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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2013

Or

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

Commission file number: 001-35676

PROTHENA CORPORATION plc
(Exact name of registrant as specified in its charter)

Ireland	**43-1256213**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
650 Gateway Boulevard South San Francisco, California	**94080**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 837-8550

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

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

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

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 ☐ No ☒

The number of ordinary shares outstanding as of July 31, 2013 was 17,679,182.

PROTHENA CORPORATION plc
Form 10Q – QUARTERLY REPORT
For the Quarter Ended June 30, 2013

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Prothena Corporation plc
Condensed Consolidated Balance Sheets
(in thousands, except share and per share data)

	June 30, 2013 (unaudited)	December 31, 2012 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 112,507	$ 124,860
Receivable from related party	55	223
Deferred tax assets	73	73
Prepaid expenses and other current assets	959	685
Total current assets	113,594	125,841
Non-current assets:		
Property and equipment, net	3,729	3,442
Deferred tax assets	607	—
Total non-current assets	4,336	3,442
Total assets	$ 117,930	$ 129,283
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 779	$ —
Accrued research and development	5,698	47
Income taxes payable	300	27
Other current liabilities	2,306	1,670
Total current liabilities	9,083	1,744
Non-current liabilities:		
Deferred rent	1,417	1,055
Deferred tax liability	201	—
Total liabilities	10,701	2,799
Shareholders' equity:		
Euro deferred shares, €22 nominal value:	—	—
Authorized shares — 10,000 at June 30, 2013 and December 31, 2012		
Issued and outstanding shares — none at June 30, 2013 and December 31, 2012		
Ordinary shares, $0.01 par value:	177	177
Authorized shares — 100,000,000 at June 30, 2013 and December 31, 2012		
Issued and outstanding shares — 17,679,182 at June 30, 2013 and December 31, 2012		
Additional paid-in capital	127,650	126,652
Accumulated deficit	(20,598)	(345)
Total shareholders' equity	107,229	126,484
Total liabilities and shareholders' equity	$ 117,930	$ 129,283

(1) Amounts have been derived from the December 31, 2012 audited consolidated financial statements.

See accompanying notes to condensed consolidated financial statements.

Prothena Corporation plc
Condensed Consolidated Statements of Operations
(in thousands, except per share data)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Revenues—related party	$ 167	$ 735	$ 338	$ 1,139
Operating expenses:				
Research and development	8,147	8,019	14,104	16,776
General and administrative	3,212	2,427	6,393	4,885
Total operating expenses	11,359	10,446	20,497	21,661
Loss from operations	(11,192)	(9,711)	(20,159)	(20,522)
Interest income, net	14	—	36	—
Loss before income taxes	(11,178)	(9,711)	(20,123)	(20,522)
Provision for income taxes	124	—	130	—
Net loss	$(11,302)	$ (9,711)	$(20,253)	$(20,522)
Basic and diluted net loss per share	$ (0.64)	$ (0.67)	$ (1.15)	$ (1.42)
Shares used to compute basic and diluted net loss per share	17,679	14,497	17,679	14,497

See accompanying notes to condensed consolidated financial statements.

Prothena Corporation plc
Condensed Consolidated Statements of Cash Flows
(in thousands)
(unaudited)

	Six Months Ended June 30,	
	2013	2012
Operating activities		
Net loss	$ (20,253)	$(20,522)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	284	228
Share-based compensation	1,082	5,225
Deferred income taxes	(406)	—
Gain on disposal of fixed asset	(29)	—
Changes in operating assets and liabilities:		
Receivable from related party	168	—
Other assets	(274)	(6)
Accounts payable, accruals and other liabilities	7,470	(3,913)
Net cash used in operating activities	(11,958)	(18,988)
Investing activities		
Purchases of property and equipment	(340)	(171)
Proceeds from disposal of fixed asset	29	—
Net cash used in investing activities	(311)	(171)
Financing activities		
Proceeds from funding provided by Elan	—	19,159
Post separation adjustments to the funding provided by Elan	(84)	—
Net cash (used in) provided by financing activities	(84)	19,159
Net decrease in cash and cash equivalents	(12,353)	—
Cash and cash equivalents, beginning of the year	124,860	—
Cash and cash equivalents, end of the period	$112,507	$ —
Supplemental cash flow information		
Cash paid for income taxes	$ 263	$ —

See accompanying notes to condensed consolidated financial statements.

