. Net cash used in operating activities for the nine months ended September 30, 2015 and 2014 was \$24.6 million and \$3.0 million, respectively. Net cash used in operating activities for the nine months ended September 30, 2015 primarily reflected the increases in net loss for the period as well as a decrease in deferred revenue, partially offset by the increases in stock-based compensation and a decrease in accounts receivable. Net cash used in operating activities for the nine months ended September 30, 2014 primarily reflected the increases in net loss for the period as well as an increase in accounts receivable and other current assets and a decrease in accrued compensation, partially offset by the increases in deferred revenues related to our collaboration agreement with Biogen, accounts payable and stock-based compensation.

Investing activities. Net cash provided in investing activities for the nine months ended September 30, 2015 was \$32.2 million, while cash used in investing activities was \$100.3 million for the nine months ended September 30, 2014. Cash flows from investing activities for both periods primarily related to purchases and maturities of investments.

Financing activities. Net cash provided by financing activities for the nine months ended September 30, 2015 and 2014 was \$20.7 million and \$104.3 million, respectively. Net cash provided by financing activities for the nine month period ended September 30, 2015 was primarily related to a \$14.5 million settlement with certain investors that were beneficial owners of our common stock related to the disgorgement of short-swing profits pursuant to Section 16 of the Securities Exchange Act of 1934, as amended as well as proceeds from the exercise of stock options. Net cash provided by financing activities for the nine month period ended September 30, 2014 was primarily attributable to \$93.8 million in net proceeds from the public offering of the Company's common stock completed in March 2014 as well as proceeds from the exercise of stock options.

Operating Capital and Capital Expenditure Requirements

We anticipate continuing to incur operating losses for at least the next several years. While our rate of cash usage may increase in the future, in particular to support our product development endeavors, we believe that the available cash resources as well as funds received from corporate collaborators, strategic partners and research grants will enable us to maintain our currently planned operations through 2016. Future capital requirements will be substantial, and if our capital resources are insufficient to meet future capital requirements, we will need to raise additional capital to fund our operations, including ZFP Therapeutic development activities, through equity or debt financing. We regularly consider fund raising opportunities and may decide, from time to time, to raise capital based on various factors, including market conditions and our plans of operation. Additional capital may not be available on terms acceptable to us, or at all. If adequate funds are not available, or if the terms of potential funding sources are unfavorable, our business and our ability to develop our technology and our ZFP Therapeutic products would be harmed. Furthermore, any sales of additional equity securities may result in dilution to our stockholders, and any debt financing may include covenants that restrict our business.

Our future capital requirements will depend on many factors and are not limited to the following:

- the initiation, progress, timing and completion of clinical trials for our product candidates;
- the outcome, timing and cost of regulatory approvals;
- the success of our collaborations with Biogen, Shire and other partners;
- · delays that may be caused by changing regulatory requirements;
- the number of product candidates that we pursue;
- the costs involved in filing and prosecuting patent applications and enforcing and defending patent claims;
- the timing and terms of future in-licensing and out-licensing transactions;
- · the cost of procuring clinical and commercial supplies, including the cost to manufacture our ZFP therapeutic products;
- · investment made in the development of internal process development and manufacturing capabilities;
- the extent to which we acquire or invest in businesses, products or technologies; and
- · the costs of litigation.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our primary exposure to market risk is interest income sensitivity relating to our cash, cash equivalents and investments, which is affected by changes in the general level of U.S. interest rates. We do not have any foreign currency or other derivative financial instruments.

Our market risks at September 30, 2015 have not changed materially from those discussed in Item 7A of our Form 10-K for the year ended December 31, 2014 on file with the SEC.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable, and not absolute, assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost benefit relationship of possible controls and procedures.

As required by the Securities and Exchange Commission Rule 13a-15(b), we carried out an evaluation, under the supervision of and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Change in Internal Control over Financial Reporting

There has been no change in our internal controls over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not party to any material pending legal proceedings.

ITEM 1A. RISK FACTORS

An investment in our common stock involves significant risk. You should carefully consider the information described in the following risk factors, together with the other information appearing elsewhere in this report, before making an investment decision regarding our common stock. While the risk factors set forth below update and supplement the risk factors set forth in our Annual Report on Form 10-K for the year ended December 31, 2014 (2014 Annual Report), you should review our 2014 Annual Report, including the section under the caption "Item 1A. Risk Factors," together with the other information appearing elsewhere in this report, before making an investment decision regarding our common stock. If any of the risks described below or in our 2014 Annual Report actually occur, our business, financial conditions, results of operation and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or a part of your investment in our common stock. Moreover, the risks described below and in our 2014 Annual Report are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also affect our business, operating results, prospects or financial condition. You should carefully consider these risk factors, together with all of the other information included in this Form 10-Q as well as our other publicly available filings with the Securities and Exchange Commission.

Risks Relating to Development, Commercialization and Regulatory Approval of our Products and Technology

ZFP Therapeutics have undergone limited testing in humans and our ZFP Therapeutics may fail safety studies in clinical trials.

We are conducting an on-going Phase 2 clinical trial (SB-728-mR-1401) of our ZFP Therapeutics for the treatment of HIV/AIDS and a Phase 1 study of the same approach in HSPCs. Preliminary data from these studies demonstrates that treatment of aviremic HIV-infected subjects with SB-728-T has been well-tolerated. In addition, data from Phase 1 and several Phase 2 clinical trials of our ZFP Therapeutic, SB-509, for diabetic neuropathy and ALS demonstrated that the drug was well tolerated in these studies. However, if one of our ZFP Therapeutic fails one of its safety studies, it could reduce our ability to attract new investors and corporate partners.

All of these studies are designed primarily to evaluate the safety and tolerability of this ZFP Therapeutic approach. Our clinical studies are a highly visible test of our ZFP Therapeutics and our investors assess the value of our technology primarily based on the continued progress of ZFP Therapeutic products into and through clinical trials. If clinical trials of our ZFP Therapeutic products were halted due to safety concerns, this would negatively affect our operations and the value of shares in our common stock.

Our progress in early Phase 1 and Phase 2 trials may not be indicative of long-term efficacy in late stage clinical trials.

The results in early phases of clinical testing are based upon limited numbers of patients and a limited follow-up period. Typically, our Phase 1 clinical trials for indications of safety enroll less than 25 patients. Our Phase 2 and late-stage clinical trials generally enroll a larger number of patients. Accordingly, any positive data obtained in early Phase 1 and Phase 2 trials may not be indicative of long-term efficacy in late-stage clinical trials.

In September 2011, we announced preliminary data from our clinical program to develop SB-728-T for the treatment of HIV/AIDS which is now in Phase 2 clinical testing. The data demonstrated a statistically significant relationship between SB-728-T and the reduction of HIV viral load. In January 2012, we initiated a Phase 2 clinical study (SB-728-902, Cohort 5) and a Phase 1/2 clinical study (SB-728-1101) for the treatment of HIV/AIDS. In December 2013, we presented data from all cohorts of these two clinical trials. Three of seven evaluable subjects in Cohort 5 showed a decrease of greater than one log in their viral load during a sixteen week treatment interruption (TI) of their antiretroviral therapy (ART) with one subject achieving a transiently undetectable viral load during the TI period and one subject achieving control of their viral load during TI for a prolonged period (>70 weeks as of January 2015). Two of three additional subjects, enrolled in Cohort 3* of this study, have demonstrated notable reductions in viral load during a TI from ART. Additional data were presented from the Company's Phase 1 study (SB-728-902, Cohorts 1-3) that demonstrated a long-term decrease in the peripheral blood mononuclear cell (PBMC) HIV reservoir using a sensitive test for integrated HIV DNA in nine of nine subjects over a 36 month period (median decrease 0.9 logs). Additional subjects were enrolled into the SB-728-1101 study to define the optimum dose of Cytoxan required to safely enhance engraftment and an additional 12 subjects have been enrolled to further test this dose including nine subjects in an ongoing Phase 2 clinical trial (SB-728mR-T-1401) that is also testing repeat dosing of modified T-cells. However, there is no guarantee that these and other future studies of SB-728-T in later stage trials involving larger patient groups may produce positive or similar results as those obtained in earlier trials. In subjects in which viral load decreased, a measurable anti-HIV immune response was also observed.

A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late stage clinical trials even after achieving promising results in earlier stage clinical trials. If a larger population of patients does not experience positive results, or if these results are not reproducible, our products may not receive approval from the FDA. Failure to confirm favorable results from earlier trials by demonstrating the safety and effectiveness of our ZFP Therapeutic products in late stage clinical trials with larger patient populations could have a material adverse effect on our business that would cause our stock price to decline significantly.

Our potential therapeutic products are subject to a lengthy and uncertain regulatory process, and we may encounter unanticipated toxicity or adverse events or fail to demonstrate efficacy, causing us to delay, suspend or terminate the development of a ZFP Therapeutic. If these potential products are not approved, we will not be able to commercialize those products.

The FDA must approve any human therapeutic product before it can be marketed in the United States. The process for receiving regulatory approval is long and uncertain, and a potential product may not withstand the rigors of testing under the regulatory approval processes.

Before commencing clinical trials in humans, we must submit an IND application to the FDA. The FDA has 30 days to comment on the application, and if the agency has no comments, we or our commercial partner may begin clinical trials. While we have stated our intention to file additional IND applications in the future, this is only a statement of intent, and we may not be able to do so because the associated product candidates may not meet the necessary preclinical requirements. In addition, there can be no assurance that, once filed, an IND application will result in the actual initiation of clinical trials. Clinical trials are subject to oversight by institutional review boards and the FDA. In addition, our proposed clinical studies require review from the Recombinant DNA Advisory Committee (RAC), which is the advisory board to the National Institutes of Health (NIH), focusing on clinical trials involving gene transfer. We will typically submit a proposed clinical protocol and other product-related information to the RAC three to six months prior to the expected IND application filing date.

Clinical trials:

- must be conducted in conformance with the FDA's good clinical practices, within the guidelines of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and other applicable regulations;
- · must meet requirements for Institutional Review Board (IRB) oversight;
- · must follow Institutional Biosafety Committee (IBC) and NIH RAC guidelines where applicable;
- · must meet requirements for informed consent;
- · are subject to continuing FDA oversight;
- · may require oversight by a Data Safety Monitoring Board (DSMB);
- · may require large numbers of test subjects; and
- · may be suspended by a commercial partner, the FDA, or us at any time if it is believed that the subjects participating in these trials are being exposed to unacceptable health risks or if the FDA finds deficiencies in the IND application or the conduct of these trials.

While we have stated our goal is to file IND applications for several ZFP Therapeutic programs in the future, we may encounter difficulties that may delay, suspend or scale back our efforts.

We have previously announced a strategy for our ZFP Therapeutic programs that enables the potential filing of two to four new IND applications per year in the foreseeable future. The preparation and submission of IND applications requires us to conduct rigorous and time-consuming preclinical testing, studies, and documentation relating to, among other things, the toxicity, safety, manufacturing, chemistry and clinical protocol of new ZFP Therapeutic products. We may experience unforeseen difficulties that could delay or otherwise prevent us from executing this strategy successfully. For example, we may encounter problems in the manufacturing of our ZFP Therapeutic products and fail to demonstrate consistency in the formulation of the drug. Our preclinical tests may produce negative or inconclusive results, which may lead us to decide, or regulators may require us, to conduct additional preclinical testing. If we cannot obtain positive results in preclinical testing, we may decide to abandon the projects altogether. In addition, our ability to complete and file certain IND applications depends on the support of our partners and the timely performance of their obligations under relevant collaboration agreements. If our partners are not able to perform such obligations or if they choose to slow down or delay the progress, we may not be able to prepare and file the intended IND applications on a timely basis or at all. Furthermore, the filing of several IND applications involves significant cost and labor, and we may not have sufficient resources and personnel to complete the filing of all intended IND applications, which may force us to scale back the number of IND applications or forego potential IND applications that we believe are promising. Any delay, suspension or reduction of our efforts to pursue our preclinical and IND strategy could have a material adverse effect on our business and cause our stock price to decline.

We may not be able to find acceptable patients or may experience delays in enrolling patients for our clinical trials.

We may experience difficulties or delays in recruiting and enrolling a sufficient number of patients to participate in our clinical trials due to a variety of reasons, including competition from other clinical trial programs for the same indication, failure of patients to meet our enrollment criteria and premature withdraws of patients prior to the completion of clinical trials. The FDA and institutional review boards may also require large numbers of patients, and the FDA may require that we repeat a clinical trial. Any delay resulting from our failure to enroll a sufficient number of patients on a timely basis may have a material adverse effect on our business.

As we cannot predict whether or when we will obtain regulatory approval to commercialize our product candidates, we cannot predict the timing of any future revenue from these product candidates.

We cannot commercialize any of our ZFP Therapeutics to generate revenue until the appropriate regulatory authorities have reviewed and approved the applications for the product candidates. We cannot ensure that the regulatory agencies will complete their review processes in a timely manner or that we will obtain regulatory approval for any product candidate that we or our collaborators develop. Satisfaction of regulatory requirements typically takes many years, is dependent upon the type, complexity and novelty of the product and requires the expenditure of substantial resources. Regulatory approval processes outside the United States include all of the risks associated with the FDA approval process. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review.

We have limited experience in conducting clinical trials.

Our most advanced clinical program is our Phase 2 trial to evaluate the safety and efficacy of a ZFP Therapeutic for HIV/AIDS. However, the FDA will require additional clinical testing which involves significantly greater resources, commitments and expertise, As such, it is likely that we would need to enter into a collaborative relationship with a pharmaceutical company that could assume responsibility for late-stage development and commercialization.

We have limited experience in conducting advanced clinical trials and may not possess the necessary resources and expertise to complete such trials. We have entered into a collaborative agreement with Biogen to provide funding and assistance in the development of certain ZFP Therapeutics through the clinical trial process. Under the agreement with Biogen, we are responsible for all research and development through the first human clinical trial for the treatment of beta-thalassemia and both parties are responsible for research and development through the submission of IND for ZFP Therapeutics to treat sickle cell disease (SCD). However, there is no guarantee that we will be able to enter into future collaborative relationships with third parties that can provide us with the funding and expertise for later stage trials.

Regulatory approval, if granted, will be limited to specific uses or geographic areas, which could limit our ability to generate revenues.

Regulatory approval will be limited to the indicated use for which we can market a product. Further, once regulatory approval for a product is obtained, the product and its manufacturer are subject to continual review. Discovery of previously unknown problems with a product or manufacturer may result in restrictions on the product, manufacturer, and manufacturing facility, including withdrawal of the product from the market. In Japan and Europe, regulatory agencies also set or approve prices.

Even if regulatory clearance of a product is granted, this clearance is limited to those specific states and conditions for which the product is useful, as demonstrated through clinical trials. We cannot ensure that any ZFP Therapeutic product developed by us, alone or with others, will prove to be safe and effective in clinical trials and will meet all of the applicable regulatory requirements needed to receive marketing clearance in a given country.

Outside the United States, our ability to market a product is contingent upon receiving a marketing authorization from appropriate regulatory authorities; therefore we cannot predict whether or when we would be permitted to commercialize our product. These foreign regulatory approval processes include all of the risks associated with FDA clearance described above.

Commercialization of our technologies will depend, in part, on strategic partnering with other companies. If we are not able to find partners in the future or if our partners do not diligently pursue product development efforts, we may not be able to develop our technologies or products, which could slow our growth and decrease the value of our stock.

We expect to rely, to some extent, on our strategic partners to provide funding in support of our research and to perform independent research and preclinical and clinical testing. Our technology is broad-based, and we do not currently possess the resources necessary to fully develop and commercialize potential products that may result from our technologies or the resources or capabilities to complete the lengthy marketing approval processes that may be required for the products. Therefore, we plan to rely on strategic partnerships to help us develop and commercialize ZFP Therapeutic products. If we are unable to find partners or if the partners we

find, such as Shire and Biogen, are unable or unwilling to advance our programs, or if they do not diligently pursue product approval, this may slow our progress and adversely affect our ability to generate revenues. In addition, our partners may sublicense or abandon development programs or we may have disagreements or disputes with our partners, which would cause associated product development to slow or cease. In addition, the business or operations of our partners may change significantly through restructuring, acquisition or other strategic transactions or decisions that may negatively impact their ability to advance our programs. There can be no assurance that we will be able to establish further strategic collaborations for ZFP Therapeutic product development. We may require significant time to secure collaborations or partners because we need to effectively market the benefits of our technology to these future collaborators and partners, which may direct the attention and resources of our research and development personnel and management away from our primary business operations. Further, each collaboration or partnering arrangement will involve the negotiation of terms that may be unique to each collaborator or partners. These business development efforts may not result in a collaboration or partnership.

The loss of partnering agreements may delay or terminate the potential development or commercialization of products we may derive from our technologies, but it may also delay or terminate our ability to test ZFP Therapeutic candidates for specific genes. If any partner fails to conduct the collaborative activities successfully or in a timely manner, the preclinical or clinical development or commercialization of the affected product candidates or research programs could be delayed or terminated.

Under typical partnering agreements, we would expect to receive revenue for the research and development of a ZFP Therapeutic product based on achievement of specific milestones, as well as royalties based on a percentage of sales of the commercialized products. Achieving these milestones will depend, in part, on the efforts of our partner as well as our own. If we, or any partner, fail to meet specific milestones, then the partnership may be terminated, which could reduce our revenues. For more information on risks relating to our third party collaborative agreements, see "Risks Relating to our Collaborative Relationships."

We may be unable to license gene transfer technologies that we may need to commercialize our ZFP technology.

In order to regulate or modify a gene in a cell, the ZFP must be efficiently delivered to the cell. We have licensed certain gene transfer technologies for our ZFP in research including AAV and mRNA technology. We are evaluating these systems and other technologies that may need to be used in the delivery of ZFP into cells for *in vitro* and *in vivo* applications, including ZFP Therapeutics. However, we may not be able to license the gene transfer technologies required to develop and commercialize our ZFP Therapeutics. We have not developed our own gene transfer technologies, and we rely on our ability to enter into license agreements to provide us with rights to the necessary gene transfer technology. Our approach has been to license appropriate technology as required. The inability to obtain a license to use gene transfer technologies with entities which own such technology on reasonable commercial terms, if at all, could delay or prevent the preclinical evaluation, drug development collaborations, clinical testing, and/or commercialization of our therapeutic product candidates.

Our gene regulation and genome editing technology is relatively new, and if we are unable to use this technology in all our intended applications, it would limit our revenue opportunities.

Our technology involves a relatively new approach to gene regulation and genome editing. Although we have generated ZFPs for thousands of gene sequences, we have not created ZFPs for all gene sequences and may not be able do so, which could limit the usefulness of our technology. In addition, while we have demonstrated the function of engineered ZFNs and ZFP TFs in mammalian cells, yeast, insects, plants and animals, we have not yet demonstrated clinical efficacy of this technology in a controlled clinical trial in humans, and the failure to do so could restrict our ability to develop commercially viable products. If we, and our collaborators or strategic partners, are unable to extend our results to new commercially important genes, experimental animal models, and human clinical studies, we may be unable to use our technology in all its intended applications.

The expected value and utility of our ZFNs and ZFP TFs is in part based on our belief that the targeted editing of genes or specific regulation of gene expression may enable us to develop a new therapeutic approach as well as to help scientists better understand the role of genes in disease, and to aid their efforts in drug discovery and development. We also believe that ZFP-mediated targeted genome editing and gene regulation will have utility in agricultural applications. There is only a limited understanding of the role of specific genes in all these fields. Life sciences companies have developed or commercialized only a few products in any of these fields based on results from genomic research or the ability to regulate gene expression. We, our collaborators or our strategic partners, may not be able to use our technology to identify and validate drug targets or to develop commercial products in the intended markets.

Effective delivery of ZFNs and ZFP TFs into the appropriate target cells and tissues is critical to the success of the therapeutic applications of our ZFP technology. In order to have a meaningful therapeutic effect, the ZFP Therapeutic must be delivered to sufficient numbers of cells in the targeted tissue. The ZFN or ZFP TF must be present in that tissue for sufficient time to effect either modification of a therapeutically relevant gene or regulation of its expression. In our current clinical and preclinical programs, we administer our ZFP Therapeutics as a nucleic acid that encodes the ZFN or ZFP TF. We use different formulations to deliver the ZFP Therapeutic depending on the required duration of expression, the targeted tissue and the indication that we intend to treat. However, there can be no assurances that we will be able to effectively deliver our ZFNs and ZFP TFs to produce a beneficial therapeutic effect.

We are conducting proprietary research to discover ZFP Therapeutic product candidates. These programs increase our financial risk of product failure, may significantly increase our research expenditures, and may involve conflicts with future collaborators and strategic partners.

Our proprietary research programs consist of research that is funded solely by us or by grant funding and in which we retain exclusive rights to therapeutic products generated by such research. This is in contrast to certain of our research programs that may be funded by corporate partners in which we may share rights to any resulting products. Conducting proprietary research programs may not generate corresponding revenue and may create conflicts with our collaborators or strategic partners over rights to our intellectual property with respect to our proprietary research activities. Any conflict with our collaborators or strategic partners could reduce our ability to enter into future collaborations or partnering agreements and negatively impact our relationship with existing collaborators and partners that could reduce our revenue and delay or terminate our product development. As we continue to focus our strategy on proprietary research and therapeutic development, we expect to experience greater business risks, expend significantly greater funds and require substantial commitments of time from our management and staff.

Even if our technology proves to be effective, it still may not lead to commercially viable products.

Even if our collaborators or strategic partners are successful in using our ZFP technology in drug discovery, protein production, therapeutic development or plant agriculture, they may not be able to commercialize the resulting products or may decide to use other methods competitive with our technology. To date, no company has received marketing approval or has developed or commercialized any therapeutic or agricultural products based on our technology. Should our technology fail to provide safe, effective, useful or commercially viable approaches to the discovery and development of these products, this would significantly limit our business and future growth and would adversely affect our value.

Even if our product development efforts are successful and even if the requisite regulatory approvals are obtained, our ZFP Therapeutics may not gain market acceptance among physicians, patients, healthcare payers and the medical community.

A number of additional factors may limit the market acceptance of our ZFP Therapeutic products including the following:

- rate of adoption by healthcare practitioners;
- · rate of a product's acceptance by the target population;
- timing of market entry relative to competitive products;
- availability of alternative therapies;
- · price of our product relative to alternative therapies;
- · availability of third-party reimbursement;
- · extent of marketing efforts by us and third-party distributors or agents retained by us; and
- · side effects or unfavorable publicity concerning our products or similar products.

Therefore, even after we have obtained the required regulatory approval for our ZFP Therapeutic products, we may not be able to commercialize these products successfully if we cannot achieve an adequate level of market acceptance.

We currently rely on third parties to conduct some or all aspects of manufacturing of our ZFP Therapeutic product candidates for preclinical and clinical development. If one of our third-party manufacturers fails to perform adequately or fulfill our needs, we may be required to incur significant costs and devote significant efforts, to find new suppliers or manufacturers.

We currently have limited experience in, and we do not own facilities for, clinical-scale manufacturing of our product candidates and we rely upon third-party contract manufacturing organizations to manufacture and supply drug product for our preclinical and clinical studies. The manufacture of pharmaceutical products in compliance with the FDA's current good manufacturing practices (cGMP), requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, including difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced cGMP requirements, other federal and state regulatory requirements and foreign regulations. If our manufacturers were to encounter any of these difficulties or otherwise fail to comply with their obligations to us or under applicable regulations, our ability to provide study drugs in our clinical studies would be jeopardized. Any delay or interruption in the supply of clinical study materials could delay the completion of our clinical studies, increase the costs associated with maintaining our clinical study programs and, depending upon the period of delay, require us to commence new studies at significant additional expense or terminate the studies completely.

All manufacturers of our product candidates must comply with cGMP requirements enforced by the FDA through its facilities inspection program. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our product candidates may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. The FDA or similar foreign regulatory agencies may also implement new standards at any time, or change their interpretation and enforcement of existing standards for manufacture, packaging or testing of products. We have little control over our manufacturers' compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall or withdrawal of product approval. If the safety of any product supplied is compromised due to our manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our products and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay of clinical studies, regulatory submissions, approvals or commercialization of our product candidates, entail higher costs or impair our reputation.

Our current agreements with our suppliers do not provide for the entire supply of the drug product necessary for all anticipated clinical studies or for full scale commercialization. If we and our suppliers cannot agree to the terms and conditions for them to provide the drug product necessary for our clinical and commercial supply needs, we may not be able to manufacture the product candidate until a qualified alternative supplier is identified, which could also delay the development of, and impair our ability to commercialize, our product candidates.

The number of third-party suppliers with the necessary manufacturing and regulatory expertise and facilities is limited, and it could be expensive and take a significant amount of time to arrange for alternative suppliers, which could have a material adverse effect on our business. New suppliers of any product candidate would be required to qualify under applicable regulatory requirements and would need to have sufficient rights under applicable intellectual property laws to the method of manufacturing the product candidate. Obtaining the necessary FDA approvals or other qualifications under applicable regulatory requirements and ensuring non-infringement of third-party intellectual property rights could result in a significant interruption of supply and could require the new manufacturer to bear significant additional costs which may be passed on to us.

We do not currently have the infrastructure or capability to manufacture, market and sell therapeutic products on a commercial scale.

In order for us to commercialize our therapeutic products directly, we would need to develop, or obtain through outsourcing arrangements, the capability to manufacture, market and sell our products on a commercial scale. Currently, we do not have the ability nor the financial resources to establish the infrastructure and organizations needed to execute these functions, including such infrastructure needed for the commercialization of any product from our HIV/AIDS, which can be complex and costly. If we are unable to establish adequate manufacturing, sales, marketing and distribution capabilities, we will not be able to directly commercialize our therapeutics products, which would limit our future growth.

Risks Relating to our Industry

If our competitors develop, acquire, or market technologies or products that are more effective than ours, this would reduce or eliminate our commercial opportunity.

Any products that we or our collaborators or strategic partners develop by using our ZFP technology platform will enter into highly competitive markets. Even if we are able to generate ZFP Therapeutics that are safe and effective for their intended use, competing technologies may prove to be more effective or less expensive, which, to the extent these competing technologies achieve market acceptance, will limit our revenue opportunities. In some cases, competing technologies have proven to be effective and less expensive. Competing technologies may include other methods of regulating gene expression or modifying genes. ZFNs and ZFP TFs have broad application in the life sciences industry and compete with a broad array of new technologies and approaches being applied to genetic research by many companies. Competing proprietary technologies with our product development focus include but are not limited to:

- For ZFP Therapeutics:
 - small molecule drugs;
 - monoclonal antibodies;
 - recombinant proteins;
 - gene therapy/cDNAs;
 - · antisense;
 - \cdot $\,$ siRNA and microRNA approaches, exon skipping;

- CRISPR/Cas9 technology;
- · TALE proteins and MegaTALs; and
- · meganucleases.
- · For our Non-Therapeutic Applications:
 - For protein production: gene amplification, meganucleases, TALE technology, insulator technology, mini-chromosomes and CRISPR/Cas9 technology;
 - · For target validation: antisense, siRNA, TALE technology and CRISPR/Cas9 technology;
 - · For plant agriculture: recombination approaches, mutagenesis approaches, meganucleases, TALE technology, CRISPR/Cas9 technology, mini-chromosomes; and
 - · For transgenic animals: somatic nuclear transfer, embryonic stem cell, TALE, CRISPR/Cas9 technology and transposase technologies.

In addition to possessing competing technologies, our competitors include pharmaceutical and biotechnology companies with:

- · substantially greater capital resources than ours;
- · larger research and development staffs and facilities than ours; and
- · greater experience in product development and in obtaining regulatory approvals and patent protection.

These organizations also compete with us to:

- · attract qualified personnel;
- · attract parties for acquisitions, joint ventures or other collaborations; and
- · license the proprietary technologies of academic and research institutions that are competitive with our technology, which may preclude us from pursuing similar opportunities.

Accordingly, our competitors may succeed in obtaining patent protection or commercializing products before us. In addition, any products that we develop may compete with existing products or services that are well established in the marketplace.

Adverse public perception in the field of gene therapy may negatively impact regulatory approval of, or demand for, our potential products.

Our potential therapeutic products are delivered to patients as gene-based drugs, or gene therapy. The clinical and commercial success of our potential products will depend in part on public acceptance of the use of gene therapy for the prevention or treatment of human diseases. Public attitudes may be influenced by claims that gene therapy is unsafe, and, consequently, our products may not gain the acceptance of the public or the medical community. Negative public reaction to gene therapy in general could result in greater government regulation and stricter labeling requirements of gene therapy products, including any of our products, and could cause a decrease in the demand for any products we may develop.

Laws or public sentiment may limit the production of genetically modified agricultural products, and these laws could reduce our partner's ability to sell such products.

Genetically modified products are currently subject to public debate and heightened regulatory scrutiny, either of which could prevent or delay production of agricultural products. We have a research license and commercial option agreement with DAS through which we provide DAS with access to our proprietary ZFP technology and the exclusive right to use our ZFP technology to modify the genomes or alter the nucleic acid or protein expression of plant cells, plants or plant cell cultures. The field-testing, production and marketing of genetically modified plants and plant products are subject to federal, state, local and foreign governmental regulation. Regulatory agencies administering existing or future regulations or legislation may not allow production and marketing of our genetically modified products in a timely manner or under technically or commercially feasible conditions. In addition, regulatory action or private litigation could result in expenses, delays or other impediments to our product development programs or the commercialization of resulting products.

The FDA currently applies the same regulatory standards to foods developed through genetic engineering as those applied to foods developed through traditional plant breeding. Genetically engineered food products, however, will be subject to pre-market review if these products raise safety questions or are deemed to be food additives. Governmental authorities could also, for social or other purposes, limit the use of genetically modified products created with our gene regulation technology.

Even if the regulatory approval for genetically modified products developed under our agreement with DAS was obtained, our success will also depend on public acceptance of the use of genetically modified products including drugs, plants, and plant products. Claims that genetically modified products are unsafe for consumption or pose a danger to the environment may influence public attitudes. Our genetically modified products may not gain public acceptance. The subject of genetically modified organisms has received negative publicity in the United States and particularly in Europe, and such publicity has aroused public debate. The adverse publicity in Europe could lead to greater regulation and trade restrictions on imports of genetically altered products. Similar adverse public reaction or sentiment in the United States to genetic research and its resulting products could result in greater domestic regulation and could decrease the demand for our technology and products.

Risks Relating to our Finances

We have incurred significant operating losses since inception and anticipate that we will incur continued losses for the foreseeable future.

We have generated operating losses since we began operations in 1995. Our net losses for the years ended December 31, 2014, 2013 and 2012 were \$26.4 million, \$26.6 million and \$22.3 million, respectively. The extent of our future losses and the timing of profitability are uncertain, and we expect to incur losses for the foreseeable future. We have been engaged in developing our ZFP technology since inception, which has and will continue to require significant research and development expenditures. To date, we have generated our funding from issuance of equity securities, revenues derived from collaboration agreements, other strategic partnerships in non-therapeutic applications of our technology, federal government research grants and grants awarded by research foundations. As of September 30, 2015, we had an accumulated deficit of \$355.2 million. Since our IPO in 2000, we have generated an aggregate of approximately \$331.4 million in gross proceeds from the sale of our equity securities. We expect to continue to incur additional operating losses for the next several years as we continue to advance our ZFP Therapeutic product candidates. If the time required to generate significant product revenues and achieve profitability is longer than we currently anticipate or if we are unable to generate liquidity through equity financing or other sources of funding, we may be forced to curtail or suspend our operations.

We may be unable to raise additional capital, which would harm our ability to develop our technology and products.