Notes to Condensed Consolidated Financial Statements
(unaudited)

1. Organization

Description of Business

Prothena Corporation plc ("Prothena," the "Company," "we," "our" or "us"), a public limited company incorporated in Ireland, is a clinical stage biotechnology company focused on the discovery and development of novel antibodies for the potential treatment of a broad range of diseases that involve protein misfolding or cell adhesion. The Company is focused on the discovery and development of potential therapeutic monoclonal antibodies directed specifically to disease causing proteins. These potential therapies have a broad range of indications including AL and AA forms of amyloidosis (NEOD001), Parkinson's disease and related synucleinopathies (PRX002) and autoimmune diseases and metastatic cancers (PRX003). The Company has initiated a Phase 1 clinical trial for NEOD001 with the first patient dosing in April 2013. The Phase 1 clinical trial of NEOD001 will evaluate safety and tolerability in AL Amyloidosis patients. The Company's strategy is to identify antibody candidates for clinical development by applying its extensive expertise in generating novel therapeutic antibodies and working with collaborators having expertise in specific animal models of disease.

Prothena's business consists of a substantial portion of Elan Corporation plc's ("Elan") former drug discovery business platform, including Neotope Biosciences Limited (and its wholly-owned subsidiary Prothena Biosciences Inc) and Onclave Therapeutics Limited, each former wholly-owned subsidiaries of Elan (which for the period prior to separation and distribution are referred to herein as the "Prothena Business"). Effective December 20, 2012, the Prothena Business separated from Elan.

Liquidity and Business Risks

As of June 30, 2013, the Company had an accumulated deficit of $20.6 million and cash and cash equivalents of $112.5 million. Based on the Company's current business plans, management believes that the Company's cash and cash equivalents at June 30, 2013 will be sufficient to meet the Company's obligations for at least the next twelve months. To operate beyond such period, or if the Company elects to increase its spending on development programs significantly above current long-term plans or enters into potential licenses and or other acquisitions of complementary technologies, products or companies, the Company will need additional capital. The Company expects to continue to finance future cash needs that exceed its operating activities primarily through its current cash and cash equivalents, and to the extent necessary, through proceeds from public or private equity or debt financings, loans and collaborative agreements with corporate partners or other arrangements.

The Company is subject to a number of risks, including but not limited to: the uncertainty of the Company's research and development ("R&D") efforts resulting in future successful commercial products; obtaining regulatory approval for new products; its ability to successfully commercialize its product candidates, if approved; significant competition from larger organizations; reliance on the proprietary technology of others; dependence on key personnel; uncertain patent protection; dependence on corporate partners and collaborators; and possible restrictions on reimbursement from governmental agencies and healthcare organizations, as well as other changes in the health care industry.

Use of Estimates

The preparation of the condensed consolidated financial statements in conformity with Generally Accepted Accounting Principles in the United States ("GAAP") requires management to make judgments, estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. Because of the uncertainties inherent in such estimates, actual results may differ materially from these estimates.

2. Summary of Significant Accounting Policies

Significant Accounting Policies

There have been no significant changes to the accounting policies during the three months ended June 30, 2013, as compared to the significant accounting policies described in Note 2 of the "Notes to Consolidated Financial Statements" in the Company's Annual Report for the year ended December 31, 2012 on Form 10-K, which was filed with the Securities and Exchange Commission ("SEC") on March 29, 2013 ("2012 Form 10-K") and Note 2 of the "Notes to Condensed Consolidated Financial Statements" in its Quarterly Report on Form 10-Q for the first quarter ended March 31, 2013, which was filed with the SEC on May 15, 2013 ("2013 First Quarter Form 10-Q").

Basis of Preparation and Presentation of Financial Information

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with GAAP and applicable rules and regulations of the SEC regarding interim financial reporting. Certain information and note disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. Therefore, these condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes included in the Company's 2012 Form 10-K.

The accompanying condensed consolidated financial statements prior to December 21, 2012 include allocations of direct costs and indirect costs attributable to the Prothena Business operations. The indirect costs included in the Company's condensed consolidated financial statements relate to certain centralized support functions that were provided by Elan. The centralized support functions provided to the Prothena Business by Elan included, but were not limited to, accounting, information technology, taxation, legal, corporate strategy, investor relations, corporate governance and other professional services, employee benefit administration, including equity award and pension services, and cash and treasury management. Centralized support costs allocated to the Prothena Business for the three and six months ended June 30, 2012 were $2.1 million and $4.1 million, respectively. These costs have been allocated to the Prothena Business for the purposes of preparing the consolidated financial statements based on its estimated usage of the resources. The estimated usage of the central support resources allocated to the Prothena Business was determined by estimating its portion of the most appropriate driver for each category of central support costs such as headcount or labor hours, depending on the nature of the costs. The Company believes that such allocations have been made on a reasonable basis, but may not necessarily be indicative of the costs that would have been incurred if it had operated on a standalone basis.