We have incurred significant operating losses and negative operating cash flows since inception and have not achieved profitability. We expect capital outlays and operating expenditures to increase over the next several years as we expand our infrastructure and research and ZFP Therapeutic product development activities. While we believe our financial resources will be adequate to sustain our current operations at least through 2016, we may need to seek additional sources of capital through equity or debt financing. In addition, as we focus our efforts on proprietary human therapeutics, we will need to seek FDA approval of potential products, a process that could cost in excess of hundreds of millions of dollars per product. Furthermore, we may experience difficulties in accessing the capital market due to external factors beyond our control such as volatility in the equity markets for emerging biotechnology companies and general economic and market conditions both in the United States and abroad. We cannot be certain that we will be able to obtain financing on terms acceptable to us, or at all. Our failure to obtain adequate and timely funding will materially adversely affect our business and our ability to develop our technology and ZFP Therapeutic products. Furthermore, any sales of additional equity securities may result in dilutions to our stockholders and any debt financing may include business and financial covenants that restricts our operations.

We are at the development phase of operations and may not succeed or become profitable.

We began operations in 1995 and are in the early phases of ZFP Therapeutic product development, and we have incurred significant losses since inception. To date, our revenues have been generated from collaboration agreements, other collaborations in non-therapeutic applications of our technology, federal government research grants and grants awarded by research foundations. Our focus on higher-value therapeutic product development and related collaboration requires us to incur substantial expenses associated with product development. In addition, the preclinical or clinical failure of any single product may have a significant effect on the actual or perceived value of our stock. Our business is subject to all of the risks inherent in the development of a new technology, which includes the need to:

- attract and retain qualified scientific and technical staff and management, particularly scientific staff with expertise to develop our early-stage technology into therapeutic products;
- · obtain sufficient capital to support the expense of developing our technology platform and developing, testing and commercializing products;
- · develop a market for our products; and
- · successfully transition from a company with a research focus to a company capable of supporting commercial activities.

Risks Relating to our Relationships with Collaborators and Strategic Partners

If conflicts arise between us and our collaborators or strategic partners, these parties may act in their self-interest, which may limit our ability to implement our strategies.

If conflicts arise between our corporate or academic collaborators or strategic partners and us, the other party may act in its self-interest, which may limit our ability to implement our strategies. Some of our academic collaborators and strategic partners are conducting multiple product development efforts within each area that is the subject of the collaboration with us. Our collaborators or strategic partners, however, may develop, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of these collaborations. Competing products, either developed by the collaborators or strategic partners or to which the collaborators or strategic partners have rights, may result in the withdrawal of partner support for our product candidates.

Some of our collaborators or strategic partners could also become our competitors in the future. Our collaborators or strategic partners could develop competing products, preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely, or fail to devote sufficient resources to the development and commercialization of products. Any of these developments could harm our product development efforts.

Our collaborators and strategic partners may control aspects of our clinical trials, which could result in delays and other obstacles in the commercialization of our proposed products.

For some programs, we depend on third party collaborators and strategic partners to design and conduct our clinical trials. As a result, we may not be able to conduct these programs in the manner or on the time schedule we currently contemplate, which may negatively impact our business operations. In addition, if any of these collaborators or strategic partners withdraws support for our programs or proposed products or otherwise impair their development; our business could be negatively affected.

In January 2012, we entered into a collaborative agreement with Shire, pursuant to which we are engaging in a joint program with Shire to research, develop and commercialize human therapeutics and diagnostics for hemophilia, Huntington's disease and other monogenic diseases based on our ZFP technology. In September 2015, we amended the Shire agreement to restructure the collaboration, under which Shire will retain the rights to develop a ZFP Therapeutic for Huntington's disease and another target yet to be named, while returning the rights to us for the development, clinical testing and commercialization of ZFP Therapeutics for hemophilia A and B. Under the amended agreement, we will provide certain target feasibility activities and upon Shire's request, certain research activities under a research plan, agreed upon by both companies. Shire is responsible for clinical development and commercialization of products generated from the research program from and after the acceptance of an IND or CTA for the product.

In addition, in January 2014 we entered into a collaborative agreement with Biogen for the clinical development and commercialization of therapeutics based on our ZFP technology for hemoglobinopathies, including beta-thalassemia and SCD. Under the agreement, we are responsible for all discovery, research and development activities through the first human clinical trial for the first ZFP Therapeutic developed for the treatment of beta-thalassemia. In the SCD program, both parties are responsible for research and development activities through the submission of an IND.

Under the agreement with Biogen, they have control and broad discretion over all or certain aspects of the clinical development and commercialization of any product developed under the agreement, and we will have little, if any, influence on how these programs will be conducted. Our lack of control over the clinical development in our agreement with Biogen could cause delays or other difficulties in the development and commercialization of our product candidates, which may prevent us from completing the intended IND filings in a timely fashion and receiving any milestone, royalty payments and other benefits under the agreement. In addition, under their respective agreement(s), Biogen and Shire have certain rights to terminate the agreements by providing us with advance notices, therefore, the actual milestone payments that we may receive under these agreements may be lower than the full amounts stated above.

Our collaborators or strategic partners may decide to adopt alternative technologies or may be unable to develop commercially viable products with our technology, which would negatively impact our revenues and our strategy to develop these products.

Our collaborators or strategic partners may adopt alternative technologies, which could decrease the marketability of ZFP technology. Additionally, because many of our collaborators or strategic partners are likely to be working on more than one development project, they could choose to shift their resources to projects other than those they are working on with us. If they do so, this would delay our ability to test our technology and would delay or terminate the development of potential products based on our ZFP technology. Further, our collaborators and strategic partners may elect not to develop products arising out of our collaborative and strategic partnering arrangements or to devote sufficient resources to the development, manufacturing, marketing or sale of these products. In September 2015, we amended our agreement with Shire pursuant to which Shire will no longer continue the clinical development of our ZFP Therapeutics for hemophilia A and B. As a result, we intend to develop these programs either ourselves or seek the support of other partners or collaborators. We may not have sufficient resources and expertise to develop these programs by

ourselves, and we may not be able to identify a suitable partner or negotiate a favorable collaboration agreement to allow us to continue the development of these programs. If any of these events occur, we may not be able to develop our technologies or commercialize our products.

If we do not successfully commercialize ZFP-based research reagents, ZFP-modified cell lines for commercial protein production, or ZFP-engineered transgenic animals under our license agreement with Sigma-Aldrich Corporation or ZFP-based agricultural products with Dow AgroSciences, or if Sigma-Aldrich Corporation or Dow AgroSciences terminates our agreements, our ability to generate revenue under these license agreements may be limited.

In July 2007, we entered into a license agreement with Sigma to collaborate in the application and development of ZFP-based products for use in the laboratory research reagents markets. The agreement provides Sigma with access to our ZFP technology and the exclusive right to use our ZFP technology to develop and commercialize products for use as research reagents and to offer services in related research fields. Under the agreement, Sigma has exclusive rights to develop and distribute ZFP-modified cell lines for commercial production of protein pharmaceuticals and, certain ZFP-engineered transgenic animals for commercial applications. In addition, under our license agreement with DAS relating to plant agriculture, DAS has the exclusive right to develop agricultural products using our ZFP technology in plant cells, plants or plant cell cultures. Both Sigma and DAS have the right to sublicense our technology in their respective areas. In addition to upfront payments, we may also receive additional license fees, shared sublicensing revenues, royalty payments and milestone payments depending on the success of the development and commercialization of the licensed products and services covered under both agreements. The commercial milestones and royalties are typically based upon net sales of licensed products.

We cannot be certain that we or our collaboration partners will succeed in the development of commercially viable products in these fields of use, and there is no guarantee that we or our collaboration partners will achieve the milestones set forth in the respective license agreements. To the extent we or our collaboration partners do not succeed in developing and commercializing products or if we or our collaboration partners fail to achieve such milestones, our revenues and benefits under the license agreements will be limited. In addition, the respective license agreements may be terminated by Sigma and DAS at any time by providing us with a 90-day notice. In the event Sigma or DAS decides to terminate the license agreements, our ability to generate revenue under such license agreements will cease.

Our collaborations with outside scientists may be subject to change, which could limit our access to their expertise.

We work with scientific advisors and collaborators at academic research institutions. These scientists are not our employees and may have other commitments that would limit their availability to us. Although our scientific advisors generally agree not to do competing work, if a conflict of interest between their work for us and their work for another entity arises, we may lose their services. Although our scientific advisors and academic collaborators sign agreements not to disclose our confidential information, it is possible that some of our valuable proprietary knowledge may become publicly known through them, which may cause competitive harm to our business.

Risks Relating to our Intellectual Property and Business Operation

Because it is difficult and costly to protect our proprietary rights, and third parties have filed patent applications that are similar to ours, we cannot ensure the proprietary protection of our technologies and products.

Our commercial success will depend in part on obtaining patent protection of our technology and successfully defending any of our patents that may be challenged. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and can involve complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date. Accordingly, we cannot predict the breadth of claims allowed in patents we own or license.

We are a party to various license agreements that give us rights under specified patents and patent applications. Our current licenses, as our future licenses frequently will, contain performance obligations. If we fail to meet those obligations, the licenses could be terminated. If we are unable to continue to license these technologies on commercially reasonable terms, or at all, we may be forced to delay or terminate our product development and research activities.

With respect to our present and any future sublicenses, since our rights derive from those granted to our sublicensor, we are subject to the risk that our sublicensor may fail to perform its obligations under the master license or fail to inform us of useful improvements in, or additions to, the underlying intellectual property owned by the original licensor.

We are unable to exercise the same degree of control over intellectual property that we license from third parties as we exercise over our internally developed intellectual property. We do not control the prosecution of certain of the patent applications that we license from third parties; therefore, the patent applications may not be prosecuted as we desire or in a timely manner.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- we or our licensors were the first to make the inventions covered by each of our pending patent applications;
- · we or our licensors were the first to file patent applications for these inventions;
- the patents of others will not have an adverse effect on our ability to do business;
- · others will not independently develop similar or alternative technologies or reverse engineer any of our products, processes or technologies;
- · any of our pending patent applications will result in issued patents;
- any patents issued or licensed to us or our collaborators or strategic partners will provide a basis for commercially viable products or will provide us with any competitive advantages;
- · any patents issued or licensed to us will not be challenged and invalidated by third parties; or
- we will develop additional products, processes or technologies that are patentable.

Others have filed and in the future are likely to file patent applications that are similar to ours. We are aware that there are academic groups and other companies that are attempting to develop technology that is based on the use of zinc finger, TALE, CRISPR/Cas9 and other DNA-binding proteins, and that these groups and companies have filed patent applications. Several patents have been issued, although we have no current plans to use the associated inventions. If these or other patents issue, it is possible that the holder of any patent or patents granted on these applications may bring an infringement action against our collaborators, strategic partners, or us claiming damages and seeking to enjoin commercial activities relating to the affected products and processes. The costs of litigating the claim could be substantial. Moreover, we cannot predict whether we, our collaborators, or strategic partners would prevail in any actions. In addition, if the relevant patent claims were upheld as valid and enforceable and our products or processes were found to infringe the patent or patents, we could be prevented from making, using, or selling the relevant product or process unless we could obtain a license or were able to design around the patent claims. We can give no assurance that such a license would be available on commercially reasonable terms, or at all, or that we would be able to successfully design around the relevant patent claims. There may be significant litigation in the genomics industry regarding patent and other intellectual property rights, which could subject us to litigation. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources.

We rely on trade secrets to protect technology where we believe patent protection is not appropriate or obtainable. Trade secrets, however, are difficult to protect. While we require employees, academic collaborators and consultants to enter into confidentiality agreements, we may not be able to adequately protect our trade secrets or other proprietary information or enforce these confidentiality agreements.

Our collaborators, strategic partners, and scientific advisors have rights to publish data and information in which we may have rights. If we cannot maintain the confidentiality of our technology and other confidential information in connection with our collaborations and strategic partnerships, then we may not be able to receive patent protection or protect our proprietary information.

If we use biological and hazardous materials in a manner that causes injury or violates laws, we may be liable for damages.

Our research and development activities involve the controlled use of potentially harmful biological materials as well as hazardous materials, chemicals, and various radioactive compounds typically employed in molecular and cellular biology. We routinely use cells in culture and gene delivery vectors, and we employ small amounts of radioisotopes in trace experiments. Although we maintain up-to-date licensing and training programs, we cannot completely eliminate the risk of accidental contamination or injury from the use, storage, handling, or disposal of these materials. In the event of contamination or injury, we could be held liable for damages that result, and any liability could exceed our resources. We currently carry insurance covering certain claims arising from our use of these materials. However, if we are unable to maintain our insurance coverage at a reasonable cost and with adequate coverage, our insurance may not cover any liability that may arise. We are subject to federal, state, and local laws and regulations governing the use, storage, handling, and disposal of these materials and specified waste products. To date, we have not experienced significant costs in complying with regulations regarding the use of these materials.

Failure to attract, retain, and motivate skilled personnel and cultivate key academic collaborations will delay our product development programs and our research and development efforts.

Our success depends on our continued ability to attract, retain, and motivate highly qualified management and scientific personnel and our ability to develop and maintain important relationships with leading research and academic institutions and scientists. Competition for skilled and qualified personnel and academic and other research collaborations is intense. We have experienced a rate of employee turnover that we believe is typical of emerging biotechnology companies. If we lose the services of

personnel with the necessary skills, including the members of our senior management team, it could significantly impede the achievement of our research and development objectives. If we fail to negotiate additional acceptable collaborations with academic and other research institutions and scientists, or if our existing collaborations are unsuccessful, our ZFP Therapeutic development programs may be delayed or may not succeed.

Risks Relating to our Common Stock and Corporate Organization

Our stock price has been volatile and may continue to be volatile, which could result in substantial losses for investors.

During the three months ended September 30, 2015, the closing price of our common stock, as reported by the NASDAQ Global Select Market, ranged from a low of \$5.64 to high of \$10.86. During the fiscal year ended December 31, 2014, our common stock price fluctuated, ranging from a low of \$9.85 to a high of \$23.86. Volatility in our common stock could cause stockholders to incur substantial losses. An active public market for our common stock may not be sustained, and the market price of our common stock may continue to be highly volatile. The market price of our common stock has fluctuated significantly in response to various factors, some of which are beyond our control, including but not limited to the following:

- · announcements by us or collaborators providing updates on the progress or development status of ZFP Therapeutics;
- data from clinical trials;
- initiation or termination of clinical trials;
- changes in market valuations of similar companies;
- · overall market and economic conditions, including the equity markets for emerging biotechnology companies;
- · deviations in our results of operations from the guidance given by us;
- · announcements by us or our competitors of new or enhanced products, technologies or services or significant contracts, acquisitions, strategic relationships, joint ventures or capital commitments;
- · announcement of changes in business and operations by our collaborators and partners;
- regulatory developments;
- · additions or departures of key personnel;
- · future sales of our common stock or other securities by us, management or directors, liquidation of institutional funds that comprised large holdings of our stock;
- · decreases in our cash balances; and
- · changes, by one or more of Sangamo's security analysts, in recommendations, ratings or coverage of our stock.

Our stock price is also influenced by public perception of gene therapy and government regulation of potential products.

Reports of serious adverse events in a retroviral gene transfer trial for infants with X-linked severe combined immunodeficiency (X-linked SCID) in France and subsequent FDA actions putting related trials on hold in the United States had a significant negative impact on the public perception and stock price of certain companies involved in gene therapy. Stock prices of these companies declined whether or not the specific company was involved with retroviral gene transfer for the treatment of infants with X-linked SCID, or whether the specific company's clinical trials were placed on hold in connection with these events. Other potential adverse events in the field of gene therapy may occur in the future that could result in greater governmental regulation of our potential products and potential regulatory delays relating to the testing or approval of our potential products. These external events may have a negative impact on public perception of our business, which could cause our stock price to decline.

Anti-takeover provisions in our certificate of incorporation and Delaware law could make an acquisition of the Company more difficult and could prevent attempts by our stockholders to remove or replace current management.

Anti-takeover provisions of Delaware law and in our certificate of incorporation and our bylaws may discourage, delay or prevent a change in control of our company, even if a change in control would be beneficial to our stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. In particular, under our certificate of incorporation our board of directors may issue up to 5,000,000 shares of preferred stock with rights and privileges that might be senior to our common stock, without the consent of the holders of the common stock. Moreover, without any further vote or action on the part of the stockholders, the board of directors would have the authority to determine the price, rights, preferences, privileges, and restrictions of the preferred stock. This preferred stock, if it is ever issued, may have preference over, and harm the rights of, the holders of common stock.

Although the issuance of this preferred stock would provide us with flexibility in connection with possible acquisitions and other corporate purposes, this issuance may make it more difficult for a third party to acquire a majority of our outstanding voting stock.

Similarly, our authorized but unissued common stock is available for future issuance without stockholder approval.

In addition, our bylaws:

- · state that stockholders may not act by written consent but only at a stockholders' meeting;
- establish advance notice requirements for nominations for election to the board of directors or proposing matters that can be acted upon at stockholders' meetings; and
- · prohibit stockholders from calling a special meeting of stockholders.

We are also subject to Section 203 of the Delaware General Corporation Law, which provides, subject to certain exceptions, that if a person acquires 15% of our voting stock, the person is an "interested stockholder" and may not engage in "business combinations" with us for a period of three years from the time the person acquired 15% or more or our voting stock. The application of Section 203 may, in some circumstances, deter or prevent a change in control of our company even when such change may be beneficial to our stockholders.

ITEM 6. EXHIBITS

(a) Exhibits:

10.1†

31.1	Rule 13a — 14(a) Certification by President and Chief Executive Officer
31.2	Rule $13a-14(a)$ Certification by Principal Financial and Accounting Officer
32.1	Certification Pursuant to 18 U.S.C. Section 1350
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

Amended and Restated Collaboration and License Agreement, dated September 1, 2015, between the Company and Shire

[†] Confidential treatment has been requested for certain information contained in this document. Such information has been omitted and filed separately with the Securities and Exchange Commission.

SIGNATURES

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.

Dated: October 30, 2015

SANGAMO BIOSCIENCES, INC.

/s/ H. WARD WOLFF

H. Ward Wolff Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer) NOTE: Portions of this Exhibit are the subject of a Confidential Treatment Request by the Registrant to the Securities and Exchange Commission (the "Commission"). Such portions have been redacted and are marked with a "[***]" in the place of the redacted language. The redacted information has been filed separately with the Commission.

AMENDED AND RESTATED

COLLABORATION AND LICENSE AGREEMENT

BETWEEN

SANGAMO BIOSCIENCES, INC.

And

SHIRE INTERNATIONAL GMBH

*** CONFIDENTIAL PORTIONS OMITTED AND FILED SEPARATELY WITH THE COMMISSION

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Waiver

Severability

AMENDED AND RESTATED COLLABORATION AND LICENSE AGREEMENT

This Amended and Restated Collaboration and License Agreement (this "Agreement"), effective as of September 1, 2015 (the "Amendment Effective Date"), is entered into by and between Sangamo BioSciences, Inc., a company organized under the laws of Delaware and having a place of business at 501 Canal Blvd. Suite A100, Richmond, CA 94804 ("Sangamo"), and Shire International GmbH (f/k/a Shire AG), a limited liability company registered under the laws of Switzerland, having a place of business at c/o LacMont Hofstrasse 1A, 6300, Zug, Switzerland ("Shire", and each of Shire and Sangamo, a "Party" or collectively the "Parties"), with respect to the following facts:

RECITALS

WHEREAS, the Parties entered into a Collaboration and License Agreement dated as of January 31, 2012 (the "Effective Date" and such agreement, the "Original Agreement"), pursuant to which Sangamo and Shire collaborated to identify products and processes employing Sangamo's zinc finger DNA-binding technology for treating certain diseases caused by particular monogenic defects, which products and processes could be advanced into human clinical trials and following regulatory approval, commercialized, and Sangamo granted Shire a license under certain of its technology to develop and commercialize the same.

WHEREAS, the Parties now desire to amend and restate the Original Agreement such that this Agreement is in effect from and after the Amendment Effective Date.

WHEREAS, under this Agreement Shire returns to Sangamo Shire's collaboration and license rights with respect to the ongoing zinc finger development programs directed at the Factor VIII gene and Factor IX gene Targets (which will become Sangamo Programs under this Agreement), as well as the Factor VII gene and Factor X gene Targets, and Shire retains the rights with respect to the ongoing zinc finger development program directed at the Huntingtin gene Target and a future program directed at one additional gene Target to be chosen later (which will be Shire Programs under this Agreement);

WHEREAS, the Parties wish to allocate their rights and obligations such that Shire will be responsible for, and have autonomy with respect to, the development and commercialization of the Shire Programs, Sangamo will be responsible for, and have autonomy with respect to, the development and commercialization of the Sangamo Programs, and the Parties will continue collaborative research only on a fee-for-service basis with respect to the identification of Development Candidates for the Shire Programs.

WHEREAS, each Party is willing to grant to the other Party licenses of certain of its technology to develop and commercialize products and processes in such programs, and each Party desires to obtain such licenses on the terms of this Agreement.

NOW THEREFORE, in consideration of the foregoing premises and the mutual covenants set forth below, the Parties agree to amend and restate the Original Agreement as of the Amendment Effective Date so that it reads in its entirety as follows:

1 DEFINITIONS

For purposes of this Agreement, the terms set forth in this Article 1 shall have the respective meanings set forth below:

- 1.1 "Additional Target" shall have the meaning set forth in Section 2.4.
- 1.2 "Additional Target Notice" shall have the meaning set forth in Section 2.4(a).
- **1.3** "Affiliate" means, with respect to any Person, any other Person which controls, is controlled by, or is under common control with, such Person. For purposes of this Agreement, a Person shall be deemed to control an entity if it owns or controls, directly or indirectly, at least 50% of the equity securities of the subject entity entitled to vote in the election of directors (or, in the case of an entity that is not a corporation, for the election of the corresponding managing authority), or otherwise has the power to control the management and policies of such other entity.
 - **1.4** "Amendment Effective Date" shall have the meaning set forth in the Preamble.
 - **1.5** "Arbitration Commencement Date" shall have the meaning provided in **Section 15.5(a)(vii)**.

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- **1.6** "BLA" or "Biologics Licensing Application" means a Biologics License Application (as defined in 21 C.F.R. §600 et seq.) or substantially similar application or submission filed with a Governmental Authority in a country or group of countries to obtain approval to market a ZF Product in that country or in that group of countries, and any amendments thereto.
- **1.7** "CDA" means that certain Confidential Disclosure Agreement between Shire Pharmaceuticals Inc. (an Affiliate of Shire) and its Affiliates and Sangamo dated March 11, 2010.
- **1.8** "Change of Control" means, with respect to a Party, (a) a merger or consolidation of such Party with a Third Party which results in the voting securities of such Party outstanding immediately prior thereto ceasing to represent at least [***] of the combined voting power of the surviving entity immediately after such merger or consolidation, or (b) a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the beneficial owner of at least [***] of the combined voting power of the outstanding securities of such Party, (c) the sale or other transfer to a Third Party of all or substantially all of such Party's business to which the subject matter of this Agreement relates.
 - **1.9** "Claim" shall have the meaning set forth in **Section 2.2(d)**.
- **1.10** "Collaboration" means activities performed by or on behalf of one or both of the Parties pursuant to the Original Agreement or the Development Plan, or in the course of performing the Services.
 - 1.11 "Collaboration ZF Products" means all Sangamo ZF Products and Shire ZF Products.
 - **1.12** "Commercially Reasonable Efforts" means:
- (a) in the case of Sangamo, the efforts and resources typically used by biotechnology companies similar in size and scope to Sangamo to perform the obligation at issue;
 - (b) in the case of Shire, the efforts and resources typically used by Shire and its Affiliates to perform the obligation at issue;

in each case, which efforts shall not be less than those efforts made with respect to other products at a similar stage of development or in a similar stage of product life, with similar developmental risk profiles, of similar market and commercial potential, taking into account the competitiveness of the market place, the proprietary position of the products, the regulatory structure involved, the profitability of the applicable products (taking into account payments made by the Responsible Party to the other Party with respect to each Collaboration ZF Product under this Agreement) and other relevant factors. Commercially Reasonable Efforts requires that the Party: (i) promptly assign responsibility for such obligation to specific employees who are held accountable for progress and monitor such progress on an ongoing basis, (ii) set and seek to achieve specific and meaningful objectives for carrying out such obligation, and (iii) make and implement decisions and allocate resources designed to advance progress with respect to such objectives.

- 1.13 "Confidential Information" means all Know-How and other proprietary information (including information about any element of a Party's technology or business) that is disclosed by a Party or its Affiliates or by any of the Party's or its Affiliates' employees or consultants (the "Disclosing Party") to the other Party or its Affiliates or to any of the other Party's or its Affiliates' employees or consultants (the "Receiving Party") except to the extent that the information: (a) as of the date of disclosure is demonstrably known to the Receiving Party, as shown by written documentation, other than by virtue of a prior confidential disclosure by the Disclosing Party, (b) as of the date of disclosure is in, or subsequently enters, the public domain, through no fault or omission of the Receiving Party or (c) as of the date of disclosure or thereafter is obtained by the Receiving Party from a Third Party free from any obligation of confidentiality to the Disclosing Party. Unless otherwise provided herein, all work product by either Party under this Agreement, including any Joint Technology, in connection with the Shire Programs is Confidential Information of each Party. The terms and conditions of this Agreement shall be considered Confidential Information of each Party. In addition, all confidential Know-How disclosed by either Party pursuant to the CDA shall be the Disclosing Party's Confidential Information hereunder (with the mutual understanding and agreement that any use or disclosure thereof that is authorized under Article 12 shall not be restricted by, or be a violation of, the CDA).
- **1.14** "Control" or "Controlled" means, with respect to any intellectual property right (including any Patent Right or Know-How), the possession of (whether by ownership or license, other than pursuant to this Agreement) the ability of a Person or its Affiliates to assign, transfer, or grant access to, or to grant a license or sublicense of, such right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party existing at the time such Person would be required hereunder to assign, transfer or grant another Person such access or license or sublicense. Notwithstanding the foregoing, with respect to any Patent Right, Know-How or other intellectual property right acquired or in-licensed by a Party after the Effective Date from a Third Party, such intellectual property will be treated as "Controlled" by the licensing Party to the extent that, and only to the extent that and for so long as, the other Party (a) agrees to and does promptly pay to the licensing Party all payments to such Third Party arising out of the grant and exercise of the license to the other Party hereunder in accordance with **Section 10.6**, (b) agrees to and does provide all reports required under the agreement with such Third Party on account of such other Party's exercise of such license, (c)

agrees to assume all obligations of a sublicensee under such Third Party agreement and (d) acknowledges in writing that its sublicense is subject to the terms and conditions of such Third Party agreement. For clarity, the previous sentence does not apply to any Patent Right, Know-How or other intellectual property right Controlled by Sangamo pursuant to an Existing Third Party License.

- **1.15** "Cover", "Covers" or "Covered" means, with respect to the relevant Patent Rights and particular materials or activities at issue, that, but for a license granted to a Person under such Patent Right, or but for such Person's ownership of such Patent Right, the manufacture, use, sale, offer for sale or importation by such Person of the materials at issue, or the conduct of the activities at issue, would infringe an issued claim of such Patent Right or, in the case of a Patent Right that is a patent application, would infringe a claim in such patent application if it were to issue as a patent, in a particular country or countries.
- **1.16** "CTA" means a clinical trial application filed with a competent European regulatory authority to support the authorization of a clinical trial on a medicinal product for human use.
- **1.17** "*Development Candidate*" means a Shire ZF Compound provided by Sangamo pursuant to **Section 3.4(d)** or under the Original Agreement, in each case that Shire selects as a development candidate and designates to Sangamo by written notice pursuant to **Section 3.5**.
 - **1.18** "Development Candidate Selection" shall have the meaning set forth in **Section 3.5**.
- **1.19** "*Development Plan*" means the description and timeline developed by Shire in its sole discretion and covering the specific activities to be performed by Shire to develop a particular Shire ZF Product up to the first Development Candidate Selection with respect to the applicable Shire Target.
- **1.20** "Donor Nucleic Acid" means, with respect to a ZF Product, a nucleic acid that has been designed to be inserted, or is capable (in the form in existence in such ZF Product) of being inserted, in the location in the genome that is cleaved by the ZF Compound-associated nucleases in such ZF Product.
 - **1.21** "Earned Royalties" shall have the meaning set forth in **Section 10.2**.
 - **1.22** "Effective Date" shall have the meaning set forth in the Recitals.
- **1.23** "Excluded Target" means any Target, other than a Reserve Target, that, on the date Sangamo receives an Additional Target Notice from Shire, is (a) any Sangamo Target, the Factor VII gene, as defined by Gene ID 2155 in the NCBI-NLM-NIH GenBank, or the Factor X gene, as defined by Gene ID 2159 in the NCBI-NLM-NIH GenBank; (b) a Target that is subject to rights granted or intended to be granted to a Third Party pursuant to a [***], existing prior to the date of Shire's Additional Target Notice; (c) a Target that is the subject of a current and active Sangamo internal research or development program on which Sangamo already has invested at least [***] with respect to such program, at least [***] of which are documented [***] provided by Third Parties for such program; or (d) a Target identified as a proposed Additional Target in Shire's Additional Target Notice where [***]. A direct expense pursuant to this **Section 1.23** means an expense that (i) arises only after a [***], (ii) is related to work undertaken [***], and (iii) is a documented expense for products or services provided by [***] based upon the amount [***] program (which shall be calculated at the [***]).
- **1.24** "Exclusive Services" means with respect to a ZF Compound, [***] services. For the avoidance of doubt, "Exclusive Services" will not include [***].
- **1.25** "Existing Third Party Licenses" means the agreements, entered into by Sangamo prior to the Effective Date, including any amendments thereto as of the Amendment Effective Date, pursuant to which Sangamo Controls Sangamo Licensed Technology. All such agreements are listed on **Schedule 1.25A**. Notwithstanding the foregoing, Shire understands and acknowledges that the License Agreement between Sangamo and [***], as amended, and the License Agreement between Sangamo and [***], as amended, are not Existing Third Party Licenses (and hence are not listed in **Schedule 1.25A**), and the licenses granted to Shire under **Section 8.1** do not include sublicenses of any licenses received by Sangamo under such agreements.
 - **1.26** "FDA" means the Food and Drug Administration of the United States, or the successor thereto.
- **1.27** "Field" means: (a) with respect to a Shire ZF Product described in **Section 1.92(a)** or **Section 1.92(b)**, [***], (b) with respect to a Shire ZF Product described in **Section 1.92(c)**, [***] that are [***] in connection with any [***] for which [***], and (c) with respect to a Sangamo ZF Product described in **Section 1.79(a)** or **Section 1.79(b)**, [***].
 - **1.28** "Final Research Report" shall have the meaning set forth in **Section 3.4(d)**.
- **1.29** "First Commercial Sale" means, with respect to a particular Collaboration ZF Product, the first Net Sales in any country of such Collaboration ZF Product for any indication.
- **1.30** "*FTE*" means a full time equivalent scientific person (with B.S., M.S. or Ph.D. level or equivalent degrees), working for a minimum of a total of [***] hours per year of scientific or other work and who is an employee of Shire or Sangamo engaged in activities related to the Research Program or the Transition Activities or otherwise conducting activities to be reimbursed by Shire or

Sangamo (as applicable) pursuant to this Agreement, including recording and writing up results, reviewing literature and references, holding scientific discussions, and managing and leading scientific staff to the extent that such management and leading is directed to any work on, directly related to or in support of the Research Program, the Transition Activities or other activities that are to be reimbursed pursuant to this Agreement.

- **1.31** "FTE Rate" means the rate for each FTE, based on a 40 hour week, up to a maximum of 40 hours per week for each FTE, of (a) \$[***] per year through [***] and (b) starting on [***] and continuing each subsequent [***], [***]% of the FTE Rate in effect on the previous day.
- **1.32** "*GLP*" means the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58 or the successor thereto, or comparable regulatory standards in jurisdictions outside the U.S.
- **1.33** "Governmental Authority" means any government or supranational administrative agency, commission or other governmental or supranational authority, body or instrumentality, or any federal, state, local, domestic or foreign governmental or supranational regulatory body.
- **1.34** "*Gross Sales*" means the gross amount invoiced for sales of a Collaboration ZF Product(s), in arm's length sales by the applicable Responsible Party or its Affiliates, permitted assigns (in accordance with **Section 16.3**), or Sublicensees to Third Parties.
- **1.35** "*IND*" means an investigational new drug application filed with the FDA for approval to commence Phase I Clinical Trials or any successor to the FDA for equivalent purposes.
- **1.36** "IND-Enabling Studies" means studies that are required to meet the requirements for filing an IND/CTA with a Governmental Authority, including ADME (absorption, distribution, metabolism, and excretion) and GLP toxicology studies, or studies required for the preparation of the CMC (chemistry, manufacturing, and controls) section of such IND, including studies relating to analytical methods and purity analysis, and formulation and manufacturing development studies, all as necessary to obtain the permission of the applicable Governmental Authority to begin human clinical testing.
 - **1.37** "*Initial Subject Matter*" shall have the meaning set forth in **Section 9.2(c)**.
 - **1.38** "Initial Target" means the Huntingtin gene, as defined by Gene ID [***] in the [***] GenBank, including [***].
 - **1.39** "*Interim Research Report*" shall have the meaning set forth in **Section 3.4(c)**.
- **1.40** "Joint Know-How" means Know-How that is conceived, discovered, invented, created, made or reduced to practice or tangible medium jointly by at least one employee of each of the Parties, their Affiliates, or their Subcontractors during the course of performing activities under this Agreement or the Original Agreement. For the avoidance of doubt, "Joint Know-How" does not include Patent Rights in the Joint Know-How.
- **1.41** "*Joint Patent Rights*" means any Patent Rights (a) claiming Joint Know-How and (b) naming at least one inventor with an obligation to assign such Patent Rights to Shire (or a Shire Affiliate) and at least one inventor with an obligation to assign such Patent Rights to Sangamo (or a Sangamo Affiliate), with inventorship determined according to U.S. patent laws.
 - 1.42 "Joint Technology" means the Joint Know-How and the Joint Patent Rights.
- **1.43** "*Know-How*" means intellectual property, data, results, preclinical and clinical protocols and study data, information, materials, compounds, inventions, know-how, formulas, trade secrets, techniques, methods, processes, procedures, and developments; except that "Know-How" does not include Patent Rights in the foregoing.
 - 1.44 "Major European Country" means France, Germany, Italy, Spain, or the United Kingdom.
- **1.45** "Marketing Approval" means, with respect to a particular country or territory, the approval of a new drug application, BLA or similar approval required to sell a ZF Product in such country or territory, including, where required by applicable law, pricing and reimbursement approval, and schedule classifications.
 - **1.46** "Negotiation Period" shall have the meaning set forth in **Section 8.7**.
- 1.47 "Net Sales" means, on a Responsible Party-by-Responsible Party basis, with respect to each Responsible Party's Collaboration ZF Products, Gross Sales, less:
- (a) Normal and customary trade, cash and quantity discounts actually given, coupons actually taken, credits, price adjustments or allowances for damaged Collaboration ZF Products, returns or rejections of Collaboration ZF Products;
- (b) Adjustments, allowances, credits, fees, reimbursements, chargeback payments, and rebates (or the equivalent thereof) for the Collaboration ZF Products granted to group purchasing organizations or other buying groups, managed health care organizations, pharmacy benefit management companies, health maintenance organizations and any other providers of health insurance coverage, health care institutions (including hospitals) or other health care organizations, Third Party health care

administrators or patient assistance or other similar programs, or to federal, state/provincial, local and other governments, including their agencies, or to wholesalers, distributors or other trade customers;

- (c) Reasonable and customary freight, shipping insurance, and other transportation expenses, each directly related to the sale of the Collaboration ZF Products (if actually borne by the Responsible Party, its Affiliates or Sublicensees without reimbursement from any Third Party);
- (d) Distribution commissions/fees paid or payable to any Third Party providing distribution services to the Responsible Party, its Affiliates, or Sublicensees;
- (e) Sales or excise taxes, tariffs and duties, including, without limitation, VAT and U.S. sales tax, and all other taxes and government charges related to the sale of Collaboration ZF Product, in each case to the extent that each such item is actually borne by the Responsible Party, its Affiliates, Sublicensees or distributors without reimbursement from any Third Party (but excluding taxes properly assessed or assessable against the income derived by the Responsible Party or its Affiliates from such sale);
 - (f) Actual bad debt expense (but not exceeding [***] percent of Net Sales); and
- (g) Any item substantially similar in character or substance to any of the foregoing, which is permitted by U.S. GAAP prevailing at the time and customary in the pharmaceutical industry at the time.

The transfer of any Collaboration ZF Products by the applicable Responsible Party or one of its Affiliates or Sublicensees to another Affiliate or Sublicensees shall not be considered Net Sales.

For the avoidance of doubt, disposal or use of Collaboration ZF Products in clinical trials, as free samples, or under compassionate use, patient assistance, named patient or test marketing programs or non-registrational studies or other similar programs or studies where the Collaboration ZF Product is supplied without charge, shall not be considered Net Sales or result in any Net Sales under this **Section 1.47**. Nor shall any Collaboration ZF Products donated by a Party, its Affiliates or Sublicensees, to non-profit institutions or government agencies for a non-commercial purpose, result in any Net Sales. Similarly, any free Collaboration ZF Products which are supplied to a Third Party in conjunction with the offer for sale, or sale of any Collaboration ZF Product (in an amount customary in the industry), will not result in any Net Sales of such free goods. The use of a Collaboration ZF Product by a Party, its Affiliates or Sublicensees for research and development purposes shall not result in any Net Sales. For clarity, there shall be no limit on the quantity of Collaboration ZF Products which may be used in clinical trials. Such amounts shall be determined from the books and records of the applicable Responsible Party maintained in accordance with U.S. GAAP, consistently applied.

In the event any Collaboration ZF Product is sold as part of a combination product (being a product containing both a Collaboration ZF Product and one or more other active ingredients, or a product in which both a Collaboration ZF Product and one or more other active ingredients are packaged, in each case where such other active ingredients are not part of or used to implement any zinc finger technology (e.g., vectors for delivering ZF Compounds or Donor Nucleic Acids whose insertion is accomplished in part using ZF Compounds are not considered other active ingredients)), the Net Sales from the combination product, for the purposes of determining royalty payments, shall be determined by multiplying the Net Sales of the combination product (as defined in the standard Net Sales definition), during the applicable royalty reporting period, by the fraction, A/(A+B), where A is the average per unit sale price of Collaboration ZF Product when sold separately as a stand-alone ZF Product in finished form in the country in which the combination product is sold and B is the average per unit sale price of the other active ingredients contained in the combination product when sold separately as stand-alone products in finished form in the country in which the combination product is sold, in each case during the applicable royalty reporting period or, if sales of stand-alone Collaboration ZF Product did not occur in such period, then in the most recent royalty reporting period in which arms-length fair market sales of such Collaboration ZF Product, as applicable, occurred. In the event that such average sale price cannot be determined for the stand alone Collaboration ZF Products or the other products, Net Sales for the purposes of determining royalty payments shall be mutually agreed upon by the Parties based on the relative value contributed by each component, such agreement not to be unreasonably withheld, conditioned or delayed.

- 1.48 "Operational Activities" means (a) participation on working teams with respect to each Research Plan and the Research Committee, (b) review and revision of any and all Research Plans (including any amendments thereto), (c) review and commentary on specific protocols and experimental design, (d) preparation and review of all Interim Research Reports and Final Research Reports, (e) technology transfer to Shire, (f) regulatory support and coordination, and (g) teleconferences and email correspondence with Shire personnel related to the activities set forth in clauses (a) through (f) (to the extent applicable) or responsive to Shire inquiries.
 - **1.49** "Original Agreement" shall have the meaning set forth in the Recitals.
 - **1.50** "*Party*" and "*Parties*" shall have the meaning set forth in the first paragraph of this Agreement.
- **1.51** "Patent Rights" means issued patents and pending patent applications in any country or region, including all provisional, non-provisionals, substitutions, continuations, continuations, continuations, continuations, renewals and all patents granted thereon, and all

reissues, reexaminations, extensions, confirmations, revalidations, registrations and patents of addition thereof, including supplementary protection certificates.

- **1.52** "*Person*" means any natural person, corporation, unincorporated organization, partnership, association, sole proprietorship, joint stock company, joint venture, limited liability company, trust or government, or Governmental Authority, or any other similar entity.
- **1.53** "*Phase I Clinical Trial*" means a human clinical trial of a Collaboration ZF Product in human subjects according to 21 C.F.R. §312.21(a), as amended, or its equivalent, as appropriate, in foreign jurisdictions.
 - **1.54** "[***]" means, with respect to [***].
 - 1.55 "Proposal" shall have the meaning provided in Section 15.5(a)(vii).
- **1.56** "*Regulatory Filings*" means any filing with any Governmental Authority with respect to the research, development, manufacture, distribution, pricing, reimbursement, marketing or sale of any Collaboration ZF Product, including any IND/CTA submission or BLA.
 - **1.57** "Released Claim" shall have the meaning set forth in **Section 2.2(d)**.
 - 1.58 "Releasees" shall have the meaning set forth in Section 2.2(d).
 - 1.59 "Releasors" shall have the meaning set forth in Section 2.2(d).
 - **1.60** "Required ROFN Information" shall have the meaning set forth in **Section 8.6(a)**.
 - 1.61 "Research Committee" means the information exchange committee comprised of representatives of Shire and Sangamo described in Article 4.
- **1.62** "*Research Plan*" means, with respect to a Shire Target, a description, timeline and budget agreed by the Parties in writing and covering the specific activities to be performed by Sangamo during the Research Term, within the scope of the activities described on **Schedule 3.3** or otherwise agreed by the Parties, to identify ZF Compounds that Specifically Bind such Shire Target and to preclinically develop Shire ZF Products for such Shire Target through Development Candidate Selection. For the avoidance of doubt, activities conducted by Sangamo with respect to a particular Shire ZF Product may extend beyond Development Candidate Selection, to the extent specified in the applicable Research Plan.
- **1.63** "*Research Program*" means the program of research related to the Shire Programs performed by the Parties in accordance with a Research Plan, under the direction and oversight of Shire, aimed at identifying ZF Compounds that Specifically Bind a Shire Target and developing Shire ZF Products for Shire Targets pursuant to the applicable Research Plan.
- **1.64** "*Research Term*" means the period of time during which (a) Sangamo is performing, or having performed on its behalf, Services under a Research Plan, including Operational Activities or (b) Shire is performing, or having performed on its behalf, activities under a Development Plan.
 - **1.65** "Reserve Target" means those Targets set forth on **Schedule 1.65**, which Shire may designate as the Additional Target at any time through [***].
 - 1.66 "Responsible Party" means (a) Shire, with respect to any Shire ZF Product and (b) Sangamo, with respect to any Sangamo ZF Product.
 - **1.67** "Results" shall have the meaning set forth in Section 3.8(a).
 - 1.68 "Reverted Targets" shall have the meaning set forth in Section 15.5(e)(v).
 - **1.69** "Royalty Cap" shall have the meaning set forth in **Section 10.3**.
- **1.70** "*Royalty Period*" means, with respect to each different Collaboration ZF Product, the period commencing on the First Commercial Sale of such Collaboration ZF Product in any country and continuing until the Responsible Party has paid to the other Party an amount equal to the Royalty Cap with respect to all (a) Sangamo ZF Products (where Sangamo is the Responsible Party) or (b) Shire ZF Products (where Shire is the Responsible Party).
 - 1.71 "Safe Harbor Locus" means a human locus that is different from the native locus of any Sangamo Target.
- 1.72 "Sangamo Know-How" means any Know-How Controlled by Sangamo (other than Joint Know-How or Know-How Controlled through the grant of a license by Shire or its Affiliates or Sublicensees hereunder) (a) as of the Amendment Effective Date or (b) that comes into the Control of Sangamo after the Amendment Effective Date and is (A) generated by or on behalf of Sangamo in the course of conducting activities under the Collaboration, (B) developed by Sangamo and related to zinc finger technology, or (C) Controlled by Sangamo pursuant to a Third Party License, that in each case (a) and (b) is (i) necessary to practice the licenses granted to Shire herein or (ii) utilized by Sangamo pursuant to the Research Program in making a Shire ZF Compound or Shire ZF Product or

(iii) part of, used to implement, or directly related to zinc finger technology and useful to practice the licenses granted to Shire herein. For the avoidance of doubt, the Sangamo Know-How does not include any Patent Rights. Notwithstanding anything in this Agreement to the contrary, in the event of a Change of Control of Sangamo, the Sangamo Know-How shall not include any Know-How that is (i) owned or Controlled by a Third Party described in the definition of "Change of Control" prior to the closing of such Change of Control, (ii) developed after such Change of Control without the use of the Sangamo Know-How in existence prior to the closing of such Change of Control, or (iii) developed after such Change of Control and not directly related to zinc finger technology.

- **1.73** "Sangamo Licensed Technology" means all Sangamo Know-How, Sangamo Patent Rights and Sangamo's interest in the Joint Technology. For the avoidance of doubt, Sangamo Licensed Technology shall not include Shire Assigned Patent Rights.
- 1.74 "Sangamo Patent Rights" means Patent Rights Controlled by Sangamo (other than Joint Know-How or Know-How Controlled through the grant of a license by Shire or its Affiliates or Sublicensees hereunder) (a) as of the Amendment Effective Date or (b) that come into the Control of Sangamo after the Amendment Effective Date and claim inventions that are (A) generated by or on behalf of Sangamo in the course of conducting activities under the Collaboration or disclosed in the Patent Rights described in (a) or (B) invented by Sangamo and related to zinc finger technology, or (C) Controlled by Sangamo pursuant to a Third Party License, in each case (a) and (b) that are (i) necessary to practice the licenses granted to Shire herein or (ii) part of, used to implement, or directly related to zinc finger technology and useful to practice the licenses granted to Shire herein. The Sangamo Patent Rights existing as of the Amendment Effective Date are set forth on Schedule 1.74 (it being understood that any Sangamo Patent Right existing as of the Amendment Effective Date that is not set forth on such schedule shall, notwithstanding such omission, still be a Sangamo Patent Right to the extent otherwise provided in this Section 1.74). Notwithstanding anything in this Agreement to the contrary, in the event of a Change of Control of Sangamo, the Sangamo Patent Rights shall not include any Patent Rights owned or Controlled by a Third Party described in the definition of "Change of Control" and (1) existing prior to the closing of such Change of Control, (2) existing after the closing of such Change of Control and claiming inventions made prior to the closing of such Change of Control, or (4) claiming only inventions made after such Change of Control and not directly related to zinc finger technology.
- **1.75** "Sangamo Program" means any program of research, development, manufacture or commercialization with respect to any Sangamo Safe Harbor ZF Compound or Sangamo ZF Product.
 - **1.76** "Sangamo Program License" shall have the meaning set forth in **Section 8.6**.
- **1.77** "Sangamo Safe Harbor ZF Compound" means any ZF Compound used in a Sangamo ZF Product. For the avoidance of doubt, any ZF Compound that was formerly a Sangamo Safe Harbor ZF Compound and that Specifically Binds a Reverted Target shall no longer be a Sangamo Safe Harbor ZF Compound.
- **1.78** "Sangamo Targets" means (a) the Factor VIII gene, as defined by Gene ID 2157 in the NCBI-NLM-NIH GenBank and (b) the Factor IX gene, as defined by Gene ID 2158 in the NCBI-NLM-NIH GenBank, in each case including all naturally occurring mutants or allelic variants of such genes; <u>provided</u>, <u>however</u>, that a Target shall cease to be a Sangamo Target when it becomes a Reverted Target.
 - **1.79** "Sangamo ZF Product" means, with respect to a Sangamo Target:
- (a) a pharmaceutical product or medical therapy for inserting, into the native locus for human serum albumin or any other Safe Harbor Locus a functional version of such Sangamo Target but not any other Target or locus, which product or therapy (i) contains or employs (A) at least two ZF Compounds, each of which Specifically Binds the native locus for human serum albumin or any other Safe Harbor Locus and (B) a Donor Nucleic Acid that encodes a functional version of the mutant protein encoded by such Sangamo Target and (ii) does not contain or employ (A) any ZF Compound that Specifically Binds a Target or other chromosomal location that is not the native locus for human serum albumin or any other Safe Harbor Locus or within the native locus for human serum albumin or any other Safe Harbor Locus, or (B) any Donor Nucleic Acid that encodes a protein (including a functional portion of a larger protein) that is not a protein encoded by such Sangamo Target; or
- (b) a pharmaceutical product or medical therapy that contains or employs a human cell or tissue made using a product or therapy described in **Section 1.79(a).**
 - **1.80** "Sangamo ZF Product Infringement" shall have the meaning set forth in **Section 11.3(a)**.
 - 1.81 "Sangamo ZF Product Infringer" shall have the meaning set forth in Section 11.3(e)(i).
 - **1.82** "Section 2.4 Rejected Target" shall have the meaning set forth in **Section 2.4(c)**.
 - **1.83** "Services" shall have the meaning set forth in Section 3.3.
 - **1.84** "Shire [***] Patent Rights" means [***].

- **1.85** "Shire Know-How" means any Know-How Controlled by Shire or its Affiliates as of the Amendment Effective Date (other than Joint Know-How or Know-How Controlled through the grant of a license by Sangamo or its Affiliates or Sublicensees hereunder) that (a) is or was used with or incorporated in any Sangamo ZF Product in the form that it exists as of the Amendment Effective Date or (b) is necessary or useful to Sangamo in connection with providing the Services. For the avoidance of doubt, the Shire Know-How does not include any Patent Rights. Notwithstanding anything in this Agreement to the contrary, in the event of a Change of Control of Shire, the Shire Know-How shall not include any Know-How that is (A) owned or Controlled by a Third Party described in the definition of "Change of Control" prior to the closing of such Change of Control or (B) developed after such Change of Control without the use of the Shire Know-How in existence prior to the closing of such Change of Control. [***].
 - 1.86 "Shire Licensed Technology" means all (a) Shire Know-How, (b) Shire Patent Rights and (c) Shire's interest in the Joint Technology.
- **1.87** "Shire Patent Rights" means Patent Rights Controlled by Shire or its Affiliates as of the Amendment Effective Date (other than through the grant of a license by Sangamo hereunder) that (a) Cover any Sangamo ZF Product in the form that it exists as of the Amendment Effective Date or (b) Cover Sangamo's performance of the Services in accordance with this Agreement. The Shire Patent Rights existing as of the Amendment Effective Date are set forth on **Schedule 1.87** (it being understood that any Shire Patent Right existing as of the Amendment Effective Date that is not set forth on such schedule shall, notwithstanding such omission, still be a Shire Patent Right to the extent otherwise provided in this **Section 1.87**). Notwithstanding anything in this Agreement to the contrary, in the event of a Change of Control of Shire, the Shire Patent Rights shall not include any Patent Rights owned or Controlled by a Third Party described in the definition of "Change of Control" and (i) existing prior to the closing of such Change of Control or (ii) existing after the closing of such Change of Control and claiming inventions made prior to the closing of such Change of Control or (iii) claiming only inventions made after such Change of Control. [***].
- **1.88** "Shire Program" means any program of research, development or commercialization conducted by or on behalf of Shire or one of its Affiliates or Sublicensees with respect to any Shire ZF Compounds or Shire ZF Products.
- **1.89** "Shire Target" means the Initial Target or the Additional Target designated as a Shire Target pursuant to Section 2.4; provided, however, that a Target shall cease to be a Shire Target when it becomes a Terminated Target. For clarity, the Shire Targets will not include any Sangamo Target.
- **1.90** "Shire ZF Compound" means any ZF Compound that Specifically Binds a particular Shire Target as shown pursuant to the Original Agreement or the activities conducted under the course of the Collaboration. For the avoidance of doubt, any ZF Compound that was formerly a Shire ZF Compound and that Specifically Binds a Terminated Target shall no longer be a Shire ZF Compound.
- **1.91** "Shire ZF Compound Patent Rights" means any Patent Right that contains only claims limited to Shire ZF Compounds. For the purposes of this Section 1.91, a "claim limited to Shire ZF Compounds" means a claim that (a) includes language that specifically describes one or more ZF Compounds that Specifically Bind a particular Shire Target, (b) if presumed to be issued, would not be infringed by a ZF Compound (or the manufacture or use of a ZF Compound) that, after reasonable inquiry (i) at the time such Patent Right is filed or (ii) with respect to a claim that is first proposed after filing, at the time of such initial proposal, is known to not Specifically Bind such Shire Target, if such ZF Compound were combined with the non-ZF Compound elements, if any, in such claim (c) does not include language that specifically describes a product (or the manufacture or use of such product) that is not a Shire ZF Product, and (d) does not include language describing any product (other than a Shire ZF Compound) or process that is Know-How, whether patentable or not, conceived, discovered, invented, created, made or reduced to practice or tangible medium, whether solely or jointly, by one or more employees, agents or contractors of Sangamo, if such Know-How is being protected as a trade secret by Sangamo to support a claim in an existing Patent Right controlled by Sangamo, or is sufficiently disclosed in an existing Patent Right controlled by Sangamo to support a claim to such Know-How in such Patent Right under 35 U.S.C. § 112 (first paragraph), or if Sangamo has not yet filed an intended patent application disclosing or claiming such Know-How (and Sangamo discloses to Shire during the review process described in Section 11.2(a)(i) or (ii), as applicable, that Sangamo intends to file such a patent application), unless Sangamo consents in writing to the inclusion of such Know-How. For clarity, Shire ZF Compound Patent Rights may include both genus and species patent claims that satisfy the criteria set forth above.
 - **1.92** "Shire ZF Product" means, with respect to a Shire Target:
- (a) a pharmaceutical product or medical therapy for deleting, inactivating, repairing, modulating the expression of, or inserting a functional version of, such Shire Target but not any other Target or locus (except, in the case of (i) the Initial Target, (ii) the Additional Target if it was a Reserve Target, or (iii) the Additional Target if it was not a Reserve Target to the extent agreed by the Parties in writing in accordance with Section 2.4(a)), [***]), which product or therapy (i) contains or employs at least one Shire ZF Compound which is known at the time of IND/CTA filing to Specifically Bind such Shire Target, and (ii) does not contain or employ (A) any other ZF Compound that, at the time of IND/CTA filing, is known after reasonable inquiry to Specifically Bind a Target or other chromosomal location that is not such Shire Target or within such Shire Target, or (B) any Donor Nucleic Acid that encodes a protein (including a functional portion of a larger protein) that is neither a protein encoded by such Shire Target nor a functional version of the protein encoded by such Shire Target;

- (b) a pharmaceutical product or medical therapy that contains or employs a human cell or tissue made using a product or therapy described in **Section 1.92(a)**; or
- (c) a diagnostic product or service for detecting the sequence or allele of such Shire Target [***] (to the extent also contained in a Target that is (i) the Initial Target, (ii) the Additional Target if it was a Reserve Target, or (iii) the Additional Target if it was not a Reserve Target to the extent agreed by the Parties in writing in accordance with Section 2.4(a)), which product or service (A) contains or employs one or more Shire ZF Compounds each of which Specifically Binds such Shire Target and (B) does not contain or employ (1) any other ZF Compound that Specifically Binds a Target or other chromosomal location that is not such Shire Target or within such Shire Target, or (2) any Donor Nucleic Acid that encodes a protein (including a functional portion of a larger protein) that is neither a protein encoded by such Shire Target nor a functional version of the protein encoded by such Shire Target.
 - 1.93 "Shire ZF Product Infringement" shall have the meaning set forth in Section 11.3(a).
 - **1.94** "Shire ZF Product Infringer" shall have the meaning set forth in Section 11.3(b)(i).
- 1.95 "Shire ZF Product Patent Rights" means any Patent Right that contains only claims limited to Shire ZF Products. For the purposes of this Section 1.95, a "claim limited to Shire ZF Products" means a claim that (a) includes language that specifically describes one or more Shire ZF Products, (b) if presumed to be issued, would not be infringed by a product (or the manufacture or use of a product) that is not a Shire ZF Product, (c) does not include language that specifically describes a product (or the manufacture or use of such product) that is not a Shire ZF Product, and (d) does not include language describing any product (other than a Shire ZF Compound) or process that is Know-How, whether patentable or not, conceived, discovered, invented, created, made or reduced to practice or tangible medium, whether solely or jointly, by one or more employees, agents or contractors of Sangamo, if such Know-How is being protected as a trade secret by Sangamo, is the subject of a claim in an existing Patent Right Controlled by Sangamo, or is sufficiently disclosed in an existing Patent Right Controlled by Sangamo to support a claim to such Know-How in such Patent Right under 35 U.S.C. § 112 (first paragraph), or if Sangamo has not yet filed an intended patent application disclosing or claiming such Know-How (and Sangamo discloses to Shire during the review process described in Section 11.2(a)(i) or (ii), as applicable, that Sangamo intends to file such a patent application), unless Sangamo consents in writing to the inclusion of such process.
 - **1.96** "[***]" means [***].
- **1.97** "Specifically Bind" means, with respect to a [***]; provided that with respect to (a) the Initial Target, (b) the Additional Target if it was a Reserve Target, or (c) the Additional Target if it was not a Reserve Target but only to the extent that the Parties agreed in writing in accordance with **Section 2.4(a)** that Shire may develop Shire ZF Products directed to [***], the determination of whether a ZF Compound "Specifically Binds" to such Shire Target shall not take into account preclinically or clinically significant effects caused by binding of such ZF Compound to the [***] that are not within such Shire Target.
 - **1.98** "Subcontractor" shall have the meaning set forth in **Section 3.6.**
- **1.99** "Sublicensee" means an Affiliate or Third Party to whom the applicable Responsible Party (or a Sublicensee or Affiliate) has granted a right to make, use, develop, sell, offer for sale or import a Collaboration ZF Product.
 - **1.100** "Sublicensing Party" shall have the meaning set forth in Section 8.3(a).
 - 1.101 "Support Memorandum" shall have the meaning provided in Section 15.5(a)(vii).
- **1.102** "Target" means a human gene, including all naturally occurring mutants or allelic variants of such gene, which contributes to a human disease or medical condition when the gene or the protein encoded by such gene is defective, including regions within such gene ([***]) and regions [***]; provided that such [***] are not in [***] and that the [***] does not affect the expression of [***].
 - 1.103 "Term" shall have the meaning provided in Section 15.1.
 - 1.104 "Terminated Product" shall have the meaning provided in Section 15.5(a)(iii).
- **1.105** "*Terminated Target*" means (a) both Shire Targets upon termination of this Agreement in its entirety by Sangamo pursuant to **Section 15.2** or **Section 15.3** or by Shire pursuant to **Section 15.4** or, if Shire so elects under **Section 15.5(d)** upon its termination pursuant to **Section 15.2** or **Section 15.3**, or (b) a single Shire Target upon termination of such particular Shire Target (but not the Agreement in its entirety) by Sangamo pursuant to **Section 15.2** or by Shire pursuant to **Section 15.4**.
 - **1.106** "Territory" means the entire world.
 - 1.107 "Third Party" means any Person or entity other than Sangamo and Shire (and their respective Affiliates).
- **1.108** "Third Party Licenses" means the Existing Third Party Licenses and any Third Party agreement entered into after the Effective Date that becomes a Third Party License as provided in **Section 11.4(b)** pursuant to which Sangamo Controls any Know-How or Patent Rights licensed under this Agreement.

- **1.109** "Transition Activities" shall have the meaning set forth in **Section 2.2(c).**
- **1.110** "*Transition Period*" shall have the meaning set forth in **Section 2.2(c)**.
- **1.111** "*UPC*" shall have the meaning set forth in **Section 11.3(f).**
- **1.112** "Value Added Tax" or "VAT" means tax applicable under Council Directive 2006/112/EC or any similar or equivalent indirect tax system operated outside of the European Union and any sales, purchase or turnover tax in any applicable jurisdiction.
 - **1.113** "Withholding Tax Action" shall have the meaning set forth in **Section 10.9(b).**
 - **1.114** "ZF Compound" means any zinc finger nucleic acid binding protein and any nucleic acid that encodes such protein.
 - **1.115** "*ZF Product*" means any therapeutic or diagnostic product containing a ZF Compound.

2 OVERVIEW

- **2.1 Effectiveness of Agreement**. This Agreement is in effect from and after the Amendment Effective Date. Without limitation, as of the Amendment Effective Date, all licenses granted to Shire and all obligations of Sangamo and of Shire under the Original Agreement with respect to (a) the Factor VII gene, as defined by Gene ID 2155 in the NCBI-NLM-NIH GenBank and (b) the Factor X gene, as defined by Gene ID 2159 in the NCBI-NLM-NIH GenBank are hereby terminated, and all rights granted by Sangamo to Shire with respect to such genes shall revert to Sangamo.
- **2.2 Factor VIII and Factor IX Program Return**. By amending and restating the Original Agreement as this Agreement, Shire is returning to Sangamo Shire's rights under the Original Agreement with respect to the Sangamo Targets and Sangamo Programs and retaining certain rights with respect to the Shire Targets and the Shire Programs. It is agreed by the Parties that each Party shall have autonomy to develop its own specific programs (i.e., the Shire Programs in the case of Shire and the Sangamo Programs in the case of Sangamo) and for Sangamo to provide research and development support to Shire through the Services and the Operational Activities on a fee-for-service basis as set forth in **Section 3.3**. Specifically, Shire will control and develop the program directed at the Initial Target and one other program directed at the Additional Target to be designated by Shire in accordance with **Section 2.4**, and Sangamo will control and develop those programs directed at the Sangamo Targets. The programs directed at these four Targets will be the only programs to which this Agreement pertains. Accordingly, as of the Amendment Effective Date:

(a) Outstanding Expenses.

- (i) The Parties stipulate and agree that Shire will have no obligation to reimburse Sangamo with respect to any costs relating to the Factor VII or Factor X gene Targets.
- (ii) **Schedule 2.2(a)** sets forth all outstanding internal and external costs incurred by Sangamo under the Original Agreement that are to be reimbursed by Shire under the Original Agreement in connection with programs directed at the Factor VIII and Factor IX genes as of the Amendment Effective Date. Within [***] of the Amendment Effective Date, Sangamo will invoice Shire for all amounts set forth on **Schedule 2.2(a)**; provided that with respect to those external costs that are identified in **Schedule 2.2(a)** as estimated amounts and that have not been invoiced to Sangamo by the applicable Third Party as of the Amendment Effective Date, such invoice will include the applicable estimated amount set forth on **Schedule 2.2(a)**. Shire will not be obligated to reimburse Sangamo for any internal or external cost identified on **Schedule 2.2(a)** that is not invoiced to Shire on or prior to [***] following the Amendment Date.
- (iii) Except for any good faith disputes promptly brought to Sangamo's attention and for which Shire is diligently seeking resolution, Shire shall pay invoices properly submitted by Sangamo under Section 2.2(a)(ii) within 30 days of the date of receipt of the invoice. With respect to any amounts disputed in good faith by Shire pursuant to the preceding sentence, Shire shall pay all such amounts determined or agreed to be due to Sangamo within 30 days of the date of the resolution of such dispute.
- (iv) Shire shall have no further responsibility to reimburse Sangamo, and Sangamo hereby releases Shire and its Affiliates from any obligation to reimburse Sangamo, for any costs or expenses incurred under the Original Agreement, other than (A) those undisputed amounts (or previously disputed amounts that have been determined from a previous resolution or otherwise agreed by the Parties to be due to Sangamo) properly invoiced by Sangamo pursuant to **Section 2.2(a)(ii)** and (B) those costs and expenses incurred as of the Amendment Effective Date in connection with the program directed at the Initial Target, which Sangamo will invoice and Shire will pay in accordance with the Original Agreement. For clarity, Sangamo will invoice, and Shire will pay, all agreed costs associated with the provision of the Services in accordance with this Agreement.
- (b) <u>Assumption of Obligations</u>. Subject to Sangamo's entry into a master services agreement with [***] as described below, Shire shall assign to Sangamo, and Sangamo shall assume, Shire's rights and obligations under the statements of work identified on **Schedule 2.2(b)** (the "SOWs"), which relate solely to the Sangamo Programs. Promptly after the execution of this Agreement, Shire shall put on hold all work under the SOWs, and Sangamo shall initiate negotiations with [***] regarding the terms of a master services agreement between [***] and Sangamo (the "Sangamo MSA"). Unless the Parties otherwise agree in writing

(which agreement may pertain to reserving a slot for [***] to perform work after execution of the Sangamo MSA), all work under the SOWs shall remain on hold until Sangamo notifies Shire that Sangamo and [***] have entered into the Sangamo MSA. Upon such notice, Shire shall notify [***] that the SOWs are no longer subject to the Master Services Agreement between Shire and [***] dated [***] but are instead governed by the Sangamo MSA, and [***] should follow Sangamo's instructions with respect thereto. If Sangamo and [***] have not entered into the Sangamo MSA within [***] after the Amendment Effective Date (or such longer period as the Parties agree upon in writing), then for each SOW Sangamo shall either (a) instruct Shire to have the SOW performed on Sangamo's behalf and reimburse Shire for all amounts owed to [***] under such SOW on account of such performance or (b) instruct Shire to terminate such SOW and reimburse Shire for any termination fees owed to [***] on account of such termination.

- (c) Transition Period. For a period of not more than [***] (the "Transition Period"), at Sangamo's request, Shire will provide Sangamo with reasonable assistance as necessary to effect the timely and orderly transfer of the Sangamo Programs to Sangamo by performing those activities related to the Sangamo Programs attached hereto as Schedule 2.2(c) (the "Transition Activities"). For clarity, Sangamo's requests will specify which Transition Activities it would like Shire to perform, Sangamo may make multiple requests during the Transition Period, and Sangamo's later requests may pertain to Transition Activities that were not the subject of its earlier requests. Sangamo shall pay all Shire FTE costs at the FTE Rate and external costs reasonably incurred by Shire and its Affiliates in the conduct of the Transition Activities in response to Sangamo's requests, up to a maximum total amount of [***]. If Sangamo requests that Shire or its Affiliates incur any Shire FTE costs or external costs in the conduct of the Transition Activities that will exceed such maximum total amount specified for performance of the Transition Activities, then, following Sangamo's agreement in writing to pay for up to a specified amount of additional Shire FTE time or additional external costs (notwithstanding such maximum total amount), Shire will invoice Sangamo for all Shire FTE costs (at the FTE Rate) and external costs reasonably incurred by Shire and its Affiliates in connection with such additional Transition Activities that exceed such maximum total amount but do not exceed such specified amount. For further clarity, after such maximum total amount has been met, Shire shall not be obligated to devote Shire FTE time or incur external costs that exceed the specified amount agreed by Sangamo in advance in writing. Shire shall accrue and report its actual costs quarterly during the Transition Period. Shire shall provide an invoice within five business days of the end of each quarter, with sufficient detail reasonably acceptable to Sangamo (including all statement, receipts or youchers documenting any external costs), for the activities performed during such quarter and external costs invoiced to Shire during such quarter. Subject to any good faith disputes promptly brought to Shire's attention and for which Sangamo is diligently seeking resolution, Sangamo shall pay such invoices within [***] of the date of receipt of the invoice to the extent that (i) such invoices do not collectively exceed the maximum total amount stated above, or (ii) if such invoices do exceed such maximum total amount, Sangamo has agreed with respect to such excess amounts in accordance with this Section 2.2(c). With respect to any amounts disputed in good faith pursuant to the preceding sentence, Sangamo shall pay all such amounts determined or agreed to be due to Shire within [***] of the date of the resolution of such dispute.
- (d) Release. Sangamo, on behalf of itself and each of its Affiliates and each of their respective successors and assigns (collectively, the "Releasors"), do hereby now and forever release, remise, hold harmless and forever discharge Shire, its Affiliates, their employees, agents and representatives and each of their respective successors and assigns (collectively, the "Releasees") of and from all debts, demands, actions, causes of action, suits, accounts, covenants, contracts, agreements, claims, rights, damages, losses or liabilities of any nature, character, or kind whatsoever, both at law or in equity, (each a "Claim") whether known or unknown, suspected or unsuspected, and which arose at any time on or prior to the Amendment Effective Date, or that thereafter could arise based on any act, fact, transaction, matter or cause which occurred on or prior to the Amendment Effective Date arising from, or relating to, the research, development, manufacturing or commercialization of the Sangamo Safe Harbor ZF Compounds or the Sangamo ZF Products, but excluding any Claims arising from or related to the gross negligence or willful misconduct of any Releasees or Shire's breach of the Original Agreement other than its breach of Section 3.2 and Section 5.1 of the Original Agreement (collectively, the "Released Claims"). The Releasors further agree that they will (i) forbear from exercising any rights or remedies against any Releasee in respect of any or all Released Claims and (ii) not commence any lawsuit or bring any legal or equitable action against any Releasee in respect of any Releasee will be an express beneficiary of the rights and releases granted under this Section 2.2(d) and will be entitled to rely on the same as a defense to any suit brought against such Releasee in contravention of the provisions of this paragraph.
- **2.3 Collaboration.** Sangamo shall conduct certain activities to identify and preclinically develop Shire ZF Products for Shire to advance through human clinical trials and bring to patients as commercial therapeutics and diagnostics in the applicable Fields, by performing the activities of the Research Program, which activities are outlined in **Article** 3. The Research Program will focus on Shire Targets. This Agreement will be a joint research agreement under 35 U.S.C. § 103(c)(3) entered into for the purpose of researching, identifying and developing Collaboration ZF Products. For the avoidance of doubt, the Research Program will continue during the Research Term until the completion of all activities under the Research Plans, unless the Agreement is terminated in its entirety as provided in **Article 15.**

- **2.4 Shire Target Selection.** Shire shall have the right to designate one additional Target (the "Additional Target") for inclusion as a Shire Target according to the procedure set forth in **Section 2.4(a)** through **Section 2.4(e)**, to the extent that such Target is not a Section 2.4 Rejected Target and is not a gene that is related to the cause or treatment of any of the following: [***]; provided that if Shire fails to designate the Additional Target by [***] (or [***] if such Additional Target is a Reserve Target), then Shire shall have no further rights to designate the Additional Target, unless Shire's failure to designate the Additional Target by such date results from Sangamo's failure to perform any of its obligations hereunder. Shire may propose up to three proposed Additional Targets that are not Reserve Targets at a given time for inclusion as the Additional Target according to the procedure set forth in **Section 2.4(a)** through **Section 2.4(e)** (but Shire may designate only one Target as the Additional Target).
- (a) <u>Notice to Sangamo</u>. Shire shall provide notice to Sangamo of its proposed Additional Targets and shall include in such notice (i) the nucleic acid sequence and locus identification number of the wild-type allele (as obtained from a mutually agreed publicly available database), (ii) the cell(s) in which the protein encoded by each such proposed Additional Target is normally expressed, (iii) whether the product or therapy of interest to Shire for each such proposed Additional Target would be designed to delete, inactivate, repair, modulate the expression of or insert a functional version of such proposed Additional Target; provided that in no event will Shire have the right to propose or designate an Additional Target for which the product or therapy of interest would be [***], (iv) if such proposed Additional Target is not a Reserve Target, whether Shire intends to develop Shire ZF Products [***] and (v) [***] (collectively, the "Additional Target Notice"). If Shire designates as the Additional Target a proposed Additional Target that is not a Reserve Target, then [***]. For clarity, subject to Section 5.5(c), nothing herein will restrict Shire's ability to freely develop and commercialize Shire ZF Products directed to [***].

(b) Additional Target Clearance.

- (i) *Reserve Targets*. Sangamo shall conduct initial *in silico* feasibility studies for all Reserve Targets prior to [***]. Following completion of the *in silico* feasibility study for the Reserve Targets, the Parties will discuss the results of such studies and potential approaches to address any issues or concerns arising from such studies.
- (ii) Other Proposed Additional Targets. For each proposed Additional Target that is not a Reserve Target, within [***] (or sooner if practicable) of receipt by Sangamo of the applicable Additional Target Notice, Sangamo shall notify Shire whether the proposed Additional Target is an Excluded Target. Following such notification, Sangamo shall conduct initial *in silico* feasibility studies for up to [***] proposed Additional Targets that are not Reserve Targets (and not Excluded Targets) at any given time. Following completion of the *in silico* feasibility study for each proposed Additional Target that is not a Reserve Target, the Parties will discuss the results of such study and potential approaches to address any issues or concerns arising from such study.
- (iii) Feasibility Notice. Prior to [***] with respect to the Reserve Targets, and no later than [***] following Sangamo's receipt of the Additional Target Notice for each proposed Additional Target that is not a Reserved Target, Sangamo shall notify Shire in writing (the "Feasibility Notice") whether or not each Reserve Target or each other proposed Additional Target, as applicable: (A) is not a technically viable candidate for developing ZF Compounds that Specifically Bind such proposed Additional Target for the type of product or therapy identified pursuant to Section 2.4(a)(iii), or (B) is subject to any other substantial, bona fide concern known to Sangamo with respect to developing a Shire ZF Product for such Reserve Target or other proposed Additional Target (as applicable). Such notification under Section 2.4(b)(iii)(A) or Section 2.4(b)(iii)(B) shall include an explanation of the reasons, containing an appropriate level of scientific and technical detail, why the Target is not a technically viable candidate or Sangamo's other substantial and reasonable bona fide concern.
- (iv) *Designation as Additional Target*. Notwithstanding anything to the contrary herein, Shire may in its sole discretion designate a proposed Additional Target as the Additional Target notwithstanding Sangamo's determination that such *in silico* feasibility studies demonstrate that such proposed Additional Target is not a technically viable candidate or is subject to any other substantial, *bona fide* concerns, unless any such concern is a substantial, *bona fide* and reasonable safety concern, in which case the proposed Additional Target will be a Section 2.4 Rejected Target and Shire will not have the right to designate such proposed Additional Target as a Shire Target.
- (v) *Costs.* Sangamo shall provide to Shire an estimate of all FTE costs (at the FTE Rate) and external costs to be reasonably incurred by Sangamo in connection with conducting its activities under this **Section 2.4(b)** and **Section 2.4(d)**, and following Shire's written approval of such proposed budget, Shire shall reimburse Sangamo for all costs included in such approved budget properly invoiced by Sangamo in accordance with **Section 3.3(g)**; provided that such costs do not exceed [***] of such budget approved by Shire; and provided further that Sangamo shall not be obligated to conduct any activities under **Section 2.4(b)** or **Section 2.4(d)** that are not reimbursed by Shire.
- (c) <u>Rejected Targets</u>. If Sangamo notifies Shire that a proposed Additional Target is rejected because the proposed Additional Target is (i) an Excluded Target or (ii) subject to substantial, *bona fide* safety concerns as articulated in the Feasibility Notice under **Section 2.4(b)(iii)** or (iii) subject to the technical viability issues or any other (non-safety-related) concerns articulated in the Feasibility Notice under **Section 2.4(b)(iii)**, and Shire does not notify Sangamo within [***] of Shire's receipt of the Feasibility Notice that Shire is exercising its right pursuant to **Section 2.4(b)(iv)** to proceed with such proposed Additional Target nevertheless (each such rejected Target under (i), (ii) or (iii), a "Section 2.4 Rejected Target"), then such Section 2.4 Rejected Target shall not be included as a Shire Target.

- (d) <u>Target Assessment</u>. If such proposed Additional Target is not a Section 2.4 Rejected Target or a Reserve Target, then Shire shall have [***] from receipt of the Feasibility Notice from Sangamo to conduct a review and evaluation of all relevant intellectual property relating to such proposed Additional Target and the Parties shall discuss the same; provided that Shire shall be solely responsible for all intellectual property assessments concerning such proposed Additional Target. With respect to all Reserve Targets, Shire may conduct its review and evaluation of all relevant intellectual property relating to such proposed Reserve Target at any time, so long as its assessment is complete sufficiently in advance to permit Shire to designate such Reserve Target as the Additional Target prior [***].
- (e) <u>Target Designation</u>. Prior to the end of the review period set forth in **Section 2.4(d)**, Shire shall, in its sole discretion, determine whether to designate a proposed Additional Target as the Additional Target, and shall notify Sangamo of such determination. If Shire does not elect under this **Section 2.4(e)** to designate a proposed Additional Target as the Additional Target by the end of the applicable review period set forth in **Section 2.4(d)**, such proposed Additional Target shall not be the Additional Target and neither Party shall have any rights or obligations to the other Party hereunder in respect of such proposed Additional Target, except as required pursuant to **Article 12**. If Shire does elect under this **Section 2.4(e)** to designate a proposed Additional Target as the Additional Target and it has not designated any other proposed Additional Target as the Additional Target, then such proposed Additional Target shall become the Additional Target and the Parties shall not have any further obligations under **Section 2.4** (other than Shire's obligation to reimburse Sangamo pursuant to **Section 2.4(b(v))**. If Shire does not designate any proposed Additional Target as the Additional Target and it has not designated any other proposed Additional Target as the Additional Target and it has not designated any other proposed Additional Target as the Additional Target as the Additional Target and it has not designated any other proposed Additional Target as the Additional Target and it has not designated any other proposed Additional Target as the Additional Target as the Additional Target and it has not designated any other proposed Additional Target as the Parties will repeat the process under this **Section 2.4**, to the extent applicable, provided that if the desires to propose a potential Additional Target that is not a Reserve Target or (ii) if such Target is not a Section 2.4 Rejected Target, the end of the [***] review period in **Section 2.4(d)**, as applicable; provided that, subject to the proviso
- (f) No Encumbrance of Reserve Targets. Sangamo shall ensure that at all times prior to the earlier of [***] or the date of Shire's designation of the Additional Target, (i) clauses (b) and (c) of the definition of Excluded Target do not apply to any Reserve Target and (ii) the nucleic acid sequence of the allele to be targeted by Sangamo or a Third Party licensee with respect to a Target described in clauses (b) and (c) of the definition of Excluded Target is not a [***] of a Reserve Target. For the avoidance of doubt, the [***] for each Reserve Target are identified on **Schedule 1.65.**

3 RESEARCH PROGRAM; RESEARCH TERM

- **3.1 Sangamo Responsibilities.** Subject to the terms of this Agreement, Sangamo shall be solely responsible for the management and direction of the Sangamo Programs in its sole discretion and at its sole cost and expense.
- **3.2 Shire Responsibilities.** Subject to the terms of this Agreement, Shire shall be solely responsible for the management and direction of the Shire Programs in its sole discretion and at its sole cost and expense. Without limitation, Shire shall be responsible for oversight of the Research Program during the Research Term and Development Plans, including activities conducted pursuant to the Research Plans, Development Plans, preclinical work, and IND/CTA submissions for each Shire Target.
- **3.3 Research and Development Services**. Shire may, in its sole discretion, engage Sangamo to provide certain (i) research and development services with respect to a Shire Target to identify or support the preclinical development of Development Candidates, to the extent that such services are described on **Schedule 3.3** (together with the Exclusive Services, the "*Services*"), and (ii) Operational Activities, which Services and Operational Activities will be described in one or more Research Plans executed by the Parties, and Sangamo hereby agrees to provide such Services and Operational Activities to Shire.
- (a) <u>Exclusive Services</u>. Solely with respect to the Exclusive Services (and no other Services), Shire shall engage only Sangamo (and no other Third Party) under this **Article 3** to conduct the Exclusive Services for the Additional Target.
- (b) Non-Exclusive Services. Nothing herein will prevent Shire from performing, or having performed on its behalf by any Third Party, any service described on **Schedule 3.3** (other than Exclusive Services), including [***] of Shire ZF Products prior to Development Candidate Selection. If Shire wishes to conduct (or have conducted) such [***], then Sangamo shall disclose [***] to Shire or its designee solely to the extent [***] that will include [***] provided, however, that Sangamo's agreement to such [***]. In any event, however, Shire will not have access to (nor will Shire reverse engineer or have reverse engineered) [***], whether such [***] is conducted by Shire or by a Third Party, and Shire will only receive access after [***]. Instead, prior to such [***], Sangamo will serve as the intermediary to the degree that [***] are to be transferred to any Third Party engaged by Shire to perform such [***]; provided, however, that Sangamo will not be obligated to serve as such an intermediary unless such Third Party enters into a confidentiality agreement with Sangamo that reasonably restricts such Third Party's disclosure and use [***]. Shire shall and hereby does, or shall cause the applicable Third Party to, [***]; provided that Shire shall [***] in the course of [***].

- (c) <u>Performance of the Exclusive Services [***</u>]. If Sangamo materially breaches its obligation to provide the Exclusive Services in accordance with the terms of this Agreement or as set forth in a Research Plan and fails to cure such breach within [***] days of receiving written notice thereof from Shire, then, at Shire's election (A) Shire may immediately terminate this Agreement in accordance with **Section 15.2**; provided that no additional cure period will be afforded to Sangamo or (B) in lieu of termination of this Agreement, Shire may cause the following to apply by providing written notice to Sangamo, in which case the following will be Shire's sole remedy for such material breach:
 - (i) the exclusivity restrictions set forth in **Section 3.3(a)** will not apply to the applicable Exclusive Services and [***];
- (ii) Sangamo shall disclose [***] that is required to enable the performance of such Exclusive Services [***], in accordance with a procedure to be mutually agreed by the Parties that will include reasonable safeguards to protect the confidentiality of Sangamo's trade secrets; provided that agreement to such procedure by Sangamo shall not be unreasonably withheld, conditioned or delayed; and
- (iii) Sangamo shall reimburse Shire for the external costs to be incurred by Shire in connection with having [***] perform such Exclusive Services.
- (d) Research Plan Content. All research and development Services and Operational Activities to be performed with respect to each Shire Target shall be set forth in one or more separate Research Plans developed by Shire and mutually agreed by the Parties; provided that agreement to the Research Plan by Sangamo shall not be unreasonably withheld, conditioned or delayed. The objective of all Services performed under each Research Plan with respect to each Shire Target will be to achieve Development Candidate Selection for at least one Shire ZF Product for such Shire Target and to perform any other additional research and development activities mutually agreed to by the Parties following such Development Candidate Selection; provided that in no event will Sangamo be obligated to conduct any activities required for Development Candidate Selection that are not described on Schedule 3.3 unless otherwise agreed by Sangamo in a Research Plan executed by the Parties. Each Research Plan will contain (i) a work plan and timeline, (ii) a description of the specific activities to be performed by Sangamo, including all Operational Activities, and the planned monthly FTE usage and maximum total number of hours that Sangamo is obligated to spend on each such Operational Activity, and (iii) an estimate, to be proposed by Sangamo and mutually agreed to by the Parties in advance of execution of the applicable Research Plan, of the FTE costs (at the FTE Rate) and the external costs to be incurred by Sangamo in the performance of the Services and Operational Activities to be provided pursuant to such Research Plan (for each Research Plan, the "Budget"). In addition, each Research Plan shall identify a Sangamo project leader, reasonably acceptable to Shire, which project leader shall devote no less than [***] of his or her time to carrying out the Research Plan during the active conduct of such Research Plan prior to Development Candidate Selection thereunder, and will participate in the working team in accordance with Section 3.4(a). Each Research Plan shall be consistent with the terms of this Agreement and shall be appended to and form a part of this Agreement. Upon execution of a Research Plan by both Parties, such Research Plan shall become effective as of the date so indicated. Sangamo shall perform the Services consistent with this Agreement and the applicable Research Plan. In the event of an inconsistency between a Research Plan and this Agreement, the terms of this Agreement will prevail except to the extent the Research Plan expressly provides that it is intended to override this Agreement. The initial Research Plan for the Initial Target as of the Amendment Effective Date, which may be subsequently modified by the Parties in accordance with **Section 3.3(e)**, is set forth in **Schedule 3.3(d)**.

(e) Research Plan and Budget Changes.

- (i) Each Research Plan shall be reviewed and updated as necessary, but at least [***], by Shire, subject to Sangamo's approval as described below. Sangamo will have the right to review and comment on each Research Plan, and all updates thereto. Changes to the Services (including the scope or timeline thereof) included in a Research Plan, or any Budget therein, or the provision of any service or activity by Sangamo not set forth in a Research Plan, may in each case only be made by mutual agreement of the Parties in writing; provided that if Shire requests that Sangamo perform additional [***] services within [***] months after the delivery of the Final Research Report pursuant to Section 3.4(d) to [***] pursuant to the Research Program that have [***], then Sangamo will perform such services upon Shire's request (and such services will be "Services" for the purposes of this Agreement regardless of whether they are identified in a Research Plan) and Shire will reimburse Sangamo for its FTE costs (at the FTE Rate) and external costs incurred in the course of performing such screening services.
- (ii) If Shire wishes to change or terminate the scope of the Services included in a Research Plan, then Shire shall so advise Sangamo and shall submit a proposed amendment with detailed specifications to Sangamo. Upon receiving such proposed amendment, Sangamo shall provide Shire with its written estimate of the FTE costs (at the FTE Rate) and external costs associated with performing the changed or additional services, and such additional costs will be included in the applicable Budget. In addition, if Sangamo reasonably anticipates that the costs of conducting, or having a Subcontractor conduct, any activity set forth in a Research Plan will exceed the amount set forth in the then-current Budget therefor, Sangamo may notify Shire and request a change to the Budget. Such notification shall include a Sangamo proposed budget change, which shall identify the activity and cost differences from the existing Budget. The Parties shall in good faith discuss all such changes to the Services requested by Shire or changes to any Budget proposed by Sangamo and will use good faith efforts to agree to any such changes within [***] of a Party's request therefor. If

the Parties are unable to agree on the specific terms of any such amendment, no changes shall be made. Further, if (i) the Parties are unable to agree with respect to the terms of any amendment to the Services or the provision by Sangamo of any new service or activity not set forth in the Research Plan, or (ii) Shire does not agree to any Budget change requested by Sangamo for any activity set forth in a Research Plan, then in each case Sangamo shall not be obligated to conduct, or cause any Subcontractor to conduct, any such activity that will not be fully reimbursed by Shire, and Shire shall have the right to perform such activity itself or freely subcontract such activity to any Third Party; provided, however, if failure to agree relates to any Exclusive Service, then Shire may [***] and (A) the exclusivity restrictions set forth in Section 3.3(a) will not apply to Shire's subcontracting of such activity [***] and (B) the terms of Section 3.3(c)(ii) will apply.

- (f) <u>Budgeted Costs</u>. Shire shall pay the Sangamo FTE costs (at the FTE Rate) and external costs incurred by Sangamo and its Affiliates in the conduct of Services in accordance with the Budget set forth in the applicable Research Plan. The FTE costs will be calculated using the FTE Rate and the number of FTEs will be calculated based on the average of the applicable percentage of weekly time attributable to the Research Program for each FTE, based on a [***] hour week, up to a maximum of [***] hours per week for each FTE. For the avoidance of doubt, external costs will be passed through to Shire with no mark-up by Sangamo. Following approval of a Budget variances from such Budget [***] shall be paid by Sangamo in accordance with Section 3.3(e), unless otherwise agreed to by Shire, other than with respect to amounts incurred by Sangamo for time spent for a particular Operational Activity in excess of the amount of time set forth in the Research Plan for such activity. Solely with respect to the Operational Activities, any assistance by Sangamo to Shire or communications between Sangamo and Shire that exceed the number of hours allocated to the applicable Operational Activity in the Research Plan will not be within the scope of the Research Plan or Budget. Instead, following Shire's request that Sangamo conduct the applicable Operational Activity, Sangamo will invoice Shire for all Sangamo FTE costs (at the FTE Rate) and external costs reasonably incurred by Sangamo and its Affiliates in connection with such additional activities in accordance with Section 3.3(g).
- (g) Invoices. Sangamo shall accrue its actual costs quarterly. Sangamo shall provide an invoice of such actual costs within [***] days of the end of each quarter, with sufficient detail reasonably acceptable to Shire (including all statement, receipts or vouchers documenting any external costs), for the activities performed during such quarter and external costs invoiced to Sangamo during such quarter. For activities set forth in the Research Plan (other than the Operational Activities), the actual number of FTEs or external costs reported in the invoice may not [***] of the expected number based on each Budget for each Research Plan; provided that the actual number is consistent with, and not more than [***], the overall Budget for a particular Research Plan. Shire shall have no obligation to pay Sangamo any amount that (i) is more than [***] the Budget for any Research Plan in any quarter, or (ii) exceeds [***] the overall Budget under a Research Plan most recently agreed by the Parties. Activities requested by Shire to be performed by Sangamo and not set forth in the Research Plan, and Operational Activities (to the extent that Sangamo expends more time than specified for such activity in the applicable Research Plan) are not subject to the preceding sentence. On a monthly basis, with respect to each Operational Activity set forth in each Research Plan, Sangamo shall provide written notice to Shire summarizing (i) a good faith estimate of the number of hours Sangamo has then spent toward such Operational Activity in such month and (ii) the number of hours forecasted to be spent by Sangamo on such Operational Activity in the upcoming month; provided, however, that the numbers of hours set forth in such monthly notices shall not be binding upon either Party and shall not limit or reduce the amounts that Shire would otherwise be obligated to pay pursuant to this Section 3.3. For clarity, and notwithstanding anything to the contrary set forth herein, Shire will not be required to reimburse Sangamo for any time spent on Operational Activities in excess of the maximum number of hours set forth in the applicable Research Plan unless Shire has agreed in advance in writing with respect to such excess time. For further clarity, Sangamo shall not be obligated to spend more time on any Operational Activity than the excess time agreed by Shire in advance in writing.
- (h) <u>Ongoing Knowledge Transfer</u>. In the course of performing Services, Sangamo will transfer to Shire all Sangamo Know-How (i) developed under the Services or (ii) reasonably requested by Shire and not previously provided to Shire, in each case by providing copies of requested documentation, materials and other embodiments of such technology, and by making available its qualified technical personnel as set forth under the applicable Research Plan to consult with Shire with respect to such technology or as otherwise reasonably requested by Shire. If the amount of time requested by Shire with respect to such technical assistance exceeds the maximum number of hours Sangamo is obligated to spend on such activity under the applicable Research Plan, then Shire shall reimburse Sangamo's FTE costs (at the FTE Rate) and external costs of such technical assistance (with no mark-up thereon). Except as provided under **Section 3.3(c)(ii)**, Sangamo shall have no obligation to transfer Know-How relating to the provision of the Exclusive Services.
- (i) <u>Quality and Timeliness</u>. Sangamo shall perform the Services using at least the same degree of care and effort that it uses to perform similar services on its own behalf for its own programs, and using qualified personnel with sufficient skill and experience and will use Commercially Reasonable Efforts to perform the Services in compliance with the timelines and work plan set forth in the Research Plan.

3.4 Conduct.

- (a) <u>Working Teams</u>. The Parties will form a working team for each Research Plan comprising at least the project leader for the Research Plan (who will be a Shire employee) and the Sangamo team leader (who will be a Sangamo employee) and one or more representatives from each of Shire and Sangamo, which team will stay in active communication about activities taking place and Results arising under the respective Research Plan. This team shall confer regularly to ensure close cooperation and exchange of information between the Parties as Sangamo fulfills its responsibilities under the Research Program. The working teams will not have decision making authority, but will facilitate the day-to-day implementation of the Research Plans. If the amount of time requested by Shire with respect to such participation on the working teams exceeds the maximum number of hours Sangamo is obligated to spend on such activity under the applicable Research Plan, then Shire shall reimburse Sangamo's FTE costs (at the FTE Rate) and external costs of such participation (with no mark-up thereon).
- (b) <u>Materials Transfer</u>. To facilitate the conduct of the Research Program or a Development Plan, or otherwise pursuant to **Section 5.4(d)**, either Party may provide to the other Party certain biological materials or chemical compounds owned by or licensed to the supplying Party for use by the other Party (such materials or compounds and any progeny and derivatives thereof, collectively, "*Materials*"). All such Materials shall remain the sole property of the supplying Party, shall be used only in the fulfillment of obligations or exercise of rights under this Agreement and solely under the control of the receiving Party, shall not be used or delivered to or for the benefit of any Third Party without the prior written consent of the supplying Party, and shall not be used in research or testing involving human subjects, unless expressly agreed. The Materials supplied under this **Section 3.4(b)** are supplied "as is" and must be used with prudence and appropriate caution in any experimental work, since not all of their characteristics may be known.
- (c) <u>Interim Research Reports</u>. During the Research Term, if Shire would like a report summarizing the Services performed by Sangamo under the Research Plans over any time period (each, an "*Interim Research Report*") Sangamo will provide any and all necessary or useful Results, information, raw data, data sets, protocols and analysis performed under the Services to enable Shire to prepare a draft of such report for Sangamo's review and revision. Sangamo shall review and revise each such draft Interim Research Report in accordance with the applicable amount of time set forth under the applicable Research Plan.
- (d) Final Research Report. With respect to the Research Program for each Shire Target, no later than [***] days after completion of Sangamo's Services and all Operational Activities contemplated at such time under such Research Program in accordance with the Research Plan, Sangamo shall prepare and submit to Shire a final written report summarizing all activities undertaken and all accomplishments achieved in connection with such Research Program in a format set forth in the Research Plan (each, a "Final Research Report"). Each Final Research Report shall contain a complete and accurate description of the results and conclusions of the Services under the applicable Research Plan, including (i) a list of all [***] set forth in the applicable Research Plan or any amendment thereto, including [***] that have [***] with more than [***], (iii) a summary of all [***] under such Research Program, in hard copy and electronic format, including relevant [***], (iv) [***] and (v) written updates to Schedule 1.74 as necessary based on applicable [***] or [***]. The contents of each Interim Research Report and Final Research Report shall be considered Confidential Information of both Parties until Development Candidate Selection by Shire, and will be considered Confidential Information of Shire following such Development Candidate Selection by Shire, and in each case shall be subject to the rights and obligations of the Parties under Article 12. If the amount of time requested by Shire with respect to assistance and preparation of the Interim Research Reports and Final Research Reports exceeds maximum number of hours Sangamo is obligated to spend on such activity under the applicable Research Plan, then Shire shall reimburse Sangamo's FTE costs (at the FTE Rate) and external costs of such assistance (with no mark-up thereon).
- **3.5 Development Candidate Selection**. With respect to each Shire Target, Shire will have the option to designate as Development Candidates one or more [***] of potential Development Candidates in any Interim Research Report or the Final Research Report ("Development Candidate Selection") in its sole discretion. Shire may make a Development Candidate Selection for a Shire ZF Compound at any time during the Term by delivering a written notice to Sangamo indicating that it elects to designate such Shire ZF Compound as a Development Candidate. Shire will not file an IND/CTA for any [***] that Shire has not designated as a Development Candidate pursuant to this **Section 3.5**.
- **3.6 Subcontractors.** In performing its activities under any Research Plan and this Agreement, Sangamo may engage any consultant, subcontractor, or other vendor to conduct Sangamo's obligations under a Research Plan (each, a "Subcontractor"); provided that all such engagements and any contracts related to such engagements are approved in advance by Shire and identified in the applicable Research Plan or an executed amendment thereto. To facilitate approval of all Subcontractors by Shire, Sangamo shall identify each Subcontractor, the activities proposed to be performed by such Subcontractor and the budget for such activities. Shire in its discretion may request a copy of the proposed contract with the Subcontractor prior to approving such contract, and any agreement with a permitted Subcontractor pertaining to the Research Program shall be consistent with the provisions of this Agreement. Without limitation, such contracts entered into with Third Party Subcontractors shall contain provisions, including those relating to intellectual property, confidentiality and non-use, adequate for Shire to enjoy the licenses and assignments granted hereunder as though Sangamo had performed the contracted work itself and that are no less stringent than those set forth in this Agreement. For the avoidance of

doubt, during the period prior to Sangamo's transfer of information and materials to Shire pursuant to Section 3.3(h) or Section 5.4(b) (as applicable), Sangamo shall, and shall require its Affiliates and any Subcontractor to, maintain such information and materials as required by law in connection with any IND or CTA anticipated to be filed in connection with the applicable ZF Compound or ZF Product. Sangamo shall be responsible for the management of its permitted Subcontractors. The engagement of any Subcontractor in compliance with this Section 3.6 shall not relieve Sangamo of its obligations under this Agreement or any applicable Research Plan.

3.7 Compliance. In performing its activities under any Research Plan and this Agreement, Sangamo will, and will require its Affiliates and any Subcontractor to, comply with all applicable laws, regulations and guidelines concerning such manufacturing and development activities. In no event shall Sangamo conduct, or be obligated to conduct, any activities under a Research Program or otherwise for Shire in compliance with Good Manufacturing Practices or GLP (or similar standards) for the performance of laboratory activities as are required by applicable law.

3.8 Records.

- (a) Research Records Sangamo shall create and maintain, and cause its employees and Subcontractors to maintain, written records and laboratory notebooks of the data and other information generated or recorded in the performance of the Services (collectively, the "Results") and all such Results shall be Know-How created under the course of the Collaboration and subject to applicable terms of this Agreement. Sangamo will maintain all such Results in sufficient detail and in a good scientific manner appropriate for (i) inclusion in filings with regulatory authorities, and (ii) obtaining and maintaining intellectual property rights and protections, including Patent Rights. Such Results shall be complete and accurate in all material respects and shall fully and properly reflect all work done, data and developments made, and results achieved. Laboratory notebooks shall be signed, dated and witnessed on a regular basis. During the Research Term Sangamo shall periodically, but not less than [***], allow Shire to inspect and, to the extent necessary or useful for such regulatory or intellectual property protection purposes, copy such Results.
- (b) Expense Records. Sangamo shall maintain complete and accurate books, records and accounts used for the determination of FTEs and external expenses incurred in connection with the performance of the Services, in sufficient detail to confirm the accuracy of any payments required under this Agreement, which books, records and accounts will be retained by Sangamo for three years after creation of the individual records, or longer as is required by applicable law. Such books, records and accounts shall be kept in accordance with U.S. GAAP and Sangamo's then-current accounting procedures. For the avoidance of doubt, if Sangamo's then-current accounting procedures are not U.S. GAAP compliant, then Sangamo shall alter its accounting procedures such that they are U.S. GAAP compliant.

3.9 Shire Audit Rights.

- (a) <u>Audit Frequency</u>. Upon [***] advance written notice by Shire and not more than once in each calendar year, Sangamo and its Affiliates shall permit an independent certified public accounting firm of internationally-recognized standing, selected by Shire and reasonably acceptable to Sangamo, at Shire's expense, to have access during normal business hours to such of the records of Sangamo and its respective Affiliates as may be reasonably necessary to verify the accuracy of the invoices provided by Sangamo to Shire pursuant to **Section 3.3(g)** for any year ending not more than 18 months prior to the date of such request. No year may be audited more than once, except for cause. The accounting firm will enter a confidentiality agreement reasonably acceptable to Sangamo governing the use and disclosure of Sangamo's information disclosed to such firm, and such firm shall disclose to Shire only whether the invoices are correct or not and the specific details concerning any discrepancies, which information shall be Confidential Information of Sangamo.
- (b) Overpayments. Unless disputed by Shire or Sangamo in good faith, if such accounting firm concludes that the amounts paid during the audited period were more or less than the amounts actually due to Sangamo, Shire shall pay any additional amounts due, and Sangamo will refund any amounts overpaid, in each case plus interest as set forth in **Section 10.12**, within 30 days after the date the written report of the accounting firm so concluding is delivered to Sangamo and Shire. The fees charged by such accounting firm shall be paid by Shire; provided that if the audit discloses that the amounts payable by Shire for such period have been overpaid by more than [***] percent, then, subject to **Section 3.9(c)**, Sangamo shall pay the reasonable fees and expenses charged by such accounting firm.
- (c) <u>Audit Disputes</u>. In the event of a good faith dispute by Shire or Sangamo regarding the result of an audit made pursuant to this **Section 3.9**, the Parties shall agree in good faith on an alternative independent certified public accounting firm of internationally-recognized standing to perform a second audit. If such audit is requested by Shire because Shire was found by the initial audit to have underpaid and the second audit confirms that Shire underpaid, then Shire shall bear all costs associated with the second audit to have overpaid and the second audit confirms that Shire overpaid, then Sangamo shall bear all costs associated with the second audit. Notwithstanding the above, in the event that the second audit confirms the findings of the first audit, the requesting Party shall pay. No over or under payment indicated by the initial audit shall be payable in the event of a dispute until the second audit is complete and such second audit shall be binding on the Parties, with any under or over payment determined thereby, plus interest as set forth in **Section 10.12**, being payable within 30 days after the date the written report of the accounting firm so concluding is delivered to Sangamo and Shire.

(d) <u>Confidential Treatment</u>. Shire shall treat all financial information disclosed by its accounting firm pursuant to this **Section 3.9** as Confidential Information of Sangamo for purposes of **Article 12** of this Agreement, and shall cause its accounting firm to do the same.

4 RESEARCH COMMITTEE

- **4.1 Composition**. The Research Committee shall be formed as soon as practicable, but no later than 30 days following the Amendment Effective Date. The Research Committee shall be comprised of an equal number of representatives from each Party, up to four and initially two. Each Party shall promptly notify the other Party in writing of its initial representatives to the Research Committee, and may substitute one or more representatives from time-to-time effective upon written notice to the other Party. A designated representative [***] shall be responsible for setting the agenda for meetings of the Research Committee, with input from the other members, and for conducting the meetings of the Research Committee.
- **4.2 Meetings**. The Research Committee shall meet in person or by teleconference not less than twice per year during the Research Term. Subject to the preceding sentence, the Research Committee shall meet on such dates and at such times and places as agreed to by the members of the Research Committee. Meetings may be in person or by tele- or videoconference. Shire shall be responsible for all its own expenses relating to attendance at or participation in Research Committee meetings, and shall reimburse all external costs incurred by Sangamo (without markup) in connection with preparing for, traveling to, attending and participating in such meetings. If the amount of time requested by Shire with respect to Sangamo's participation on the Research Committee exceeds the maximum number of hours Sangamo is obligated to spend on such activity under the applicable Research Plan, then Shire shall reimburse Sangamo's FTE costs (at the FTE Rate) of such participation. Within 10 days following each Research Committee meeting, Shire shall cause to be prepared and will provide to Sangamo a draft of reasonably detailed written minutes describing all matters discussed at each meeting of the Research Committee and shall provide to all representatives of the Research Committee copies of all Interim Research Reports and Final Research Reports as may be presented and discussed at each Research Committee Meeting. The minutes and the drafts of any minutes shall be the Confidential Information of both Parties.
- **4.3 Information Exchange.** The Research Committee will be an information sharing and discussion body only and will review and discuss the activities being performed under the Research Program or a Development Plan (to the extent relevant), all Results generated under each Research Plan and all Interim Research Reports and Final Research Reports. Additionally, with respect to each Research Plan, the project leader for each Research Plan will, for information purposes only, (a) at least one Research Committee meeting each year, present to the Research Committee each then-current Research Plan and (b) at each meeting, present to the Research Committee an update of the key activities conducted and Results achieved under each then-current Research Plan.

5 DEVELOPMENT AND COMMERCIALIZATION

- **5.1 Shire's Diligence Obligations.** Shire shall: (a) use Commercially Reasonable Efforts to file [***]; (b) for each Shire Target for which an IND or CTA is filed for a Shire ZF Product directed to such Shire Target, use Commercially Reasonable Efforts to obtain Marketing Approval for at least one therapeutic Shire ZF Product directed to such Shire Target in the United States or at least one Major European Country; and (c) use Commercially Reasonable Efforts to [***] each Shire ZF Product in [***]. Sangamo's sole and exclusive remedy for any breach by Shire of this **Section 5.1** shall be [***].
- **5.2 Sangamo's Diligence Obligations.** Sangamo shall: (a) use Commercially Reasonable Efforts to file an IND or CTA for at least one Sangamo ZF Product that contains or employs [***]; (b) for each Sangamo Target for which an IND or CTA is filed for a Sangamo ZF Product directed to such Sangamo Target, use Commercially Reasonable Efforts to obtain Marketing Approval for at least one therapeutic Sangamo ZF Product directed to such Sangamo Target in the United States or at least one Major European Country; and (c) use Commercially Reasonable Efforts to commercialize each Sangamo ZF Product in each country in which Marketing Approval of such Sangamo ZF Product is obtained. Shire's sole and exclusive remedy for any breach by Sangamo of this **Section 5.2** shall be [***].
- **5.3 Shire Responsibilities.** After Development Candidate Selection, other than any Services to be provided by Sangamo, subject to **Section 5.1**, Shire shall assume sole responsibility for and have sole discretion over all development, regulatory, manufacturing and commercialization activities for Shire ZF Products (including any Shire ZF Compounds included therein), including (a) the planning, execution and submission of, and expenses associated with, IND-Enabling Studies and clinical trials of such Shire ZF Products; (b) the selection of the countries in which Shire will pursue and maintain Marketing Approvals for such Shire ZF Products and expenses related to obtaining and maintaining such Marketing Approvals; and (c) commercialization of such Shire ZF Products in the Territory and expenses associated with the commercialization of such Shire ZF Products. Shire and its Affiliates shall comply with all applicable laws, regulations and guidelines in conducting its clinical development, manufacturing and commercialization activities under this Agreement; provided, however, that Sangamo's sole remedy for Shire's or its Affiliate's breach of this last sentence of **Section 5.3** will be [***], and Sangamo will have [***].

5.4 Sangamo Responsibilities.

- (a) <u>Sangamo ZF Products</u>. Subject to **Section 5.2**, Sangamo shall have sole responsibility for and sole discretion over all development, regulatory, manufacturing and commercialization activities for Sangamo ZF Products (including any Sangamo Safe Harbor ZF Compound included therein), including (a) the planning, execution and submission of, and expenses associated with, IND-Enabling Studies and clinical trials of such Sangamo ZF Products; (b) the selection of the countries in which Sangamo will pursue and maintain Marketing Approvals for such Sangamo ZF Products and expenses related to obtaining and maintaining such Marketing Approvals; and (c) commercialization of such Sangamo ZF Products in the Territory and expenses associated with the commercialization of such Sangamo and its Affiliates shall comply with all applicable laws, regulations and guidelines in conducting its clinical development, manufacturing and commercialization activities under this Agreement; provided, however, that Shire's sole remedy for Sangamo's or its Affiliate's breach of this last sentence of **Section 5.4(a)** [***], and Shire will have [***] by Sangamo or its Affiliates.
- (b) <u>Selection Knowledge Transfer</u>. No later than [***] days following each Development Candidate Selection, and in accordance with the Research Plan, with respect to such Development Candidate, Sangamo will complete the transfer to Shire of all of the following, to the extent not already in Shire's possession: (i) Results, (ii) a written summary, in a form specified in the Research Plan, of all [***] activities (including [***]) for the applicable Target performed by Sangamo under the applicable Research Plan and (iii) all relevant Sangamo Know-How (including synthesis protocols and documentation) necessary or useful (to the extent actually used by Sangamo at such time or in the course of the Collaboration with respect to the applicable Shire Target) for Shire to manufacture supplies of such Shire ZF Product according to the specifications and manufacturing techniques then in use by Sangamo for such Shire ZF Product [***]. Sangamo will provide such technical assistance Services to Shire as necessary to complete the transfer of such Sangamo Know-How in accordance with the Research Plan. If the amount of time requested by Shire with respect to such transfer or technical assistance exceeds the maximum number of hours Sangamo is obligated to spend on such activity under the applicable Research Plan, then Shire shall reimburse Sangamo's FTE costs (at the FTE Rate) and external costs of such technical assistance (with no mark-up thereon). In addition, reasonably promptly after the date on which Shire provides notification to Sangamo of Development Candidate Selection, (A) Sangamo will supply to Shire any then-existing supplies of any and all such Shire ZF Product (including any applicable Shire ZF Compound included therein) manufactured by or on behalf of Sangamo (except to the extent that any such supplies need to be retained by Sangamo or its manufacturer, consistent with the requirements of regulatory authorities or otherwise as required by law), and (B) to the extent any manufacturing contracts between Sangamo a
- (c) Ownership Assignments. Following each Development Candidate Selection by Shire, with respect to such Development Candidate, Sangamo shall (i) promptly transfer to Shire all information and materials in Sangamo's possession and Control that are required, or could reasonably be expected to be required, whether by law, regulation or otherwise, to be maintained by the holder of an IND/CTA, or that are useful or necessary to file an IND/CTA, (ii) for any information and materials of the type otherwise described in clause (i) but that are in Sangamo's Control and in the possession of a Third Party service provider, Sangamo will either (A) if requested by Shire, assign to Shire such contract (which contract Shire shall assume), to the extent assignable, or (B) if not assignable (either by its terms or because it does not relate solely to such Shire ZF Product), provide access to such information and materials to Shire; provided that Shire bears all costs for maintenance of and access to such information and materials, (iii) provide Shire access, to the extent reasonably requested by Shire and necessary or useful for Shire to pursue the clinical development and Marketing Approval of (or the maintenance of Marketing Approval of) such Shire ZF Product, to any information and materials in Sangamo's Control that are related to such Shire ZF Product and used or generated in conducting activities under the applicable Research Plan but are not addressed in clause (i) or (ii), which information and materials Sangamo shall maintain for two years following Development Candidate Selection and shall not thereafter destroy without providing Shire notice and the opportunity to access such information and materials, and (iv) provide, at Shire's expense (including FTE costs and external costs), such Services as Shire may reasonably request to assist Shire in the clinical development, Marketing Approval and commercialization of such Shire ZF Product during the Royalty Period for such Shire ZF Product, to the extent that such activi
- (d) Shire ZF Compound Changes. If, after completion of activities under a Research Plan for a Shire Target, Shire desires [***] of one or more Shire ZF Compounds in the Shire ZF Product directed to such Shire Target (regardless of whether they have been designated as Development Candidates pursuant to Section 3.5), Shire shall notify Sangamo in writing, identifying the proposed change; provided that any [***] to a Shire ZF Compound shall not change the Shire Target to which such Shire ZF Compound Specifically Binds and shall not cause such Shire ZF Compound to Specifically Bind any other Target or chromosomal location other than the Shire Target. For clarity, Shire shall not have the right under this Section 5.4(d) [***] Shire ZF Compound for the purpose of [***]. Within [***] days following Sangamo's receipt of such notice from Shire, Sangamo shall notify Shire in writing whether (i) Sangamo will conduct the necessary Services to change one or more Shire ZF Compounds in such Shire ZF Product, in which case Sangamo shall use Commercially Reasonable Efforts to [***] ZF Compound, at Shire's expense, pursuant to a new Research Plan in

accordance with the terms of **Section 3.3** or (ii) Sangamo declines to conduct any necessary Services. If Sangamo declines to conduct any necessary Exclusive Services pursuant to the preceding clause (ii), then Shire will have the right [***] to perform such Exclusive Services and (A) the exclusivity restrictions set forth in **Section 3.3(a)** will not apply to [***] (B) the terms of **Section 3.3(c)(i)** and **Section 3.3(c)(ii)** will apply. Except as required under **Section 3.3(c)(ii)**, in no event will Sangamo be obligated to disclose to Shire any Know-How related to [***]. Upon successful development of the [***] ZF Compound by Sangamo or Shire, the [***] ZF Compound shall be a Shire ZF Compound.

5.5 Preclinical and Clinical Development.

- (a) <u>Development Plan</u>. Each Development Plan will be developed, and amended from time to time, by Shire. Each Development Plan, including each such amendment, will be presented in the form of a written summary provided to Sangamo that includes sufficient detail for Sangamo to understand the activities planned by Shire and Shire's anticipated timelines for performing such activities.
- (b) <u>Development Reports</u>. Up until the time of [***] for the applicable Collaboration ZF Product, for each Collaboration ZF Product, each Responsible Party shall keep the other Party informed about the status of the Responsible Party's preclinical and clinical development activity by providing, at least [***] and in a timely manner, detailed written updates describing such developments in a form substantially similar to that set forth on **Schedule 5.5(b)**.
- (c) <u>Development Directed to [***</u>]. If a particular Shire ZF Product has [***] not within the applicable Shire Target, then Shire may develop and commercialize such Shire ZF Product to treat the diseases or conditions associated with such other Target; provided that Shire will first use Commercially Reasonable Efforts to develop such Shire ZF Product for the purpose of obtaining Marketing Approval with respect to the disease or condition associated with the applicable Shire Target; and further provided that (i) at the time of Development Candidate Selection for the Shire ZF Compound in any Shire ZF Product, Shire has adopted a plan and allocated an internal team to develop such Shire ZF Product for such disease or condition, and (ii) any subsequent cessation of such development is primarily attributable to changes in the development risk profile or commercial potential for such Shire ZF Product.
- (d) <u>Safety Data Exchange Agreement</u>. Two months prior to the first IND filing respecting any (i) ZF Product developed by Sangamo in connection with a Sangamo Target (other than a Sangamo ZF Product) or (ii) Shire ZF Product, the Parties agree to meet to negotiate and draft a detailed Safety Data Exchange Agreement in the form of Shire's Safety Data Exchange Agreement template, as it stands at the time of such first IND filing, outlining each Party's respective obligations surrounding pharmacovigilance activities, including but not limited to, timely transferring information related to adverse events or adverse reactions and maintaining a global safety database, to the extent required for each Party to comply with applicable laws and regulations.

6 SUPPLY AND MANUFACTURE

- **6.1 Shire's Exclusive Right to Manufacture.** Except for activities conducted by Sangamo under a Research Plan, Shire shall have the exclusive right in the Territory to (and Sangamo shall not) manufacture Shire ZF Compounds and Shire ZF Products for use in the applicable Field, either directly or through one or more Affiliates or contract manufacturers selected by Shire in its sole discretion.
- **6.2 Sangamo's Exclusive Right to Manufacture**. Sangamo shall have the exclusive right in the Territory to (and Shire shall not) manufacture Sangamo Safe Harbor ZF Compounds and Sangamo ZF Products for use in the applicable Field, either directly or through one or more Affiliates or contract manufacturers selected by Sangamo in its sole discretion.

7 REGULATORY AFFAIRS

7.1 Shire ZF Products. Subject to Section 5.1, Shire will have sole control and discretion with respect to (a) (i) planning the appropriate regulatory strategy for each Shire ZF Product, (ii) preparing and submitting all Regulatory Filings for Shire ZF Products, including all pre-pre-IND, pre-IND, and IND/CTA regulatory submissions and BLAs for Shire ZF Products, (iii) obtaining and maintaining all Marketing Approvals for Shire ZF Products in each country; and (b) communications with Governmental Authorities with respect to any of the foregoing, or otherwise with respect to any Shire ZF Product. Except as otherwise agreed in writing by the Parties, Sangamo may not communicate with any Governmental Authority with respect to the Shire Programs or any Shire ZF Compound or Shire ZF Product. Sangamo will cooperate with Shire with respect to any and all regulatory matters with respect to any Shire ZF Product, including making appropriate Sangamo personnel available to assist with the preparation of any Regulatory Filings and to participate in any communications with applicable Governmental Authorities. If the amount of time requested by Shire with respect to such regulatory support and cooperation exceeds maximum number of hours Sangamo is obligated to spend on such activity under the applicable Research Plan, then Shire shall reimburse Sangamo's FTE costs (at the FTE Rate) and external costs of such assistance and cooperation (with no mark-up thereon). Ownership of all right, title and interest in and to any and all Regulatory Filings and Marketing Approvals directed to any Shire ZF Product in each country of the Territory will be held in the name of Shire, its Affiliate, Sublicensee or designee.

7.2 Sangamo ZF Products. Subject to **Section 5.2**, Sangamo will have sole control and discretion with respect to (a) (i) planning the appropriate regulatory strategy for each Sangamo ZF Product, (ii) preparing and submitting all Regulatory Filings for Sangamo ZF Products, including all pre-pre-IND, pre-IND, and IND/CTA regulatory submissions and BLAs for Sangamo ZF Products, (iii) obtaining and maintaining all Marketing Approvals for Sangamo ZF Products in each country; and (b) communications with Governmental Authorities with respect to any of the foregoing, or otherwise with respect to any Sangamo ZF Product. Shire may not communicate with any Governmental Authority with respect to the Sangamo Programs or any Sangamo Safe Harbor ZF Compound or Sangamo ZF Product. Ownership of all right, title and interest in and to any and all Regulatory Filings and Marketing Approvals directed to any Sangamo ZF Product in each country of the Territory will be held in the name of Sangamo, its Affiliate, Sublicensee or designee.

8 GRANT OF LICENSES

8.1 Grant by Sangamo. Subject to the terms and conditions of this Agreement, Sangamo hereby grants to Shire an exclusive, royalty-bearing license, with the right to sublicense as provided in **Section 8.3**, under the Sangamo Licensed Technology, (i) to make, have made, use, and import Shire ZF Compounds in the Territory solely for the purpose of developing and commercializing Shire ZF Products pursuant to the license granted in **Section 8.1(ii)**, and (ii) to make, have made, use, develop, sell, offer for sale, and import Shire ZF Products in the applicable Field in the Territory.

8.2 Grant by Shire.

- (a) <u>Research License</u>. Subject to the terms and conditions of this Agreement, Shire hereby grants to Sangamo a royalty-free, non-exclusive license, with the right to grant sublicenses only to permitted Subcontractors under **Section 3.6**, under all Patent Rights and other intellectual property rights Controlled by Shire and its Affiliates as of the Amendment Effective Date or that come into the Control of Shire and its Affiliates during the Research Term solely as necessary for Sangamo to perform Services in accordance with one or more Research Plans during the Research Term or other mutually agreed activities under this Agreement with respect to Shire ZF Products.
- (b) <u>Exclusive License Grant</u>. Subject to the terms and conditions of this Agreement, Shire hereby grants to Sangamo an exclusive, royalty-bearing license, with the right to sublicense as provided in **Section 8.3**, under the Shire Licensed Technology, (i) to make, have made, use, and import Sangamo [***] in the Territory solely for the purpose of developing and commercializing Sangamo ZF Products pursuant to the license granted in **Section 8.2(b)(ii)**, and (ii) to make, have made, use, develop, sell, offer for sale, and import Sangamo ZF Products in the applicable Field in the Territory.

8.3 Sublicenses.

- (a) <u>Affiliates</u>. Subject to the terms and conditions of this Agreement, each Party may grant to one or more of its Affiliates a sublicense under the rights granted to it under **Section 8.1** and **Section 8.2(b)** (as applicable to such Party) (the "Sublicensing Party"). Such sublicense may be in whole or in part of the rights granted to such Party under **Section 8.1** and **Section 8.2(b)** (as applicable) and may be on a country by country basis. The Sublicensing Party shall remain responsible for the performance of such Affiliates under such rights to the same extent as if such activities were conducted by the Sublicensing Party, and shall remain responsible for any payments due hereunder with respect to activities of such Affiliates.
- (b) Third Parties. Subject to the terms and conditions of this Agreement, each Party may also grant, through one or more tiers, to Third Parties a sublicense under the rights granted to it under Section 8.1 and Section 8.2(b) (as applicable to such Party). Such sublicense may be in whole or in part of the rights granted to such Party under Section 8.1 and Section 8.2(b) (as applicable) and may be on a country by country basis. The Sublicensing Party shall remain responsible for any payments due hereunder with respect to activities of the Sublicensee. In the event of a termination of this Agreement by either Party pursuant to Section 15.2 or Section 15.3, any permitted sublicense by the other Party under this Section 8.3(b) shall, at the Sublicensee's option, survive such termination; provided that the Sublicensee is not in material breach of any of its obligations under such sublicensee. In the event of termination of this Agreement by Shire pursuant to Section 15.4, any permitted sublicense under this Section 8.3(b) shall, at the Sublicensee's option and with Sangamo's prior written consent, not to be unreasonably withheld, conditioned or delayed, survive such termination; provided that the Sublicensee is not in material breach of any of its obligations under such sublicensee. In order to effect this provision, at the request of the Sublicensee and, if applicable, with consent of Sangamo pursuant to the preceding sentence, the non-Sublicensing Party shall enter into a direct license with the Sublicensee on substantially the same terms as the sublicense; provided that the non-Sublicensing Party shall not be required to undertake obligations in addition to those required by this Agreement, and that the non-Sublicensing Party's rights under such direct license shall be consistent with its rights under this Agreement, taking into account the scope of the license granted under such direct license.
- (c) <u>Notice</u>. With respect to any sublicense agreement that includes a sublicense under a Third Party License that requires Sangamo to provide the applicable Third Party licensor a copy of any sublicense agreement or a summary of the terms of such sublicense agreement, Shire shall provide Sangamo with such copy or summary within 15 days of the execution of such sublicense agreement. Any such copy or summary shall be treated by Sangamo as Shire's Confidential Information.

- (d) <u>Requirements</u>. Each agreement in which a Party grants a sublicense under the license granted in **Section 8.1** or **Section 8.2(b)** (as applicable to such Party) shall be subject to (i) the applicable terms and conditions of this Agreement and (ii) the applicable terms and conditions set forth in **Schedule 8.10B** of any Third Party Licenses sublicensed to the Sublicensee, and shall expressly include the terms set forth in **Schedule 8.3(d)** respecting each Third Party License sublicensee.
- (e) <u>Direct Sublicense from Sangamo</u>. If Sangamo cannot grant further sublicenses under a particular Third Party License, then at Shire's request in conjunction with Shire's granting of a sublicense to a Sublicensee under this **Section 8.3**, subject to **Section 8.3(f)**, Sangamo shall grant a sublicense under such Third Party License to such Sublicensee on terms that are consistent with the Third Party License, the sublicense granted by Shire to such Sublicensee and the terms of this Agreement.
- (f) <u>Payments under Third Party Licenses</u>. To the extent that Shire receives a sublicense under a Third Party License, Shire shall be solely responsible for paying any sublicense issuance and sublicense maintenance fees owed to Third Parties pursuant to such Third Party License on account of the grant of a sublicense by such Party or its Sublicensees or by Sangamo pursuant to **Section 8.3(e)**.
- **8.4 Exclusivity.** During the Term, Sangamo shall not work independently of this Agreement for itself or any Affiliate or Third Party (including the grant of any license to any Third Party) with respect to the discovery or research of any product that is intended to be used clinically or diagnostically to (a) [***], or (b) [***], other than through the [***]. During the Term, Sangamo shall not work independently of this Agreement for itself or any Affiliate or Third Party (including the grant of any license to any Third Party) with respect to the development or commercialization, for therapeutic or diagnostic purposes, of (i) any product that can be used clinically or diagnostically to (A) [***], or (B) [***], other than through the [***], (ii) any Shire ZF Product or (iii) any ZF Compound that Specifically Binds a Shire Target. In addition, Sangamo shall not work independently of this Agreement for itself or any Affiliate or Third Party (including the grant of any license to any Third Party) with respect to the discovery, research, development or commercialization [***] unless and until the [***] and (C) unless and until such Shire Target becomes a Terminated Target. For the avoidance of doubt and not by way of limitation, during the Term, Sangamo shall not work independently of this Agreement for itself or any Affiliate or Third Party (including the grant of any license to any Third Party) on any therapeutic product containing a ZF Compound or process employing a ZF Compound that, with respect to either Shire Target, corrects expression of such defective Shire Target or provides a functional copy of the protein encoded by the non-defective version of such Shire Target. Sangamo's obligations under this Section 8.4 shall terminate with respect to a Target when it ceases to be a Shire Target and becomes a Terminated Target. Shire acknowledges that Sangamo, prior to the Effective Date, entered into agreements pursuant to which it granted licenses to Third Parties with respect to research and agricultural uses of
- **8.5** Competing Program Acquisition. If Sangamo acquires a Third Party that is, prior to such acquisition, conducting research on, developing or commercializing a product or service described in the first two sentences of Section 8.4, Sangamo shall (a) promptly provide written notice to Shire regarding such acquisition, [***]. In addition, in the event of a Change of Control of Sangamo during the Term, the obligations of Sangamo under Section 8.4 shall not apply to any product or service that (i) is owned or controlled by a Third Party described in the definition of "Change of Control" or its Affiliates prior to the closing of such Change of Control or (ii) becomes owned or controlled by such Third Party or its Affiliates after the closing of such Change of Control if such product or service (A) does not employ or is not developed using any zinc finger technology, or (B) is not developed using any Know-How, and is not Covered by any Patent Rights, that were Controlled by Sangamo prior to the closing of the Change of Control.
- **8.6** Sangamo Program Buy-Back Right. Sangamo shall notify Shire in writing (the "ROFN Notice") promptly if during the Term Sangamo decides to initiate discussions with a Third Party with respect to a license to commercialize one or more Sangamo ZF Products or an acquisition of Sangamo's assets related to one or more Sangamo ZF Products (any such license or acquisition with respect to the applicable Sangamo ZF Products, a "Sangamo Program License"); provided, however, that Sangamo may not grant any [***]. Within [***] after Shire's receipt of the ROFN Notice, Shire shall notify Sangamo of whether or not it is interested in entering into discussions with Sangamo with respect to the applicable Sangamo Program License, and following Sangamo's receipt of such notice from Shire, Sangamo shall provide to Shire (if not previously provided) a complete set of then-available data and information in Sangamo's Control for the applicable Sangamo ZF Products to which the Sangamo Program License relates [***] (collectively, the "Required ROFN Information"). For clarity, this Section 8.6 does not apply to a Change of Control of Sangamo as described in Section 1.8(a), (b) or (c) or any discussions related thereto.
- (a) <u>ROFN</u>. If, within [***] days following its receipt of the Required ROFN Information from Sangamo, Shire notifies Sangamo that Shire desires to negotiate with respect to such Sangamo Program License, then the Parties will exclusively negotiate in good faith regarding the terms under which Shire might obtain a Sangamo Program License with respect to such Sangamo ZF Product, which terms may include an [***] days commencing upon Shire's receipt of such Required ROFN Information (the "*ROFN*"). In addition, Sangamo shall provide any updates to the Required ROFN Information to Shire that come into Sangamo's Control during the applicable ROFN period.
- (b) <u>ROFN Suspension</u>. If Shire does not notify Sangamo of its desire to negotiate with respect to a Sangamo Program License during the initial [***] day period under **Section 8.6** or in the [***] day period following Sangamo's provision of the

Required ROFN Information, or if the Parties do not enter into a definitive agreement within the [***] day ROFN period, then Shire's ROFN for the applicable Sangamo ZF Products will be suspended [***] and [***] Sangamo may enter into a Sangamo Program License with respect to such Sangamo ZF Products with any Third Party; provided that if the Parties commenced negotiations during such ROFN period, the terms of the definitive agreement extended by the Third Party, when taken as a whole, are more favorable to Sangamo than those extended by Shire to Sangamo in its last written offer during such ROFN period described in **Section 8.6(a)**. For clarity, in the event that [***], and Shire will have no further ROFN with respect to the applicable Sangamo ZF Products, and if Sangamo enters into a Sangamo Program License with Shire, then Sangamo will no longer be [***] of those Sangamo ZF Products licensed or assigned under such Sangamo Program License (unless specified in the applicable definitive agreement).

- (c) <u>ROFN Reinstatement</u>. If Sangamo does not enter into a Sangamo Program License with a Third Party [***] described in **Section 8.6(b)** with respect to such applicable Sangamo ZF Product, [***] within such Sangamo Program during such [***] period, then Shire's ROFN will be reinstated if Sangamo decides to initiate or continue licensing or acquisition discussions with respect to the same Sangamo Program License or a new Sangamo Program License, consistent with the terms and conditions of **Section 8.6(a)** and **Section 8.6(b)**. [***] Sangamo entering into a Sangamo Program License with respect to such Sangamo ZF Product, then Sangamo shall promptly deliver to Shire [***] over a [***].
- **8.7 Other Sangamo Programs**. Sangamo shall notify Shire promptly if it decides to [***], or if it is contacted by a Third Party to [***], in each case other than a Sangamo Program License but with respect to a [***] that is directed to a [***]; <u>provided</u>, <u>however</u>, that Sangamo shall not be obligated to [***]. Upon Shire's request within [***] after such notice, the Parties will negotiate in good faith for up to [***] (the "*Negotiation Period*") regarding the terms under which Sangamo might [***]. Sangamo may engage in [***].
- **8.8 No Implied Rights.** Except as expressly provided in this Agreement, neither Party shall be deemed by estoppel, implication or otherwise to have granted the other Party any license or other right with respect to any intellectual property of such Party.
- **8.9 Negative Covenant.** Each Party covenants that it will not knowingly use or practice any of the other Party's intellectual property rights licensed to it under this **Article** 8 except for the purposes expressly permitted in the applicable license grant.
- **8.10 Third Party Licenses.** The licenses granted to Shire in **Section 8.1** include sublicenses under Sangamo Licensed Technology licensed to Sangamo pursuant to Third Party Licenses, which sublicenses are subject to the terms set forth on **Schedule 8.10A**, which terms Shire hereby acknowledges. **Schedule 8.10B** sets forth those obligations under the Third Party License that are obligations of Shire under this Agreement. Shire hereby agrees to be bound by the terms set forth in **Schedule 8.10B**.

9 REPRESENTATIONS AND WARRANTIES

- 9.1 Mutual Representations. Each Party represents and warrants to the other Party as of the Amendment Effective Date as follows:
 - (a) Organization. Such Party is duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is organized.
- (b) <u>Authorization and Enforcement of Obligations</u>. Such Party: (i) has the requisite power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder, (ii) has the requisite resources and expertise to perform its obligations hereunder, and (iii) has taken all requisite action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms.
- (c) <u>Consents</u>. All necessary consents, approvals and authorizations of all Governmental Authorities and other persons or entities required to be obtained by such Party in connection with the execution and delivery of this Agreement have been obtained.
- (d) No Conflict. The execution and delivery of this Agreement and the performance of such Party's obligations hereunder: (i) do not conflict with or violate any requirement of applicable laws, regulations or orders of governmental bodies, (ii) do not conflict with, or constitute a breach or default under, any contractual obligation of such Party, and (iii) do not conflict with or result in a breach of any provision of the organizational documents of such Party.
- (e) <u>Litigation</u>. There are no actions, suits, proceedings or investigations pending or, to such Party's knowledge, threatened against such Party before any court, government or regulatory body, agency, commission, official or any arbitrator that is reasonably expected to have an adverse effect on such Party's ability to consummate the transactions contemplated hereby.
 - **9.2 Additional Sangamo Representations**. Sangamo further represents, warrants and covenants to Shire as follows:
- (a) <u>No Conflicts</u>. As of the Amendment Effective Date, Sangamo has not granted, and will not grant during the Term, any rights that are inconsistent with the rights granted to Shire herein. Neither Sangamo nor its Affiliates has entered into any agreement,

arrangement or understanding with any Third Party that is inconsistent with the provisions of this Agreement. Sangamo has the right to grant the licenses granted in **Section 8.1**.

- (b) <u>Sangamo Intellectual Property.</u> As of the Amendment Effective Date, **Schedule 1.74** is an accurate listing by owner, inventors, serial number, filing date, country, and status of all of the Sangamo Patent Rights. Except as set forth in **Schedule 9.2(b)**, (i) the inventorship of each Sangamo owns, is the licensee in good standing of, or Controls all Sangamo Licensed Technology. Except as set forth in **Schedule 9.2(b)**, (i) the inventorship of each Sangamo Patent Right owned by Sangamo and, to Sangamo's knowledge, of each Sangamo Patent Right licensed to Sangamo, is properly identified on each patent, (ii) Sangamo, including its employees and agents, has complied with its U.S. PTO duty of disclosure respecting the prosecution of all of the Sangamo Patent Rights, and, to Sangamo's knowledge, the licensors of the Existing Third Party Licenses, including their employees and agents, have complied with the U.S. PTO duty of disclosure respecting the prosecution of the applicable Sangamo Patent Rights, and (iii) none of the Sangamo Patent Rights owned by Sangamo, and to Sangamo's knowledge none of the Sangamo Patent Rights licensed to Sangamo, is currently involved in any interference, reissue, re-examination, cancellation or opposition proceeding and neither Sangamo, nor any of its Affiliates, has received any written notice from any Person of such actual or threatened proceeding,
- (c) <u>Third Party Intellectual Property</u>. Sangamo agrees to immediately notify Shire in writing in the event that Sangamo becomes aware of any patent, trade secret or other right of the nature referred to in **Section 8.2(d)** of the Original Agreement. For the avoidance of doubt, a disclosure of any item or other matter in **Section 8.2(d)** of the Original Agreement is not an admission or indication that such item or other matter is required to be disclosed, or an admission of any current or potential obligation or liability to any Third Party or of any actual or potential breach or violation of any law or regulation.
- (d) Existing Third Party Licenses. As of the Amendment Effective Date, the Existing Third Party Licenses are in full force and effect as modified or amended prior to the Amendment Effective Date. As of the Amendment Effective Date, neither Sangamo nor, to Sangamo's knowledge, any Third Party licensor is in default with respect to a material obligation under, and neither such party has claimed or, to Sangamo's knowledge, has grounds upon which to claim that the other party is in default with respect to a material obligation under, any Existing Third Party License. Sangamo will promptly provide Shire with a copy of any amendments to the Existing Third Party Licenses made after the Amendment Effective Date and will not amend the Existing Third Party Licenses in a manner that will materially adversely affect Shire's rights under this Agreement, without Shire's prior written consent. Except as identified in **Schedule 9.2(d)**, Sangamo does not Control any other Third Party intellectual property necessary or useful for Shire to practice the licenses granted under this Agreement.
- (e) Other Encumbrances. As of the Amendment Effective Date, (i) No order has been made, no petition has been presented, no board meeting has been convened to consider a resolution, and no resolution has been passed, for the winding up or dissolution of Sangamo; (ii) no agreement or arrangement with creditors for an assignment of Sangamo's intellectual property assets for the benefit of creditors exists or has been proposed in respect of the Sangamo Patent Rights or Sangamo Know-How; and (iii) no event has occurred causing, or which upon instruction or notice by any Third Party may cause, any security interest to be perfected in the Sangamo Patent Rights or Sangamo Know-How.
- **9.3 Additional Shire Representations**. Shire further represents and warrants to Sangamo as of the Amendment Effective Date that: (a) the Transition Activities represent all activities that are reasonably required to be performed by Shire to affect the successful transition of the Sangamo Programs to Sangamo, and (b) Shire International GmbH is the same entity as the entity that was known as Shire AG on the Effective Date.
- **9.4 Disclaimer**. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH HEREIN, THE PARTIES MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, AND PARTICULARLY THE PARTIES DISCLAIM ALL IMPLIED WARRANTIES OF TITLE, NON-INFRINGEMENT, MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

10 PAYMENTS AND VALUE ADDED TAX

- 10.1 Ongoing Research and Development Payments. Shire shall pay Sangamo for (a) the Services conducted by or on behalf of Sangamo under the Research Plans as specified in Section 3.3(g); (b) activities requested by Shire to be performed by Sangamo and not set forth in a Research Plan, and (c) to the extent not paid under clause (a), Operational Activities to the extent that (i) Sangamo exceeds the maximum total number of hours specified for such activity in the applicable Research Plan and (ii) Shire has agreed in writing in advance with respect to the excess time to be spent by Sangamo on such activities). Subject to any good faith disputes promptly brought to Sangamo's attention and for which Shire is diligently seeking resolution, Shire shall pay such invoices within 30 days of the date of receipt of the invoice. All payments made pursuant to this Section 10.1 shall be non-creditable and non-refundable
- **10.2 Earned Royalties**. Subject to the terms and conditions of this Agreement, during the Royalty Period for the relevant Collaboration ZF Product, the [***] shall pay [***] percent of the Net Sales of all [***] ZF Products [***]. Only one Earned Royalty shall be payable on a single Collaboration ZF Product regardless of the number of Sangamo Patent Rights, Shire Patent Rights, Joint

Patent Rights and Shire Assigned Patent Rights, if any, Covering such Collaboration ZF Product. For the avoidance of doubt, only one Earned Royalty shall be payable on a single Collaboration ZF Product regardless of the number of ZF Compounds in the Collaboration ZF Product and regardless of whether the Collaboration ZF Product contains both diagnostic and therapeutic components.

- **10.3 Royalty Cap.** Notwithstanding the foregoing, no Responsible Party shall be required to [***] (the "Royalty Cap"). Following a Responsible Party's payment to the other Party of cumulative Earned Royalties for all such Responsible Party's Collaboration ZF Products [***], no further Earned Royalties shall be payable by the Responsible Party to the other Party in respect of Net Sales of such Responsible Party's Collaboration ZF Products; provided that notwithstanding the [***], if any payments are due by Sangamo to Third Parties under the Third Party Licenses on account of Shire's or its Affiliates' or Sublicensees' development or sale of a Shire ZF Product in a country, then Shire shall continue to pay to Sangamo such amounts due to such Third Parties under any such Third Party License.
- **10.4 Effect of Royalty Period Expiration**. Following expiration of the Royalty Period for any Collaboration ZF Product, the licenses granted to the Responsible Party hereunder with respect to such Collaboration ZF Product shall be fully paid-up, exclusive, irrevocable and royalty-free; provided, however, that if after the expiration of the Royalty Period for a Collaboration ZF Product any payments are due by the Responsible Party to Third Parties under the Third Party Licenses on account of such Responsible Party's or its Affiliates' or Sublicensees' development or sale of a Collaboration ZF Product, the sublicense with respect to the applicable other Party's in-licensed technology shall be fully-paid up, exclusive, irrevocable and royalty-free only after all payment obligations under **Section 10.3** expire.
- **10.5 Payment of Earned Royalties**. On a Collaboration ZF Product-by-Collaboration ZF Product basis, Earned Royalties shall become due and payable 45 days following the end of the calendar quarter during which such First Commercial Sales occur, and within 45 days of the end of each calendar quarter thereafter during the Royalty Period, for sales made during each such calendar quarter.
- **10.6 Payments for Third Party IP Rights Under New Third Party Licenses.** To the extent that Sangamo obtains a license to any Third Party intellectual property rights after the Effective Date and Sangamo Controls such intellectual property rights licensed thereunder as provided in **Section 11.4(b)** such that such intellectual property rights are sublicensed to Shire under **Article** 8, Shire shall pay to Sangamo all applicable payments under such license, as described in **Section 11.4(b)**, within 30 days after the applicable due date in such Third Party License and provide to Sangamo, at least 10 days before the applicable due date in such Third Party License all reports required under the applicable license agreement between Sangamo and such Third Party on account of Shire's and its Affiliates' and Sublicensees' development, manufacture and commercialization of Shire ZF Products, such that Sangamo may comply with all payment and reporting obligations under such license agreements. Provided it receives such items in a timely manner, Sangamo shall pay such amounts to, and file such reports with, the applicable Third Party on or before the applicable due date.

10.7 Royalty Reports.

- (a) <u>Timing of Reports</u>. Within 45 days after the end of each calendar quarter during the Royalty Period, the Responsible Party shall furnish to the other Party a written report showing in reasonably specific detail, on a Collaboration ZF Product-by-Collaboration ZF Product and country-by-country basis: (i) the Gross Sales of all Collaboration ZF Product sold by such Responsible Party, its Sublicensees hereunder and their respective Affiliates during such calendar quarter, (ii) the calculation of Net Sales from Gross Sales of the applicable Collaboration ZF Product, (iii) the withholding taxes, if any, required by law to be deducted with respect to royalties due on such sales and (iv) the exchange rates, if any, used in determining the amount payable by the Responsible Party to the other Party in United States dollars.
- (b) <u>Currency Conversion</u>. With respect to sales of all Collaboration ZF Product invoiced in United States dollars, all such amounts shall be expressed in United States dollars. With respect to sales of Collaboration ZF Product invoiced in a currency other than United States dollars, all such amounts shall be expressed both in the currency in which the amount is invoiced and in the United States dollar equivalent. Whenever for the purpose of calculating Net Sales, conversion from any foreign currency shall be required, the amount of such sales in foreign currencies shall be converted into U.S. dollars using the exchange rate for the relevant month as determined by Shire's accounting policies (the "Monthly Rate"), such Monthly Rate being determined as the last price rate of exchange for such currencies on the last business day of the immediately preceding calendar month as published on Bloomberg page FXC (or such other publication as may be agreed between the Parties from time-to-time).
- (c) <u>Records</u>. The Responsible Party shall keep complete and accurate records in sufficient detail to enable the royalties payable under this **Article 10** to be determined.

10.8 Audits.

(a) <u>Audit Frequency</u>. Upon 14 days advance written request by a Party and not more than once in each calendar year, the Responsible Party, its Sublicensees and their Affiliates shall permit an independent certified public accounting firm of internationally-recognized standing, selected by the auditing Party and reasonably acceptable to the Responsible Party, at the auditing Party's

expense, to have access during normal business hours to such of the records of the Responsible Party, its Sublicensees hereunder and their respective Affiliates as may be reasonably necessary to verify the accuracy of the royalty reports hereunder for any year ending not more than 18 months prior to the date of such request. No year may be audited more than once, except for cause. The accounting firm will enter a confidentiality agreement reasonably acceptable to the Responsible Party governing the use and disclosure of the Responsible Party's information disclosed to such firm, and such firm shall disclose to the auditing Party only whether the reports are correct or not and the specific details concerning any discrepancies, which information shall be Confidential Information of the Responsible Party.

- (b) <u>Audit Payments</u>. Unless disputed by Shire or Sangamo in good faith, if such accounting firm concludes that the royalties paid during the audited period were more or less than the royalties due, the Responsible Party shall pay any additional amounts due, and the other Party will refund any amounts overpaid, in each case plus interest as set forth in **Section 10.12**, within 30 days after the date the written report of the accounting firm so concluding is delivered to Sangamo and Shire. The fees charged by such accounting firm shall be paid by the auditing Party; provided that if the audit discloses that the royalties payable by the Responsible Party for such period have been underpaid by more than [***], then, subject to **Section 10.8(c)**, the Responsible Party shall pay the reasonable fees and expenses charged by such accounting firm.
- (c) <u>Audit Disputes</u>. In the event of a good faith dispute by Shire or Sangamo regarding the result of an audit made pursuant to this **Section 10.8**, the Parties shall agree in good faith on an alternative independent certified public accounting firm of internationally-recognized standing to perform a second audit. If such audit is requested by the Responsible Party because the Responsible Party was found by the initial audit to have underpaid and the second audit confirms that the Responsible Party under **Section 10.8(a)** because the Responsible Party was found by the initial audit to have overpaid and the second audit confirms that the Responsible Party overpaid, then the auditing Party shall bear all costs associated with the second audit. Notwithstanding the above, in the event that the second audit confirms the findings of the first audit, the requesting Party shall pay. No over or under payment indicated by the initial audit shall be payable in the event of a dispute until the second audit is complete and such second audit shall be binding on the Parties, with any under or over payment determined thereby, plus interest as set forth in **Section 10.12**, being payable within 30 days after the date the written report of the accounting firm so concluding is delivered to Sangamo and Shire.
- (d) <u>Confidential Treatment</u>. The auditing Party shall treat all financial information disclosed by its accounting firm pursuant to this **Section 10.8** as Confidential Information of the Responsible Party for purposes of **Article 12** of this Agreement, and shall cause its accounting firm to do the same.

10.9 Withholding Taxes.

- (a) Reasonable Assistance. Each Party shall use reasonable efforts to minimize tax withholding on payments made to the other Party pursuant to this Agreement and shall cooperate with the other Party's efforts to do so. Notwithstanding such efforts, if a paying Party concludes that tax withholdings under the laws of any country are required with respect to payments to the other Party pursuant to this Agreement, such paying Party shall first notify the receiving Party and provide such receiving Party within 20 days to determine whether there are actions either Party can undertake to eliminate or reduce such withholding. The paying Party shall refrain from making such payment to the receiving Party unless and until the earlier of (i) the receiving Party's written instructions to make such payment, if the receiving Party instructs the paying Party by written notice during such 20-day period that the receiving Party intends to take actions (satisfactory to both Parties) that shall obviate or reduce the need for such withholding, and provides to the paying Party satisfactory evidence that such actions have been taken by the receiving Party, in which case the paying Party shall provide any reasonable cooperation requested by the receiving Party, (ii) the date the paying Party instructs the receiving Party by written notice during such 20-day period that it should make such payment and withhold the required amount and pay it to the appropriate Governmental Authority or (iii) expiration of such 20-day period without notice from the receiving Party under the preceding clauses (i) or (ii). For clarity, payment and withholding in accordance with this Section 10.9(a) shall not be considered a Withholding Tax Action for the purposes of Section 10.9(b). If the paying Party withholds any taxes from a payment under this Agreement, the paying Party shall submit appropriate proof of payment of the withholding taxes to the other Party within a reasonable period of time. Upon request, the paying Party shall give the other Party such reasonable assistance, which shall include the provision of appropriate certificates of such deductions made together with other supporting documentation as may be required by the relevant tax authority, to enable such Party to claim exemption from such withholding or other tax imposed or obtain a repayment thereof or reduction thereof and shall upon request provide such additional documentation from time-to-time as is reasonably required to confirm the payment of tax.
- (b) <u>Withholding Tax Actions</u>. Notwithstanding **Section 10.9(a)**, if the paying Party is required to make a payment to the other Party that is subject to a deduction or withholding of tax, then if such withholding or deduction obligation arises as a result of any action by the paying Party, including any assignment or sublicense, or any failure on the part of the paying Party to comply with applicable laws or filing or record retention requirements, that has the effect of modifying the tax treatment of the Parties hereto (a " *Withholding Tax Action*"), then the sum payable by the paying Party (in respect of which such deduction or withholding is required to

be made) shall be increased to the extent necessary to ensure that the other Party receives a sum equal to the sum which it would have received had no such Withholding Tax Action occurred.

(c) <u>Withholding Tax Deductions</u>. Notwithstanding **Section 10.9(a)**, if the paying Party is required to make a payment to the other Party that is subject to a deduction or withholding of tax, then if such withholding or deduction obligation arises as a result of any action by such non-paying Party, including any assignment or any failure on the part of such Party to comply with applicable laws or filing or record retention requirements, that has the effect of modifying the tax treatment of the Parties hereto, then the sum payable by the paying Party (in respect of which such deduction or withholding is required to be made) shall be made to such non-paying Party after deduction of the amount required to be so deducted or withheld, which deducted or withheld amount shall be remitted to the proper Governmental Authority in accordance with applicable laws.

10.10 Value Added Tax.

- (a) All payments stated in **Section 2.2(c)**, **Section 3.3** and **Section 10.1** of this Agreement are for the purposes of VAT considered to be both exclusive of VAT and consideration for the supply of services.
- (b) For the purposes of this **Section 10.10**, references to a Party refer not only to such Party but also to any business that this Agreement or part interest in this Agreement may be transferred to by such Party.
- (c) For the purposes of VAT, the services performed by either Party under this agreement shall be considered to be covered by Art 44 of Council Directive 2006/112/EC (or any equivalent provision in the country of performance if performed outside the European Union) and as such will be considered to be liable for VAT in the country where the recipient is established. For the purposes of this agreement, it is understood that Sangamo is established in the USA and Shire is established in Switzerland.
- (d) If at any stage, the local tax authorities assert that they consider the services performed by either Party to be subject to local VAT, the Party performing such services shall in the first instance undertake all reasonable steps to refute any such assertions by the local tax authority. Only once this process is completed should the Party performing services raise valid tax invoices for the additional VAT liability.
- (e) The Party receiving services under this Agreement shall take all reasonable steps to recover any additional VAT liability from the same local tax authorities by submitting regular claims. The Party providing services under this Agreement shall provide all reasonably necessary assistance to facilitate the recovery of this tax. However, if in the event that the tax cannot be recovered then the Party receiving services shall be entitled to offset this tax against future payments to the Party providing services.
- (f) The responsibility for paying any penalties or interest accruing to incorrect VAT treatment of the supplies made by Sangamo will rest with Sangamo.
- (g) Should these any services performed under this Agreement be considered to be subject to Art 44 of Council Directive 2006/112, each of Sangamo and Shire warrants that it will fulfill all its necessary VAT reporting requirements in respect of such services.
- (h) In the event that an invoice is raised that is subject to VAT but is raised in a currency other than the local currency of the territory from where the tax is being charged, the invoice must additionally display this tax in the local currency of the territory having been converted using the relevant monthly exchange rate published on Bloomberg.
- (i) Sangamo hereby represents and warrants that, as of the Amendment Effective Date, it is not, has never been and has no obligation for whatever reason to be established for VAT purposes in any jurisdiction outside the United States of America. Solely on this basis Shire acknowledges and agrees that: (i) as of the Amendment Effective Date, it is a fully taxable entity for VAT purposes in Switzerland; and (ii) as of the Amendment Effective Date, Shire expects to recover any self-assessed Swiss VAT that Shire will need to report to the Swiss VAT authorities in relation to payments to made by Shire to Sangamo under this Agreement.
- (j) In the event that this Agreement is terminated, Shire will be entitled to withhold from any remaining sums payable to Sangamo any outstanding VAT claims from the local tax authority. These sums will be paid to Sangamo upon successful refunding of the claims from the local tax authority.
- **10.11 Payment Method.** All payments by the paying Party to the other Party hereunder shall be in United States dollars in immediately available funds and shall be made by wire transfer to a bank account designated in writing to the paying Party by the other Party.
- **10.12 Late Payments.** If a Party does not receive payment of any sum due to it on or before the due date therefor, simple interest shall thereafter accrue on the sum due to the Party from the due date until the date of payment at a per-annum rate of two percent over the then-current prime rate reported in *The Wall Street Journal* or the maximum rate allowable by applicable laws, whichever is lower.

11 INTELLECTUAL PROPERTY

11.1 Ownership.

- (a) <u>Inventions</u>. Except as provided in **Section 11.1(b)**, (i) each Party, as between such Party and the other Party, shall own all Know-How conceived, discovered, invented, created, made or reduced to practice or tangible medium solely by employees, agents or contractors of such Party (and all Patent Rights claiming such Know-How), and (ii) the Parties shall jointly own and have an undivided one-half interest in and to all Joint Know-How and Joint Patent Rights. All determinations of inventorship under this Agreement shall be made in accordance with the patent law of the United States. Each Party may exploit any Joint Technology without accounting to or obtaining consent from the other Party, subject to the exclusive licenses of each Party's interest thereunder granted, as part of the Sangamo Licensed Technology under **Section 8.1** and as part of the Shire Licensed Technology under **Section 8.2(b)**, <u>provided</u>, <u>however</u>, that nothing in this **Section 11.1(a)** shall be construed as a grant to any other intellectual property held by the other Party.
- (b) Shire [***] Patent Rights. Sangamo [***] Shire, Sangamo's [***] to any Shire [***] Patent Rights. In each case, Sangamo shall execute and deliver to Shire [***], in a mutually agreeable form, within 30 days after such Patent Right comes into existence. Any such Shire [***] Patent Rights shall [***] constitute Confidential Information of Shire for the purposes of this Agreement [***] to Sangamo in accordance with this Section 11.1(b), in which case it shall constitute the Confidential Information of Sangamo. Notwithstanding the foregoing or anything to the contrary in this Agreement, Shire shall not, directly or indirectly through Affiliates or Third Parties, practice any of the Shire [***] Patent Rights outside of the scope of the licenses granted to Shire under this Agreement. For any Patent Right that ceases to be a Shire [***] Patent Right at any time during the Term by virtue of an amendment of the claims, Shire shall [***], effective as of the date of such claim amendment, its entire right, title and interest in and to each such Patent Right to Sangamo. In each case, Shire shall execute and deliver to Sangamo a [***], in a mutually agreeable form, within 30 days after the date such Patent Right ceased to be a Shire [***] Patent Right.
- (c) <u>Personnel Obligations</u>. Each employee, agent or independent contractor of a Party or its respective Affiliates performing work under this Agreement shall, prior to commencing such work, be bound by invention assignment obligations, including: (i) promptly reporting any invention, discovery, process or other intellectual property right; (ii) presently assigning to the applicable Party or Affiliate all of his or her right, title and interest in and to any invention, discovery, process or other intellectual property; (iii) cooperating in the preparation, filing, prosecution, maintenance and enforcement of any patent and patent application; and (iv) performing all acts and signing, executing, acknowledging and delivering any and all documents required for effecting the obligations and purposes of this Agreement. It is understood and agreed that such invention assignment agreement need not reference or be specific to this Agreement.

11.2 Preparation, Filing, Prosecution and Maintenance of Patent Rights.

(a) Shire [***] Patent Rights.

(i) <u>Preparation of Shire [***] Patent Rights</u>. With respect to the preparation of any patent application that will be a Shire [***] Patent Right, the Parties shall collaborate in reviewing relevant data, in preparing drafts, and in preparing a final version for filing of such patent application. Shire shall have [***], respecting the content of any application that will be a Shire [***] Patent Right; provided that Shire shall not include in any such application any information beyond that required to meet the requirements of 35 U.S.C. § 112. Shire shall consider in good faith, take into account, and implement where possible the reasonable comments made by Sangamo respecting the preparation and content of any Shire [***] Patent Rights. For the avoidance of doubt, Sangamo [***]. For the purpose of this Section 11.2(a)(i), a [***] means a claim that (A) includes language that specifically describes one or more ZF Compounds that Specifically Bind a particular Shire Target, (B) if presumed to be issued, would not be infringed by a ZF Compound (or the manufacture or use of a ZF Compound) that, after reasonable inquiry (i) at the time such Patent Right is filed or (ii) with respect to a claim that is first proposed after filing, at the time of such initial proposal, is known to not Specifically Bind such Shire Target, if such ZF Compound were combined with the non-ZF Compound elements, if any, in such claim, (C) does not include language that specifically describes a product (or the manufacture or use of such product) that is not a Shire ZF Product, and (D) does not include language describing any product (other than a Shire ZF Compound) or process that is Know-How, whether patentable or not, conceived, discovered, invented, created, made or reduced to practice or tangible medium, whether solely or jointly, by one or more employees, agents or contractors of Sangamo, if such Know-How is being protected as a trade secret by Sangamo, or is the subject of a claim in an existing Patent Right controlled by Sangamo, or is sufficiently disclosed in an existing Patent Right controlled by Sangamo to support a claim to such Know-How in such Patent Right under 35 U.S.C. § 112 (first paragraph), or if Sangamo has not yet filed an intended patent application disclosing or claiming such Know-How (and Sangamo discloses to Shire during the review process described in Section 11.2(a)(i) or (ii), as applicable, that Sangamo intends to file such a patent application), unless Sangamo consents in writing to the inclusion of such Know-How.

(ii) <u>Filing, Prosecution and Maintenance of Shire [***] Patent Rights</u>. Shire, at its own expense, shall have the sole right (subject to **Section 11.2(e))** to [***]. Shire shall [***], including by providing Sangamo with [***] and shall provide Sangamo [***], within a reasonable amount of time in advance of [***]. Shire shall consider in good faith, take into account and implement where possible the [***]; provided that, Shire shall not be required to [***] where Shire reasonably determines that [***].

- (b) Shire Patent Rights. Shire, at its own expense, shall have the [***].
- (c) Sangamo Patent Rights.
- (i) Sangamo, at its own expense, shall have the sole right (subject to **Section 11.2(f)**) to prepare, file, prosecute and maintain, throughout the world, the Sangamo Patent Rights.
- (ii) Sangamo shall keep Shire informed as to material developments with respect to the filing, prosecution and maintenance of such Sangamo Patent Rights, including by providing Shire with copies of all material communications (including office actions and notices of interferences, reissues, re-examinations or oppositions) from any patent office regarding such Sangamo Patent Rights and shall provide Shire drafts of submissions relating thereto, including drafts of any material filings or responses to be made to such patent offices, including notice of all interferences, reissues, re-examinations, oppositions or requests for patent term extensions, within a reasonable amount of time in advance of submitting such filings or responses to permit Shire an opportunity to review and comment thereon. Sangamo shall consider in good faith, take into account and implement where possible the reasonable comments made by Shire, including comments directed to preventing any detrimental effect of Sangamo's patent prosecution actions on the prosecution or enforcement of [***]; provided that Sangamo does not reasonably determine such comments to be detrimental to the prosecution or enforcement of any [***].
- (d) Joint Patent Rights. If the Parties make any Joint Know-How, the Parties shall promptly meet to discuss and determine whether to seek Joint Patent Rights thereon. If either Party decides to seek any Joint Patent Rights, then Sangamo shall have the first right, but not the obligation, to prepare, file, prosecute and maintain throughout the world, at its expense, any Joint Patent Right (other than a Shire [***] Patent Right, the prosecution of which is governed by Section 11.2(a)) that claims the composition, manufacture or use of a ZF Compound or of a product or method containing, employing or made using a ZF Compound, using patent counsel or patent agent selected by Sangamo and reasonably acceptable to Shire. Shire shall have the first right, but not the obligation, to prepare, file, prosecute and maintain throughout the world, at its expense, any other Joint Patent Right [***]; using patent counsel or patent agent selected by Shire and reasonably acceptable to Sangamo. The prosecuting Party shall keep the non-prosecuting Party informed as to material developments with respect to the filing, prosecution and maintenance of the Joint Patent Rights, including by providing copies of all material communications (including office actions and notices of interferences, reissues, re-examinations or oppositions) from any patent office regarding such Joint Patent Rights and shall provide the non-prosecuting Party drafts of submissions relating thereto, including drafts of any material filings or responses to be made to such patent offices, within a reasonable amount of time in advance of submitting such filings or responses to permit the non-prosecuting Party an opportunity to review and comment thereon. The prosecuting Party shall consider in good faith, take into account and implement where possible the reasonable comments made by the non-prosecuting Party.
- (e) Shire Abandonment. If Shire elects not to file a patent application covering any Joint Know-How or Know-How that would be a Shire [***] Patent Right, or elects to cease the prosecution and maintenance of any Joint Patent Right or Shire [***] Patent Right in any country or as a PCT application (and does not elect to file one or more new patent applications covering the subject matter claimed in such Patent Right), Shire will promptly provide Sangamo with written notice, but not less than 30 days if reasonably practicable, before any action is required, and will permit Sangamo, at Sangamo's sole discretion and expense, to file such patent application or continue prosecution or maintenance of such patent application or patent in such country, as applicable. Upon request from Sangamo, Shire will execute such documents and perform such acts as may be reasonably necessary to permit Sangamo to make such filing or continue such prosecution or maintenance, as applicable, in Shire's name. Notwithstanding the foregoing, if such Patent Right is a Shire [***] Patent Right that (i) would have been solely owned by Sangamo but for the [***] pursuant to Section 11.1(b) and is a filing in Australia, Canada, a Major European Country, Japan or the United States, then Shire [***] Patent Right in such jurisdiction or (ii) would have been jointly owned by the Parties but for the [***] pursuant to Section 11.1(b) and is a filing in Australia, Canada, a Major European Country, Japan or the United States, then Shire shall [***], effective upon Sangamo's written request, to Sangamo an undivided one-half interest in such Shire [***] Patent Right in such jurisdiction. Such [***] Patent Rights shall not, after [***] from Shire to Sangamo pursuant to the preceding sentence, be included in Sangamo Patent Rights if they pertain to Australia, Canada, a Major European Country, Japan or the United States.
- (f) <u>Sangamo Abandonment</u>. If Sangamo elects not to file a patent application covering any Joint Know-How, or elects to cease the prosecution and maintenance of any Sangamo Patent Right or Joint Patent Right in any country or as a PCT application (and does not elect to file one or more new patent applications covering the subject matter claimed in such Sangamo Patent Right or Joint Patent Right, as applicable), Sangamo will promptly provide Shire with written notice, but not less than 30 days before any action is required, and will permit Shire, at Shire's sole discretion and expense, to continue prosecution or maintenance of any such Sangamo Patent Right or Joint Patent Right in such country, as applicable, to the extent that no Third Party has a prior right to assume the prosecution or maintenance of such Sangamo Patent Right. Upon request from Shire, Sangamo will execute such documents and perform such acts as may be reasonably necessary to permit Shire to continue such prosecution or maintenance, as applicable.
- (g) <u>Patent Term Extensions</u>. In connection with the Marketing Approval of a Shire ZF Product, Shire shall consult with Sangamo before determining which Patent Right, if any, is to be extended, by way, for example, of a Patent Term Restoration and a Supplementary Protection Certificate. Shire shall not have the right to extend in any country (i) a Sangamo Patent Right or (ii) a Joint Patent Right that is the subject of any such extension for a product other than a Shire ZF Product. Shire shall have the sole discretion

to determine whether a Shire Patent Right or a Shire [***] Patent Right is to be extended. Sangamo shall have the sole discretion to determine whether a Sangamo Patent Right is to be extended. Each Party shall cooperate with the other Party to the extent reasonably requested by such Party to effectuate the intent of this **Section 11.2(g)**.

- (h) <u>Orange Book Listing</u>. In connection with the Marketing Approval of a Collaboration ZF Product, the Responsible Party shall have the sole right, in accordance with applicable laws and regulations, to choose whether a patent is to be listed in the Orange Book or in any similar equivalent thereto in the Territory. The other Party shall cooperate with the Responsible Party to the extent reasonably requested by the Responsible Party to effectuate the intent of this **Section 11.2(h)**.
- (i) <u>Third Party Rights</u>. For the avoidance of doubt, Shire's rights under this **Section 11.2** to [***], and Sangamo's rights under this **Section 11.2** to file, prosecute and maintain any Shire Patent Right Controlled by Shire pursuant to a Third Party License may be exercised in Shire's name and for the benefit of Shire; provided that this **Section 11.2** shall be subject to the terms of such Third Party License.

11.3 Enforcement of Patent Rights.

(a) <u>Notice</u>. If either Shire or Sangamo becomes aware of any infringement, anywhere in the world, of (i) any issued patent within the Sangamo Patent Rights or Joint Patent Rights on account of any Third Party's manufacture, use or sale of a Shire ZF Compound or Shire ZF Product in the Field, or (ii) any issued patent within the Shire [***] Patent Rights (a "Shire ZF Product Infringement"), such Party will promptly notify the other Party in writing to that effect. If either Sangamo or Shire becomes aware of any infringement, anywhere in the world, of any issued patent within the Shire Patent Rights or Joint Patent Rights on account of a Third Party's manufacture, use or sale of a Sangamo Safe Harbor ZF Compound or a Sangamo ZF Product in the Field (a "Sangamo ZF Product Infringement"), such Party will promptly notify the other Party in writing to that effect.

(b) Enforcement of Joint Patent Rights and Shire [***] Patent Rights against a Shire ZF Product Infringer.

- (i) In the case of any Shire ZF Product Infringement, Shire shall have the first right, but not the obligation, to take action to obtain a discontinuance of the Shire ZF Product Infringement or bring suit against the applicable Third Party (such Third Party, the "Shire ZF Product Infringer") under the applicable Joint Patent Rights and Shire [***] Patent Rights, within six months from the date of notice and, if with respect to the Joint Patent Rights, to join Sangamo as a party plaintiff. Shire shall bear all the expenses of any suit brought by it claiming Shire ZF Product Infringement of any such Patent Rights. Sangamo shall cooperate with Shire in any such suit as reasonably requested by Shire and at Shire's expense and shall have the right to consult with Shire and to participate in and, if appropriate, be represented by independent counsel in such litigation at its own expense. Shire shall not, without Sangamo's prior written consent, enter into any settlement or consent decree that requires any payment by or admits or imparts any other liability to Sangamo or admits the invalidity or unenforceability of any such Patent Rights, which consent shall not be unreasonably withheld, conditioned or delayed. If Shire has not taken steps to obtain a discontinuance of infringement of such Patent Rights or filed suit against any such infringer of such Patent Rights within six months from the date of notice of such Shire ZF Product Infringement, then Sangamo shall have the right, but not the obligation, to bring suit against such Shire ZF Product Infringer; provided that Sangamo shall bear all the expenses of such suit. Shire shall cooperate with Sangamo in any such suit for infringement of such Patent Rights brought by Sangamo against a Shire ZF Product Infringer (including joining as a party plaintiff) at Sangamo's request and expense, and shall have the right to consult with Sangamo and to participate in and be represented by independent counsel in such litigation at its own expense. Sangamo shall not, without Shire's prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed, enter into any settlement or consent decree that requires any payment by or admits or imparts any other liability to Shire or admits the invalidity or unenforceability of any such Patent Rights, or adversely impacts Shire's Net Sales, or impacts market share, of Shire ZF Products. The enforcing Party under this Section 11.3(b)(i) shall keep the other Party reasonably informed of all material developments in connection with any such suit.
- (ii) Any recoveries obtained by either Party as a result of any proceeding against a Shire ZF Product Infringer under this **Section 11.3(b)** shall be allocated as follows:
- (A) Such recovery shall first be used to reimburse the enforcing Party for all out-of-pocket litigation costs in connection with such litigation paid by that Party, and then to reimburse out-of-pocket litigation costs paid by the other Party;
 - (B) With respect to any remaining portion of such recovery, Sangamo shall receive an amount equal to [***] of such amount; and
- (C) Any amounts paid to Sangamo pursuant to **Section 11.3(b)(ii)(B)** will count towards the Royalty Cap on payments to be made by Shire to Sangamo.
- (c) Shire ZF Product Infringement of Sangamo Patent Rights. With respect to any Shire ZF Product Infringement of a Sangamo Patent Right, Sangamo shall have the first right, but not the obligation, to take action to obtain a discontinuance of the Shire ZF Product Infringement or bring suit against the applicable Shire ZF Product Infringer under the applicable Sangamo Patent Rights within six months from the date of notice and to join Shire as a party plaintiff. Sangamo shall bear all the expenses of any suit brought by it claiming Shire ZF Product Infringement of any such Patent Rights. Shire shall cooperate with Sangamo in any such suit as

reasonably requested by Sangamo and at Sangamo's expense and shall have the right to consult with Sangamo and to participate in and, if appropriate, be represented by independent counsel in such litigation at its own expense. Sangamo shall not, without Shire's prior written consent, enter into any settlement or consent decree that requires any payment by or admits or imparts any other liability to Shire or admits the invalidity or unenforceability of any such Patent Rights, which consent shall not be unreasonably withheld, conditioned or delayed. If Sangamo has not taken steps to obtain a discontinuance of Shire ZF Product Infringement of such Patent Rights or filed suit against any such Shire ZF Product Infringer of such Patent Rights within [***] months from the date of notice of such Shire ZF Product Infringement, then upon Sangamo's written consent (not to be unreasonably withheld, conditioned or delayed), Shire shall have the right, but not the obligation, to bring suit under such Sangamo Patent Rights against such Shire ZF Product Infringer; provided that Shire shall bear all the expenses of such suit. Sangamo shall cooperate with Shire in any such suit for infringement of such Patent Rights brought by Shire against a Shire ZF Product Infringer (including joining as a party plaintiff) at Shire's expense, and shall have the right to consult with Shire and to participate in and be represented by independent counsel in such litigation at its own expense. Shire shall not, without Sangamo's prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed, enter into any settlement or consent decree that requires any payment by or admits or imparts any other liability to Sangamo or admits the invalidity or unenforceability of any such Patent Rights. The enforcing Party under this Section 11.3(c) shall keep the other Party reasonably informed of all material developments in connection with any such suit.

- (i) *Recoveries*. Any recoveries obtained by either Party as a result of any proceeding against a Shire ZF Product Infringer under this **Section 11.3(c)** shall be allocated as follows:
- (A) Such recovery shall first be used to reimburse the enforcing Party for all out-of-pocket litigation costs in connection with such litigation paid by that Party, and then to reimburse out-of-pocket litigation costs paid by the other Party;
 - (B) With respect to any remaining portion of such recovery, Sangamo shall receive an amount equal to [***] of such amount; and
- (C) Any amounts paid to Sangamo pursuant to **Section 11.3(c)(i)(B)** will count towards the Royalty Cap on payments to be made by Shire to Sangamo.
- (ii) *Third Party Rights*. For the avoidance of doubt, with respect to any Sangamo Patent Right licensed to Sangamo by a Third Party, Shire's rights under this **Section 11.3(c)** may be exercised in Sangamo's name, provided that Shire's rights under this **Section 11.3(c)** shall be subject to the rights of such Third Party to enforce such Sangamo Patent Right and to receive a portion of any recoveries obtained as a result of any proceeding against a Third Party infringer under such Sangamo Patent Right.
- (d) Other Infringement of Joint Patent Rights. With respect to any Third Party infringement of any Joint Patent Right, other than in the case of a Shire ZF Product Infringement of a Joint Patent Right, which is subject to Section 11.3(e), each Party shall promptly notify the other Party of such infringement and the Parties shall meet as soon as reasonably practicable thereafter to discuss such infringement and determine an appropriate course of action. Unless the Parties agree to jointly address such infringement, if the infringement relates to ZF Compounds or ZF Products or their manufacture, delivery or use, Sangamo shall have the first right but not the obligation, and if the infringement does not relate to ZF Compounds or ZF Products, Shire shall have the first right but not the obligation, to bring an action against such infringer or otherwise address such alleged infringement within six months from the date of notice and to control such litigation or other means of addressing such infringement. If, after the expiration of the [***] month period (or, if earlier, the date upon which the Party with the first right provides written notice that it does not plan to bring suit), the Party with the first right has not obtained a discontinuance of infringement of such Joint Patent Right or filed suit against any such infringer of such Joint Patent Right, then the other Party shall have the right, but not the obligation, to bring suit against such infringer of such Joint Patent Right; provided that such other Party shall bear all the expenses of such suit. In any suit under this Section 11.3(c), the non-enforcing Party shall cooperate with the enforcing Party, at the enforcing Party's request and expense, in any such suit and shall have the right to consult with the enforcing Party and to participate in and be represented by independent counsel in such litigation at its own expense. Any recoveries obtained by either Party as a result of any such proceeding against a Third Party infringer shall be allocated as follo
- (i) Such recovery shall first be used to reimburse each Party for all out-of-pocket litigation costs in connection with such litigation paid by that Party; and
- (ii) With respect to any remaining portion of such recovery, the enforcing Party shall receive an amount equal to [***], and the other Party shall receive the remaining [***] if the Parties brought such proceeding jointly, such remaining portion shall be [***].
 - (e) Enforcement against a Sangamo ZF Product Infringer.
- (i) In the case of any Sangamo ZF Product Infringement, Sangamo shall have the first right, but not the obligation, to take action to obtain a discontinuance of the Sangamo ZF Product Infringement or bring suit against the applicable Third Party (such Third Party, the "Sangamo ZF Product Infringer") under the applicable Shire Patent Rights or Joint Patent Rights, within [***] from the date of notice and to join Shire as a party plaintiff. Sangamo shall bear all the expenses of any suit brought by it claiming

Sangamo ZF Product Infringement of any such Patent Rights. Shire shall cooperate with Sangamo in any such suit as reasonably requested by Sangamo and at Sangamo's expense and shall have the right to consult with Sangamo and to participate in and, if appropriate, be represented by independent counsel in such litigation at its own expense. Sangamo shall not, without Shire's prior written consent, enter into any settlement or consent decree that requires any payment by or admits or imparts any other liability to Shire or admits the invalidity or unenforceability of any such Patent Rights, which consent shall not be unreasonably withheld, conditioned or delayed. If Sangamo has not taken steps to obtain a discontinuance of infringement of such Patent Rights or filed suit against any such infringer of such Patent Rights within [***] from the date of notice of such Sangamo ZF Product Infringement, then Shire shall have the right, but not the obligation, to bring suit against such Sangamo ZF Product Infringer; provided that Shire shall bear all the expenses of such suit. Sangamo shall cooperate with Shire in any such suit for infringement of such Patent Rights brought by Shire against a Sangamo ZF Product Infringer (including joining as a party plaintiff) at Shire's request and expense, and shall have the right to consult with Shire and to participate in and be represented by independent counsel in such litigation at its own expense. Shire shall not, without Sangamo's prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed, enter into any settlement or consent decree that requires any payment by or admits or imparts any other liability to Sangamo or admits the invalidity or unenforceability of any such Patent Rights, or adversely impacts Sangamo's Net Sales, or impacts market share, of Sangamo ZF Products. The enforcing Party under this Section 11.3(e)(i) shall keep the other Party reasonably informed of all material developments in connection with any such suit.

(ii) Any recoveries obtained by either Party as a result of any proceeding against a Sangamo ZF Product Infringer under this **Section 11.3(e)** shall be allocated as follows:

- (A) Such recovery shall first be used to reimburse the enforcing Party for all out-of-pocket litigation costs in connection with such litigation paid by that Party, and then to reimburse out-of-pocket litigation costs paid by the other Party;
 - (B) With respect to any remaining portion of such recovery, Shire shall receive an amount equal to [***]; and
 - (C) Any amounts paid to Shire pursuant to **Section 11.3(e)(ii)(B)** will count towards the Royalty Cap on payments to be made by

Sangamo to Shire.

(f) EU Unitary Patent System. Without limitation of Shire's rights under Section 11.4, Shire shall, following consultation with Sangamo and good faith consideration of Sangamo's comments, have the exclusive right to opt-in and opt-out (i) the Joint Patent Rights that do not claim the composition, manufacture or use of a ZF Compound or product or method containing, employing or made using a ZF Compound (unless any such Patent Right is a unitary European patent) and (ii) the Shire [***] Patent Rights from the jurisdiction of the EU Unified Patent Court, in accordance with the terms of Unified Patent Court Regulation (EU) Nos 16351/12 (Agreement on a Unified Patent Court), 1257/2012 and 1260/2012 and its applicable Annexes and Rules of Procedure, as amended and from time-to-time in effect (the "UPC"), and shall be solely responsible for all costs and expenses it incurs in connection with such opt-in and opt-out. If Shire has expressly opted out of (and not subsequently opted back in to) the EU Unitary Patent System with respect to a given Joint Patent Right that does not claim the composition, manufacture or use of a ZF Compound or product or method containing, employing or made using a ZF Compound or a Shire [***] Patent Right, Sangamo shall not initiate any action to enforce any such Patent Right under the EU Unitary Patent System without Shire's prior written approval. Without limitation of Sangamo's rights under Section 11.4, Sangamo shall, following consultation with Shire and good faith consideration of Shire's comments, have the exclusive right to opt-in and opt-out all Sangamo Patent Rights and all Joint Patent Rights that claim the composition, manufacture or use of any ZF Compound or product or method containing, employing or made using a ZF Compound (unless any such Patent Right is a unitary European patent) from the jurisdiction of the UPC, and shall be solely responsible for all costs and expenses it incurs in connection with such opt-in and opt-out. If Sangamo has expressly opted out of (and not subsequently opted in to) the EU Unitary Patent System with respect to a given Joint Patent Right that claims the composition, manufacture or use of a ZF Compound or product or method containing, employing or made using a ZF Compound, or Sangamo Patent Right or Shire Patent Right, Shire shall not initiate any action to enforce any such Patent Right under the EU Unitary Patent System without Sangamo's prior written approval. Each Party shall cooperate with the other Party to the extent reasonably requested by such Party to effectuate the intent of this Section 11.3(f).

11.4 Infringement and Third Party Licenses.

- (a) Existing Third Party Licenses. Sangamo shall be solely responsible for [***], except as provided in Section 10.2 and Section 10.3.
- (b) New Third Party Licenses. Schedule 11.4(b) sets forth all license agreements with Third Parties entered into by Sangamo after the Effective Date and prior to the Amendment Effective Date pursuant to which Sangamo received a license under any Patent Rights or Know-How necessary or useful for the development, manufacture or commercialization of any Shire ZF Compound or Shire ZF Product. Shire will have the option to be granted a sublicense pursuant to Section 8.1 under such scheduled license agreements as well as any license agreement with a Third Party entered into by Sangamo after the Amendment Effective Date pursuant to which Sangamo receives a sublicensable license under any Patent Rights or Know-How necessary for the development, manufacture or commercialization of any Shire ZF Compound or Shire ZF Product. If Shire elects to be granted such a sublicense by Sangamo, then Shire must agree to (i) pay to Sangamo [***], (ii) provide all reports required under the agreement with such Third

Party licensor on account of Sangamo's exercise of such license, (iii) assume all obligations of a sublicensee under such Third Party agreement, and must acknowledge in writing that its sublicense is subject to the terms and conditions of such Third Party agreement. Only upon agreeing in writing to make such payments and fulfill such other obligations will such license agreement become a Third Party License for the purposes of this Agreement and such Patent Rights or Know-How licensed under such license agreement be Controlled by Sangamo for the purposes of this Agreement. Notwithstanding anything in this Agreement to the contrary, in the event of a Change of Control of Sangamo, the provisions of this Section 11.4(b) will not apply to any license agreements entered into by the Third Party acquiror prior to the effective date of such Change of Control. Accordingly, (A) no such license agreements entered into by such Third Party acquiror will become Third Party Licenses for the purposes of this Agreement, and (B) no Patent Rights or Know-How licensed under such license agreements will be Controlled by Sangamo for purposes of this Agreement.

- (c) [***]. Sangamo will use Commercially Reasonable Efforts to [***] that is substantially similar in substance the form of [***]. If Sangamo fails to enter into such an [***], Sangamo shall ensure that such jointly invented [***]. For clarity, during the Term until such time, if any, that the [***] will not enter into any new agreement with the [***].
- (d) <u>Infringement of Third Party Patents</u>; <u>Course of Action</u>. If the conduct of the Research Program or the development, manufacture or commercialization in the Field of any Shire ZF Compound, Sangamo Safe Harbor ZF Compound or Collaboration ZF Product is alleged by a Third Party to infringe a Third Party's patent or other intellectual property rights, the Party becoming aware of such allegation shall promptly notify the Responsible Party for the Collaboration ZF Product to which such infringement relates.
- (e) Third Party Infringement Suit. Subject to a Party's obligations to indemnify and defend the other Party pursuant to Article 13, if a Third Party sues a Party or any of such Party's Affiliates or any Sublicensees (each Person so sued a "Sued Party") alleging that the Sued Party's development, manufacture or commercialization of a Collaboration ZF Product infringed or will infringe such Third Party's intellectual property rights, upon the Sued Party's request and in connection with the Sued Party's defense of any such Third Party infringement suit, the other Party shall provide reasonable assistance to the Sued Party for such defense, at the Sued Party's expense. The Sued Party shall keep the other Party reasonably informed of all material developments in connection with any such suit and shall not, without the other Party's prior written consent, enter into any settlement or consent decree that requires any payment by or admits or imparts any other liability to the other Party.

11.5 Declaratory Judgment Actions by Third Party.

- (a) Shire's Rights. If a Third Party brings a declaratory judgment suit against Shire with respect to Joint Patent Rights that do not claim the composition, manufacture or use of a ZF Compound or a product or method containing, employing or made using a ZF Compound, or Shire [***] Patent Rights or any other Patent Rights owned or Controlled by Shire (other than a Shire Patent Right if such suit is also brought against Sangamo and is related to a Sangamo ZF Product Infringement), then Shire shall have the sole right, but not the obligation, to control the defense of such suit. Sangamo shall cooperate with Shire in any such suit as reasonably requested by Shire and at Shire's expense. If the suit involves any such Joint Patent Right or any Shire [***] Patent Right, then Sangamo also shall have the right to consult with Shire, and to participate in and be represented by independent counsel in such litigation at its own expense. Shire shall not, without Sangamo's prior written consent, enter into any settlement or consent decree that requires any payment by or admits or imparts any other liability to Sangamo or admits the invalidity or unenforceability of any Joint Patent Rights or Shire [***] Patent Rights, which consent shall not be unreasonably withheld, conditioned or delayed.
- (b) <u>Sangamo's Rights</u>. If a Third Party brings a declaratory judgment suit against Sangamo respecting the Joint Patent Rights that claim the composition, manufacture or use of a ZF Compound or product or method containing, employing or made using a ZF Compound or any Sangamo Patent Rights or Shire Patent Rights (solely to the extent related to a Sangamo ZF Product Infringement), then Sangamo shall have the sole right, but not the obligation, to control the defense of such suit. Shire shall cooperate with Sangamo in any such suit as reasonably requested by Sangamo and at Sangamo's expense, and Shire shall have the right to consult with Sangamo and to participate in and, if appropriate, be represented by independent counsel in such litigation at its own expense in the event the loss of such Patent Rights would adversely impact Shire's Net Sales, or market share, of a Shire ZF Product. Sangamo shall not, without Shire's prior written consent, enter into any settlement or consent decree that requires any payment by or admits or imparts any other liability to Shire or admits the invalidity or unenforceability of any Sangamo Patent Rights, Shire Patent Rights or Joint Patent Rights, which consent shall not be unreasonably withheld, conditioned or delayed.
- (c) Other Rights. If a Third Party brings a declaratory judgment suit against Shire with respect to Sangamo Patent Rights, then Sangamo shall have the first right, but not the obligation, to control the defense of such suit with respect to such Sangamo Patent Rights. If Sangamo exercises such right, then Shire shall cooperate with Sangamo in any such suit as reasonably requested by Sangamo and at Sangamo's expense. Shire shall have the right to consult with Sangamo and to participate in and be represented by independent counsel in such litigation at its own expense. Sangamo shall not, without Shire's prior written consent, enter into any settlement or consent decree that requires any payment by or admits or imparts any other liability to Shire or admits the invalidity or unenforceability of any Sangamo Patent Rights, which consent shall not be unreasonably withheld, conditioned or delayed. If Sangamo informs Shire that Sangamo does not intend to exercise its first right to control the defense of such suit, then Shire shall control the defense of such suit and Sangamo shall cooperate with Shire in any such suit as reasonably requested by Shire and at Shire's expense. With respect to such Sangamo Patent Rights, Sangamo shall have the right to consult with Shire and to participate in and be represented by independent counsel in such litigation at its own expense. Shire shall not, without Sangamo's prior written

consent, enter into any settlement or consent decree that requires any payment by or admits or imparts any other liability to Sangamo or admits the invalidity or unenforceability of any Sangamo Patent Rights, which consent shall not be unreasonably withheld, conditioned or delayed.

11.6 Interference, Opposition, Revocation and Declaratory Judgment Actions by Parties. If the Parties mutually determine that, based upon the review of a Third Party's patent or patent application or other intellectual property rights and subject to applicable laws and regulations, it may be desirable in connection with [***] to provoke or institute an interference, opposition, revocation or declaratory judgment action with respect thereto, then the Parties shall consult with one another and shall reasonably cooperate in connection with such an action. Unless otherwise agreed to by the Parties, if the Third Party patent or patent application Covers a Shire Target or the making, using or selling in the Field of a Shire ZF Compound or Shire ZF Product, then in connection with an opposition, revocation or declaratory judgment action Shire may, at its discretion, control such action and select counsel for such action. Shire shall be responsible for, and shall bear, all the out-of-pocket expenses of any such action brought by Shire. If the Third Party patent or patent application is otherwise directed to [***] may, at its discretion, control such action and select counsel for such action. Sangamo shall be responsible for, and shall bear, all the out-of-pocket expenses of any such action involved in the interference may, at its discretion, control such action and select counsel for such action, and shall be responsible for and bear all the out-of-pocket expenses of, any such action. The prosecuting Party shall consider in good faith, take into account and implement where possible the reasonable comments made by the non-prosecuting Party.

12 CONFIDENTIALITY

12.1 Confidentiality. During the Term and for [***] years thereafter, each Party shall maintain in confidence the Confidential Information of the other Party, shall not use or grant the use of the Confidential Information of the other Party except as expressly permitted under this Agreement (which includes the exercise of any rights or the performance of any obligations hereunder), and shall not disclose the Confidential Information of the other Party except on a need-to-know basis to such Party's directors, officers and employees, and to such Party's consultants working on such Party's premises or Subcontractors, to the extent such disclosure is necessary in connection with such Party's activities as expressly authorized by this Agreement. To the extent that disclosure to any Person is authorized by this Agreement (including Subcontractors as described in Section 3.6), prior to disclosure, a Party shall obtain, or shall have obtained prior to the date of this Agreement, written agreement of such Person to hold in confidence and not disclose, use or grant the use of the Confidential Information of the other Party except as expressly permitted under this Agreement. Each Party shall notify the other Party promptly upon discovery of any unauthorized use or disclosure of the other Party's Confidential Information.

12.2 Terms of Agreement. Neither Party shall disclose any terms or conditions of this Agreement to any Third Party without the prior written consent of the other Party; provided that a Party may disclose the terms or conditions of this Agreement, (a) on a need-to-know basis to its legal and financial advisors to the extent such disclosure is reasonably necessary in connection with such Party's activities as expressly permitted by this Agreement, and (b) to a Third Party in connection with: (i) an equity investment in or by, or underwriting by, such Third Party, (ii) a merger, consolidation or similar transaction involving such Third Party, or (iii) the sale of all or substantially all of the assets of the Party to such Third Party; *provided*, *further*, that such Party shall make such disclosure only under appropriate conditions of confidentiality by the Third Party. Notwithstanding the foregoing, Sangamo may disclose the terms and conditions of this Agreement to the extent that such disclosure is required pursuant to the terms of any Third Party License; provided that the licensor of such Third Party License is bound by a confidentiality obligation reasonably acceptable to Shire. Shire acknowledges that the licensors of all Existing Third Party Licenses are bound by confidentiality obligations reasonably acceptable to Shire.

12.3 Permitted Disclosures. Notwithstanding Section 12.1 and Section 12.2, each Party may disclose Confidential Information of the other Party to the extent required by applicable law, regulation or order of a governmental agency or a court of competent jurisdiction, or in prosecuting or defending litigation; provided that such Party shall provide advance written notice thereof (to the extent practicable) to the other Party, consult with the other Party with respect to such disclosure, use reasonable efforts to minimize the amount of information necessary to be disclosed and provide the other Party sufficient opportunity to object to any such disclosure or to request confidential treatment thereof. Notwithstanding Section 12.1 and Section 12.2, Sangamo may disclose Confidential Information of Shire to the extent required by any Third Party License; provided that the licensor of such Third Party License is bound by a confidentiality obligation reasonably acceptable to Shire. Shire acknowledges that the licensors of all Existing Third Party Licenses are bound by confidentiality obligations reasonably acceptable to Shire. The Parties acknowledge that either or both Parties may be obligated to file a copy of this Agreement with the SEC or other Governmental Authorities. Each Party shall be entitled to make such a required filing subject to the provisions of this Section 12.3; provided that any request by the other Party to redact information is consistent with the legal requirements governing redaction of information from material agreements that must be publicly filed.

12.4 Confidentiality and Disclosure Agreement. The terms of the CDA, attached hereto as **Schedule 12.4**, are incorporated herein by reference. To the extent there are any conflicts between this Agreement and the CDA, this Agreement shall control.

12.5 Press Release and Publications. On or after the Amendment Effective Date, Sangamo may issue a press release relating to this Agreement in the mutually agreed upon form set forth in Schedule 12.5. Each Party will have autonomy to issue press releases, public announcements, presentations and publications regarding its own programs, but neither Party will issue any press release, public announcement, presentation or publication regarding the other Party's programs without such other Party's consent. Any other press release, public announcement, presentation or publication (including abstracts, posters, or other scientific publications) that Sangamo proposes to present or issue specifically regarding this Agreement or any of the activities performed hereunder with respect to any Shire Program or data arising from any Shire Program, must be agreed upon in writing by Shire in its sole discretion in advance of its release by Sangamo, with at least [***] days notice to be provided by Sangamo to Shire prior to any submission for publication. Subject to this Section 12.5, however, Sangamo shall not be required to seek the permission of Shire to repeat any such information that has already been publicly disclosed by Sangamo; provided that (a) such information remains consistent with the most recent information publically disclosed by Shire on any particular topic that Sangamo is or should be aware of, in each case as of such time of disclosure by Sangamo; and (b) Sangamo will use its Commercially Reasonable Efforts to provide Shire with advance notification of any such public disclosure. Any other press release, public announcement, presentation or publication (including abstracts, posters, or other scientific publications) that Shire proposes to present or issue specifically regarding this Agreement or any of the activities performed hereunder with respect to any Sangamo Program or data arising from any Sangamo Program, must be agreed upon in writing by Sangamo in its sole discretion in advance of its release by Shire, with at least [***] days notice to be provided by Shire to Sangamo prior to any submission for publication. Notwithstanding the foregoing, each Party shall have the right to issue press releases without the prior consent of the other Party that disclose any information required by the rules and regulations of the United States Securities and Exchange Commission or similar federal, state or foreign authorities, as determined in good faith by independent legal counsel to the disclosing Party, subject to Section 12.3 and provided that the disclosing Party shall use reasonable efforts to give the other Party prior notice of the content and timing of such press release. In addition, to the extent practicable, the Responsible Party shall provide the other Party with notice in advance of any press release to be issued if the primary purpose of such release is to disclose (i) the first report of any serious adverse event or any clinical trial hold or other material development in clinical trials related to the Responsible Party's Collaboration ZF Product, or (ii) any intent to terminate this Agreement, whether in its entirety or with respect to a Shire Target or Sangamo Target (as applicable).

13 INDEMNIFICATION

13.1 Sangamo. Sangamo shall indemnify, defend and hold harmless Shire and its Affiliates and Sublicensees, and each of its respective directors, officers, employees and agents (collectively "Shire Indemnified Party"), from and against all losses, liabilities, damages and expenses, including reasonable attorneys' fees and costs (collectively, "Liabilities"), to the extent resulting from any claims, demands, actions or other proceedings by any Third Party arising out of (a) the material breach of any representation, warranty or covenant by Sangamo under this Agreement; (b) the practice by Sangamo of the licenses granted by Shire, (c) the development, clinical testing, manufacture, use, handling, storage, distribution, marketing, promotion or sale of any ZF Compound or ZF Product by Sangamo, its Affiliates or licensees, as licensed or granted to Sangamo pursuant to **Section 8.2** and **Section 15.5(a)** (including any such Liabilities arising out of or alleged to arise out of any ZF Compound or ZF Product (including any Sangamo Safe Harbor ZF Compound or Sangamo ZF Product) manufactured, sold or distributed by or for Sangamo, its Affiliates or licensees or any violation of law by Sangamo, its Affiliates or licensees); (d) the recklessness, negligence or intentional misconduct of any Sangamo Indemnified Party or licensees; (e) the practice by Sangamo, its Affiliates or licensees of the Sangamo Licensed Technology, and (f) the breach by Sangamo of any Third Party License (other than such breach caused directly by the act or omission of Shire); except, in each case ((a), (b), (c) (d), (e) and (f)), to the extent caused by the gross negligence or intentional misconduct of any Shire Indemnified Party or a breach by Shire of any of its representations, warranties or covenants set forth in this Agreement.

13.2 Shire. Shire shall indemnify, defend and hold harmless Sangamo and its Affiliates, and each of its respective directors, officers, employees and agents (collectively "Sangamo Indemnified Party"), from and against all Liabilities to the extent resulting from any claims, demands, actions or other proceedings by any Third Party arising out of (a) the material breach of any representation, warranty or covenant by Shire under this Agreement; (b) the practice of the licenses granted by Sangamo or the development, clinical testing, manufacture, use, handling, storage, distribution, marketing, promotion or sale of Shire ZF Product manufactured, sold or distributed by or for Shire, its Affiliates or Sublicensees or any violation of law by Shire, its Affiliates or Sublicensees); (c) the development, clinical testing, manufacture, use, handling, storage, distribution, marketing, promotion or sale of any ZF Compound or ZF Product by Shire, its Affiliates or licensees, as licensed or granted to Shire pursuant to Section 15.5(e) (including any such Liabilities arising out of or alleged to arise out of any such ZF Compound or ZF Product manufactured, sold or distributed by or for Shire, its Affiliates or licensees or any violation of law by Shire, its Affiliates or licensees); (d) any claim of infringement or misappropriation of Third Party intellectual property rights with respect to performance of the Research Program in accordance with a Research Plan; or (e) the recklessness, negligence or intentional misconduct of any Shire Indemnified Party; except,

in each case ((a), (b), (c), (d) and (e)), to the extent caused by the gross negligence or intentional misconduct of any Sangamo Indemnified Party or a breach by Sangamo of any of its representations, warranties or covenants set forth in this Agreement.

13.3 Procedure. If a Party (the "Indemnitee") intends to claim indemnification under this Article 13, it shall promptly notify the other Party (the "Indemnitor") in writing of any claim, demand, action or other proceeding for which the Indemnitee intends to claim such indemnification, and the Indemnitor shall have the right to participate in, and, to the extent the Indemnitor so desires, to assume the defense thereof with counsel of its choice, which counsel shall be reasonably acceptable to the Indemnitee; provided that an Indemnitee shall have the right to retain its own counsel at its expense. Further, the obligations of this Article 13 shall not apply to amounts paid in settlement of any claim, demand, action or other proceeding if such settlement is effected without the consent of the Indemnitor, which consent shall not be unreasonably withheld, conditioned or delayed. The Indemnitor shall not settle any claim, demand, action or other proceeding without the prior written consent of the Indemnitee, not to be unreasonably withheld, conditioned or delayed unless the settlement involves only the payment of money. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any such action, to the extent prejudicial to its ability to defend such action, shall relieve the Indemnitor of any obligation to the Indemnitee under this Article 13. The Indemnitee, its employees and agents, shall reasonably cooperate with the Indemnitor and its legal representatives in the investigation of any claim, demand, action or other proceeding covered by this Article 13.

14 INSURANCE

14.1 Insurance.

- (a) <u>Shire</u>. During the Research Term and for a tail period [***] thereafter, and for so long as Shire develops or sells Shire ZF Products anywhere in the world and for a tail period [***] thereafter, Shire shall, at its expense, maintain (i) comprehensive General Liability insurance covering death and bodily injury and property damage, with limits of [***], which policy shall include blanket contractual liability applicable to this Agreement; (ii) Product Liability insurance, with limits of [***]; and (iii) Workers' Compensation insurance including Employers Liability limit of not less than [***] per accident or disease. All of the insurance policies required under this **Section 14.1(a)** shall be underwritten by insurers having a A.M. Best's Rating [***] or higher.
- (b) <u>Sangamo</u>. During the Research Term and for a tail period [***] thereafter, and for so long as Sangamo develops or sells Sangamo ZF Products anywhere in the world and for a tail period [***] thereafter, Sangamo shall, at its expense, maintain (i) comprehensive General Liability insurance covering death and bodily injury and property damage, with limits of [***], which policy shall include blanket contractual liability applicable to this Agreement; (ii) Product Liability insurance, with limits of [***]; and (iii) Workers' Compensation insurance including Employers Liability limit of not less than [***] per accident or disease. All of the insurance policies required under this **Section 14.1(b)** shall be underwritten by insurers having a A.M. Best's Rating of [***] or higher.
- **14.2 Certificates of Insurance**. At the request of a Party, the other Party shall furnish proof of all insurance coverages outlined in this **Article 14** in the form of insurance certificates reasonably acceptable to the other Party. Each Party shall provide the other Party with written notice at least 30 days prior to the cancellation, non-renewal or material change in such insurance or self-insurance which materially adversely affect the rights of the other Party hereunder.

15 TERM; TERMINATION; EFFECTS OF TERMINATION

- **15.1 Term.** Unless earlier terminated as provided herein, the term of this Agreement shall commence on the Amendment Effective Date and shall continue until such time as all payment obligations with respect to all Collaboration ZF Products expire (the "*Term*").
- 15.2 Termination for Breach. A Party's material breach of this Agreement shall entitle the non-breaching Party to give to the breaching Party notice specifying the nature of the material breach, requiring it to make good or otherwise cure such material breach, and stating its intention to terminate if such material breach is not cured. If such material breach is not cured within [***] after the receipt of such notice (or within [***] after the receipt of such notice in the event such material breach is solely based upon a Party's failure to pay any amounts due hereunder), the non-breaching Party shall be entitled, without prejudice to any of its other rights conferred on it by this Agreement, and in addition to any other remedies available to it by law or in equity, to terminate this Agreement in its entirety or with respect to the other Party's Target to which the material breach relates; provided that any right to terminate under this Section 15.2 shall be stayed in the event that, during such cure period, the Party alleged to have been in material breach shall have initiated dispute resolution in good faith in accordance with Section 16.2 with respect to the alleged material breach, which stay shall last so long as the initiating Party diligently and in good faith cooperates in the prompt resolution of such dispute resolution proceedings. Notwithstanding the foregoing, Sangamo may not terminate this Agreement as to any particular Shire Target due to a material breach by Sangamo respecting a different Shire Target, and Shire may not terminate this Agreement as to any particular Sangamo Target due to a material breach by Sangamo respecting a different Sangamo Target.

- **15.3 Termination for Insolvency**. This Agreement may be terminated by either Party upon notice to the other should the other Party: (a) consent to the appointment of a receiver or a general assignment for the benefit of creditors or (b) file or consent to the filing of a petition under any bankruptcy or insolvency law or have any such petition filed against it which has not been stayed within [***] of such filing.
- **15.4 Termination by Shire for Convenience**. Shire may terminate this Agreement in its entirety (which will halt all of the Shire Programs) or with respect to any particular Shire Target (which will halt just the Shire Program that relates to such Terminated Target), in each case effective upon at least [***] prior written notice to Sangamo.

15.5 Effects of Termination.

- (a) <u>By Sangamo for Cause or Shire for Convenience</u>. If this Agreement is terminated by Sangamo (in its entirety or with respect to one or more Shire Targets) pursuant to **Section 15.2** (other than with respect to a breach of Shire's diligence obligations) or in its entirety pursuant to **Section 15.3**, or if this Agreement is terminated by Shire (in its entirety or with respect to a particular Shire Target) pursuant to **Section 15.4**, then subject to **Section 15.5(f)**, in addition to any remedy available at law, then the following will apply:
- (i) Upon such termination of this Agreement, whether in its entirety or for a particular Shire Target, all licenses and obligations with respect to the applicable Terminated Target, including all Shire ZF Compounds and all Shire ZF Products directed to or developed with respect to such Terminated Target, shall terminate.
 - (ii) Shire shall assign to Sangamo any IND/CTA relating to any Terminated Product.
- (iii) Shire shall assign to Sangamo all Marketing Approvals and other Regulatory Filings in respect of any Shire ZF Products that relate to the Terminated Target for which Shire has conducted clinical development (each, a "Terminated Product").
 - (iv) Such Terminated Target shall no longer be a Shire Target.
- (v) Within [***] of notice of termination, to the extent Sangamo elects, Shire shall [***] Patent Rights that (A) relate to the Terminated Target and (B) [***].
- (vi) Within [***] of notice of termination, to the extent Sangamo elects, solely with respect to all Terminated Products and not any Shire ZF Products directed to a Shire Target that is not a Terminated Target, Shire shall (A) promptly transfer to Sangamo all information and materials in Shire's possession and Control that are required, or could reasonably be expected to be required, whether by law, regulation or otherwise, to be maintained by the holder of an IND/CTA, or that are useful or necessary to file an IND/CTA, (B) for any information and materials of the type otherwise described in clause (A) but that are in Shire's Control and in the possession of a Third Party service provider, Shire will either (1) if requested by Sangamo, assign to Sangamo the contract with such service provider (which contract Sangamo shall assume), to the extent assignable, or (2) if not assignable (either by its terms or because it does not relate solely to such Terminated Products), provide access to such information and materials to Sangamo; provided that Sangamo bears all costs for maintenance of and access to such information and materials, and (C) provide Sangamo access, to the extent reasonably requested by Sangamo and necessary or useful for Sangamo to pursue the clinical development and Marketing Approval of (or the maintenance of Marketing Approval of) such Terminated Products, to any information and materials in Shire's Control that are related to such Terminated Products and used or generated in conducting activities under the Collaboration.
- (vii) Within [***] of notice of termination, if Sangamo elects, [***] grant by Shire to Sangamo of a worldwide right and license, with the right to sublicense through multiple tiers in any country, such grant to sublicense only in conjunction with a sub-license or assignment of the applicable Shire ZF Product(s), of any intellectual property rights then Controlled by Shire or its Affiliates and necessary to develop, manufacture, use, sell, offer to sell, import and otherwise commercialize any Terminated Product, provided that such agreement shall include, if the license is non-exclusive, a covenant by Shire not to practice or license such licensed intellectual property within the scope of the license granted to Sangamo. In the event that the Parties are unable to agree upon commercially reasonable terms [***], then the Parties shall submit the determination of commercially reasonable terms [***]. If the Parties do not agree on an arbitrator within [***], then either Party may request [***]. The date on which such arbitrator is selected or appointed will be [***]. The arbitration shall be conducted [***], each Party will prepare and deliver to both the arbitrator and the other Party [***]; provided that unless the Parties agree otherwise in writing in advance, neither [***]. Neither Party may have [***] provided by the Parties the [***] that he or she believes [***] except for those amounts due to such [***]. The decision of the arbitrator [***], Sangamo shall notify Shire of [***]. The arbitrator's fees and expenses will be shared equally by the Parties. Each Party shall otherwise bear its own costs.
- (viii) At Sangamo's request, Shire shall assign to Sangamo all right, title and interest in and to the trademarks then used by Shire in connection with the commercialization of the Terminated Products (excluding any such trademarks that include, in whole or part, any corporate name or logo of Shire or its Affiliate or Sublicensee), provided that Sangamo first reimburse Shire for the reasonable costs incurred by Shire for securing such trademarks.

- (ix) Shire shall, at Sangamo's expense, provide reasonable consultation and assistance for a period of no more than 180 days for the purpose of transferring or transitioning to Sangamo all Know-How described in Section 15.5(a)(vi) not already in Sangamo's possession and, at Sangamo's request, all then-existing commercial arrangements relating specifically to Terminated Products that Shire is able, using reasonable commercial efforts, to transfer or transition to Sangamo, in each case, to the extent reasonably necessary or useful for Sangamo to commence or continue developing, manufacturing, or commercializing Terminated Products. The foregoing shall include, without limitation, transferring, upon request of Sangamo, any agreements with Third Party suppliers or vendors that specifically cover the supply or sale of Terminated Products. If any such contract between Shire and a Third Party is not assignable to Sangamo (whether by such contract's terms or because such contract does not relate specifically to Terminated Products) but is otherwise reasonably necessary or useful for Sangamo to commence or continue developing, manufacturing, or commercializing Terminated Products or if Shire manufactures the Terminated Product itself (and thus there is no contract to assign), then Shire shall reasonably cooperate with Sangamo to negotiate for the continuation of such license or supply from such entity, and Shire shall supply such Terminated Product, as applicable, to Sangamo, for a reasonable period (not to exceed 12 months) until Sangamo establishes an alternative, validated source of supply for the Terminated Products. Sangamo shall pay Shire for such supply an amount equal to Shire's cost of supplying, without markup.
- (x) Sangamo shall have the right to purchase from Shire any or all of the inventory of Terminated Products held by Shire as of the date of termination (that are not committed to be supplied to any Third Party or Sublicensee, in the ordinary course of business, as of the date of termination) at a price equal to Shire's actual cost to acquire or manufacture such inventory. Sangamo shall notify Shire within 60 days after the effective date of termination whether Sangamo elects to exercise such right.
- (xi) The rights and obligations of the Parties with respect to the Shire Target that is not such Terminated Target shall remain in full force and effect.
- (xii) If this Agreement is terminated in its entirety with respect to both Shire Targets, then Sangamo shall have the right to elect, by written notice to Shire delivered no later than the effective date of termination, either (A) to keep its license from Shire under **Section 8.2(b)** in full force and effect, subject to all payment obligations under **Article 10**, or (B) to terminate such license, in which case all rights and obligations of the Parties with respect to the Sangamo Targets, Sangamo Safe Harbor ZF Compounds and Sangamo ZF Products will terminate.
- (b) <u>Special Effects of Termination Due to Shire's Breach of Diligence Obligations</u>. If this Agreement is terminated by Sangamo pursuant to **Section 15.2** (in its entirety or with respect to one or more Shire Targets) due to Shire's breach of its diligence obligations set forth in **Section 5.1**, then in lieu of the effects of termination set forth under **Section 15.5(a)**, the following will apply:
- (i) Upon such termination of this Agreement, whether in its entirety or for a particular Shire Target, all licenses and obligations with respect to the applicable Terminated Target, including all Shire ZF Compounds and all Shire ZF Products directed to or developed with respect to such Terminated Target, shall terminate.
 - (ii) Such Terminated Target shall no longer be a Shire Target.
- (iii) The rights and obligations of the Parties with respect to the Shire Target that is not such Terminated Target shall remain in full force and effect.
- (iv) If this Agreement is terminated with respect to both Shire Targets, then Sangamo shall have the right to elect, by written notice to Shire delivered no later than the effective date of termination, either (A) to keep its license from Shire under **Section 8.2(b)** in full force and effect, subject to all payment obligations under **Article 10**, or (B) to terminate such license, in which case all rights and obligations of the Parties with respect to the Sangamo Targets, Sangamo Safe Harbor ZF Compounds and Sangamo ZF Products will terminate.
- (v) At Sangamo's request, the Parties shall negotiate in good faith and on commercially reasonable economic terms pursuant to which the [***], which negotiations will include the [***]. In the event of a deadlock between the Parties with respect to the economic terms that are to govern such reversion [***] will apply to resolve the appropriate [***].
- (c) <u>Special Effects of Termination during the Research Term</u>. If this Agreement is terminated by Sangamo (in its entirety or with respect to one or more Shire Targets) pursuant to **Section 15.2** (other than with respect to a breach of Shire's diligence obligations) or **Section 15.3**, or if this Agreement is terminated by Shire in its entirety or with respect to a particular Shire Target pursuant to **Section 15.4**, in each case during the Research Term, then in addition to the effects of termination set forth under **Section 15.5(a)**, then the following will apply:
- (i) During the applicable [***] day notice period (or if this Agreement was terminated by Sangamo pursuant to **Section 15.3** or **Section 15.3**, during the 90 day period following such termination), Sangamo shall wind down the Research Plan for the Terminated Target, and Shire shall pay all FTE costs of Sangamo for direct work reasonably necessary for Sangamo to wind down such Research Plan. Upon expiration of such [***] day period, no further payments shall accrue and be due with respect to such Terminated Target, except as provided in **Section 15.5(c)(ii)**. Such reasonably necessary costs shall be invoiced as provided in **Section 3.3(g)**. Sangamo shall use best efforts to minimize any costs incurred following any notice of termination governed by this **Section 15.5(c)(i)**.

- (ii) Shire shall pay any non-cancelable costs relating to such Terminated Target to which Sangamo has committed after the Effective Date prior to such notice of termination. Such non-cancelable costs shall be invoiced as provided in **Section 3.3(g)**. Sangamo shall use best efforts to minimize any non-cancelable costs incurred following any notice of termination governed by this **Section 15.5(c)**.
- (d) <u>Termination by Shire for Cause</u>. If Shire has the right to terminate this Agreement in its entirety or with respect to a Sangamo Target pursuant to **Section 15.2** (other than with respect to a breach of Sangamo's diligence obligations) or **Section 15.3**, then subject to **Section 15.5(f)**, in addition to any remedy available at law, the following will apply:
- (i) *Shire Target Breach.* If the breach by Sangamo giving rise to the termination right relates solely to the Shire Targets, then (A) all rights and obligations of the Parties with respect to the [***] will remain in effect (including the licenses granted to Sangamo with respect to the [***] and any payment obligations under **Article 10**) and (B) Shire will have the right to elect, by written notice to Sangamo delivered no later than the effective date of termination, either (1) to keep its license from Sangamo under **Section 8.1** in full force and effect, subject to all payment obligations under **Article 10** or (2) to terminate such license, in which case all rights and obligations of the Parties with respect to the Shire Targets, Shire ZF Compounds and Shire ZF Products will terminate; and
- (ii) Sangamo Target Breach. If the breach by Sangamo giving rise to the termination right relates solely to one or both Sangamo Targets or if this Agreement is terminated by Shire pursuant to **Section 15.3**, then (A) all rights and obligations of the Parties with respect to the terminated Sangamo Targets, and [***] directed to or developed with respect to such Sangamo Targets (including the licenses granted to Sangamo with respect to such [***] and any payment obligations under **Article 10**), will terminate and (B) if Shire has the right to and chooses to terminate this Agreement in its entirety, then Shire will have the right to elect, by written notice to Sangamo delivered no later than the effective date of termination, either (1) to keep its license from Sangamo under **Section 8.1** in full force and effect, subject to all payment obligations under **Article 10**; or (2) to terminate such license, in which case all rights and obligations of the Parties with respect to the Shire Targets, Shire ZF Compounds and Shire ZF Products will terminate.
- (e) <u>Special Effects of Termination Due to Sangamo's Breach of Diligence Obligations</u>. If this Agreement is terminated by Shire pursuant to **Section 15.2** (in its entirety or with respect to one or more Sangamo Targets) due to Sangamo's breach of its diligence obligations set forth in **Section 5.2**, then in lieu of the effects of termination set forth under **Section 15.5(d)**, the following will apply:
- (i) In the case of termination of this Agreement in its entirety, all rights and licenses granted by Shire to Sangamo under this Agreement shall automatically terminate.
- (ii) If this Agreement is terminated with respect to only one Sangamo Target, then such terminated Target shall no longer be a Sangamo Target.
- (iii) The rights and obligations of the Parties with respect to the Sangamo Target that is not such terminated Target shall remain in full force and effect.
- (iv) If this Agreement is terminated with respect to both Sangamo Targets, then Shire shall have the right to elect, by written notice to Sangamo delivered no later than the effective date of termination, either (A) to keep its license from Sangamo under **Section 8.1** in full force and effect, subject to all payment obligations under **Article 10**, or (B) to terminate such license, in which case all rights and obligations of the Parties with respect to the Shire Targets, Shire ZF Compounds and Shire ZF Products will terminate.
- (v) At Shire's request, the Parties shall negotiate in good faith and on commercially reasonable economic terms pursuant to which the applicable [***], which negotiations will include the subject matter set forth under [***]. In the event of a deadlock between the Parties with respect to the economic terms [***] will apply to resolve the appropriate [***].
- (f) <u>Survival of Certain Obligations</u>. Expiration or termination of this Agreement shall not relieve the Parties of any obligation that accrued before such expiration or termination. In addition to all other provisions contained in this Agreement that by their terms survive expiration or termination of this Agreement, the following provisions also shall survive expiration or termination of this Agreement: Sections 2.1, 2.2(a)(iv), 2.2(b), 2.2(d), 3.1, 3.2, 3.3(g), 3.8, 3.9, 5.3 (last sentence only), 5.4(a) (last sentence only), 10.7(c), 10.8, 10.9, 10.10, 10.12, 11.1(a), 12.1, 12.2, 12.3, 15.5, and Articles 1, 13, 14, and 16. In addition to the foregoing, in the event of any termination of this Agreement by Shire pursuant to Section 15.2 or Section 15.3, if Shire elects pursuant to Section 15.5(d)(i) or Section 15.5(d)(ii) to keep its license from Sangamo under Section 8.1 in full force and effect, then Shire's rights, and Sangamo's obligations, in each case to prosecute, maintain, enforce and defend all applicable Patent Rights as set forth under the following provisions also shall survive: Sections 11.2 and 11.3.

16 MISCELLANEOUS

16.1 Governing Law. This Agreement shall be governed by the laws of Delaware without regard to its choice of law principles; provided that the United Nations Convention on Contracts for the International Sale of Goods shall not apply.

16.2 Dispute Resolution.

- (a) <u>Notice of Dispute</u>. The Parties recognize that a *bona fide* dispute as to certain matters may from time-to-time arise during the term of this Agreement that relates to either Party's rights or obligations hereunder. In the event of any dispute between the Parties with respect to any matter relating to this Agreement, one Party may provide the other Party with a notice of dispute.
- (b) <u>Internal Resolution</u>. Upon a Party's receipt of a notice of dispute, the Parties shall first use their good faith efforts to resolve such dispute among themselves without resorting to Executive Resolution pursuant to **Section 16.2(c)**.
- (c) Executive Resolution. In the event that such dispute is not resolved within 30 days of providing a notice of dispute, the dispute shall be taken to the Chief Executive Officer or an Executive Vice President of Sangamo and a Senior Vice President of Shire for resolution. If these individuals are unable to resolve the dispute within 30 days of the request for such meeting, then the Parties shall be free to pursue any avenue available to them under law or equity to resolve the dispute.
- 16.3 Assignment. Neither this Agreement nor any right or obligation hereunder may be assigned or delegated, in whole or part, by either Party without the prior express written consent of the other, which consent shall not be withheld, conditioned or delayed unreasonably; provided that either Party may assign or delegate any right or obligation hereunder, in whole or in part, to any of its Affiliates so long as such entity remains an Affiliate; provided, however, that the assigning Party shall remain liable for its obligations hereunder to the extent not fulfilled by assignee. Either Party may assign this Agreement in its entirety to a successor in interest in connection with a Change of Control of such Party. Section 8.5 shall be applicable upon a Change of Control of Sangamo. The Party assigning this Agreement shall cause any permitted assignee to assume all obligations of the assignor under this Agreement, including its obligation to pay Earned Royalties in accordance with Section 10.2, and any permitted assignment shall be binding on the successors of the assigning Party. Any purported assignment in violation of this Section 16.3 shall be void. Notwithstanding the foregoing, Sangamo shall not assign or delegate any right or obligation in full or in part to an Affiliate incorporated in [***] without Shire's prior written consent, which Shire shall not unreasonably withhold, other than in connection with a Change of Control. For the avoidance of doubt, a [***].
- **16.4 Independent Contractors.** The relationship of the Parties is that of independent contractors. Neither Party shall be deemed to be the agent, partner or joint venturer of the other for any purpose as a result of this Agreement or the transactions contemplated thereby.
- **16.5 Further Actions**. Each Party agrees to execute, acknowledge and deliver such further documents and instruments and to perform all such other acts as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.
- **16.6 Notices.** All requests and notices required or permitted to be given to the Parties hereto shall be given in writing, shall expressly reference the section(s) of this Agreement to which they pertain, and shall be delivered to the other Party by mail, any commercial delivery service or by email transmission, in all cases with confirmation of receipt and with delivery to be effective on receipt, at the appropriate address as set forth below or to such other addresses as may be designated in writing by the Parties from time-to-time during the Term.

If to Shire:

Shire International GmbH c/o LacMont Hofstrasse 1A 6300 Zug, Switzerland Att: Legal Department

Copy to: Shire Human Genetic Therapies, Inc. 300 Shire Way Lexington, MA 02421 Att: Legal Department Additional copy to: Ropes & Gray LLP Prudential Tower; 800 Boylston Street Boston, MA 02199 Att: David M. McIntosh

Email: david.mcintosh@ropesgray.com

If to Sangamo:

Sangamo BioSciences, Inc. Point Richmond Tech Center II 501 Canal Boulevard, Suite A100 Richmond, California 94804 Att: Chief Executive Officer

Copy to:
Cooley LLP
3175 Hanover Street
Palo Alto, CA 94304
Att: Marya A. Postner, Esq.
Email: mpostner@coolev.com

- **16.7 Force Majeure**. Nonperformance of a Party (other than for the payment of money) shall be excused to the extent that performance is rendered impossible by strike, fire, earthquake, flood, governmental acts or orders or restrictions, terrorist acts, failure of suppliers, or any other reason where failure to perform is beyond the reasonable control and not caused by the negligence, intentional conduct or misconduct of the nonperforming Party; provided that the nonperforming Party shall use Commercially Reasonable Efforts to resume performance as soon as reasonably practicable.
- 16.8 No Consequential Damages. IN NO EVENT SHALL A PARTY BE LIABLE FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, INCLUDING LOST PROFITS ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING NOTHING IN THIS SECTION 16.8 IS INTENDED TO LIMIT OR RESTRICT THE DAMAGES AVAILABLE FOR A BREACH OF SECTION 8.4, A BREACH OF ARTICLE 12 OR THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY UNDER ARTICLE 13.
- **16.9 Complete Agreement.** This Agreement constitutes the entire agreement between the Parties regarding the subject matter hereof, and all prior representations, understandings and agreements (other than the Original Agreement) regarding the subject matter hereof, either written or oral, expressed or implied, are superseded and shall be of no effect. The foregoing shall not be interpreted as a waiver of any remedies available to either Party as a result of any breach, prior to the Amendment Effective Date, by the other Party of its obligations pursuant to the CDA or the Original Agreement.
- **16.10** Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original and together shall be deemed to be one and the same agreement. Counterparts may be signed and delivered by facsimile or digital transmission, each of which shall be binding when received by the applicable Party.
- **16.11 Headings**. The captions to the several sections hereof are not a part of this Agreement, but are included merely for convenience of reference only and shall not affect its meaning or interpretation.
- 16.12 Construction. This Agreement was negotiated and executed in English, and the original language version shall be controlling; all communications and notices hereunder shall be in English. The Parties acknowledge that they have both had the opportunity to negotiate regarding any issues in connection with this Agreement that were of concern to them and, therefore, expressly waive the benefit of any presumption that ambiguities should be construed in favor of or against either Party. Except where the context otherwise requires, the use of any gender herein shall be deemed to be or include the other genders, the use of the singular shall be deemed to include the plural (and vice versa) and the word "or" is used in the inclusive sense commonly associated with the term "and/or". The words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation." The word "will" shall be construed to have the same meaning and effect as the word "shall." Unless the context requires otherwise, (a) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time-to-time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (b) any reference herein to any Person shall be construed to include the Person's successors and assigns, (c) the words "herein", "hereof" and "hereunder", and words of similar

import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof and (d) all references herein to sections, Schedules or Exhibits shall be construed to refer to sections, Schedules or Exhibits of this Agreement.

- **16.13 Amendment**. No amendment, modification or supplement of any provision of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.
- **16.14 Waiver**. No provision of the Agreement shall be waived by any act, omission or knowledge of a Party or its agents or employees except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer of the waiving Party. The waiver by either of the Parties of any breach of any provision hereof by the other Party shall not be construed to be a waiver of any succeeding breach of such provision or a waiver of the provision itself. All remedies of either Party hereunder will be cumulative and the pursuit of one remedy will not be deemed a waiver of any other remedy.
- **16.15 Severability**. If any clause or portion thereof in this Agreement is for any reason held to be invalid, illegal or unenforceable, the same shall not affect any other portion of this Agreement, as it is the intent of the Parties that this Agreement shall be construed in such fashion as to maintain its existence, validity and enforceability to the greatest extent possible. In any such event, this Agreement shall be construed as if such clause or portion thereof had never been contained in this Agreement, and there shall be substituted therefor such provision as will most nearly carry out the intent of the Parties as expressed in this Agreement to the fullest extent permitted by applicable law.

[The remainder of this page is left blank intentionally.]

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*** CONFIDENTIAL PORTIONS OMITTED AND FILED SEPARATELY WITH THE COMMISSION

IN WITNESS	WHEREOF, the Pa	arties have caused th	nis Agreement to	be executed by tl	heir respective du	ly authorized o	fficers as of the da	ay and year
first above written.								

By:	
Name:	
Title:	
SHIRE	INTERNATIONAL GMBH
SHIRE By:	INTERNATIONAL GMBH
	INTERNATIONAL GMBH

SANGAMO BIOSCIENCES, INC.

 $[Signature\ Page\ to\ Amended\ and\ Restated\ Collaboration\ and\ License\ Agreement]$

*** CONFIDENTIAL PORTIONS OMITTED AND FILED SEPARATELY WITH THE COMMISSION

CERTIFICATION

I, Edward O. Lanphier II, certify that:

- I have reviewed this quarterly report on Form 10-Q of Sangamo BioSciences, Inc. ("registrant")
- 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 the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter 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:
 - (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: October 30, 2015

/s/ Edward O. Lanphier II

Edward O. Lanphier II

President and Chief Executive Officer

CERTIFICATION

I, H. Ward Wolff, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Sangamo BioSciences, Inc. ("registrant")
- 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 the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter 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:
 - (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: October 30, 2015

/s/ H. Ward Wolff

H. Ward Wolff Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)

Certification Pursuant to 18 U.S.C. §1350, as Adopted Pursuant to §906 of the Sarbanes-Oxley Act of 2002

Each of the undersigned hereby certifies pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002 in his capacity as an officer of Sangamo BioSciences, Inc. (the "Company"), that:

- (1) the Quarterly Report of the Company on Form 10-Q for the quarterly period ended September 30, 2015, as filed with the Securities and Exchange Commission (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Edward O. Lanphier II

Edward O. Lanphier II
President and Chief Executive Officer
(Principal Executive Officer)

Date: October 30, 2015

/s/ H. Ward Wolff

H. Ward Wolff

Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)

Date: October 30, 2015