The condensed consolidated financial statements include the accounts of Prothena and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated.

The Condensed Consolidated Balance Sheet as of December 31, 2012, included herein, was derived from the audited financial statements as of that date but does not include all disclosures, including notes required by GAAP.

Certain amounts in the condensed consolidated financial statements have been reclassified to conform to the current year presentation.

In the opinion of management, the accompanying unaudited condensed consolidated financial statements reflect all normal recurring adjustments necessary to present fairly the financial positions, results of operations and cash flows for the interim periods, but are not necessarily indicative of the results of operations to be anticipated for the year ending December 31, 2013 or any future periods.

Comprehensive Loss

Comprehensive loss is comprised of net loss and other comprehensive income (loss). The Company has no components of other comprehensive income (loss). Therefore net loss equals comprehensive loss for all periods presented and, accordingly, the Condensed Consolidated Statements of Comprehensive Loss is not presented in a separate statement.

Geographical and Customer Concentration

The Company's revenues have been from Ireland for all periods presented, while all of its assets were held in the United States. Revenue recorded in the statements of operations consists of fees earned from the provision of non-clinical research support to Elan, primarily in the areas of safety, toxicology and regulatory. The fees charged to Elan were calculated based on the expenses incurred by the Company in the provision of those R&D services, plus a contractually determined mark-up of those expenses.

Recent Accounting Pronouncements

As an Emerging Growth Company under the Jumpstart Our Business Startups Act ("JOBS Act"), unlike other public companies, the Company is eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not Emerging Growth Companies. The Company has an extended transition period for adopting new or revised accounting standards that have different effective dates for public and private companies until such time as those standards apply to private companies. There have been no new accounting pronouncements or changes to accounting pronouncements during the six months ended June 30, 2013, as compared to the recent accounting pronouncements described in the Company's 2012 Form 10-K, that are of significance or potential significance to the Company.

3. Fair Value Measurements

The Company measures certain financial assets and liabilities at fair value on a recurring basis, including cash equivalents. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability. A three-tier fair value hierarchy is established as a basis for considering such assumptions and for inputs used in the valuation methodologies in measuring fair value:

Level 1 — observable inputs such as quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2 — include other inputs that are based upon quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, and model-based valuation techniques for which all significant inputs are observable in the market or can be derived from observable market data. Where applicable, these models project future cash flows and discount the future amounts to a present value using market-based observable inputs including interest rate curves, foreign exchange rates, and credit ratings.

Level 3 — unobservable inputs that are supported by little or no market activities, which would require the Company to develop its own assumptions.

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

Based on the fair value hierarchy, the Company classifies its cash equivalents within Level 1. This is because the Company values its cash equivalents using quoted market prices. The Company's Level 1 securities, valued using quoted prices in active markets, consist of $91.6 million and $103.5 million in money market funds included in cash and cash equivalents at June 30, 2013 and December 31, 2012, respectively.

4. Composition of Certain Balance Sheet Items

Property and Equipment

Property and equipment consisted of the following at (in thousands):

	June 30, 2013	December 31, 2012
Machinery and equipment	$ 5,633	$ 5,449
Leasehold improvements	1,920	1,651
Purchased computer software	85	85
	7,638	7,185
Less: accumulated depreciation and amortization	(3,909)	(3,743)
	$ 3,729	$ 3,442

Depreciation expense was $0.2 million and $0.3 million for the three and six months ended June 30, 2013, respectively, compared to $0.1 million and $0.2 million for the three and six months ended June 30, 2012, respectively.

Other Current Liabilities

Other current liabilities consisted of the following at (in thousands):

	June 30, 2013	December 31, 2012
Payroll and related expenses	$ 1,185	$ 1,592
Professional services	591	27
Other	530	51
	$ 2,306	$ 1,670

5. Net Loss Per Share

Basic net loss per share is calculated by dividing net loss by the weighted-average number of ordinary shares outstanding during the period. Shares used in diluted net income per share would include the dilutive effect of ordinary shares potentially issuable upon the exercise of stock options outstanding and restricted stock units. However, potentially issuable ordinary shares are not used in computing diluted net loss per share as their effect would be anti-dilutive due to the loss recorded during the periods presented, therefore diluted net loss per share is equal to basic net loss per share. Prior to the separation and distribution, the Company operated as part of Elan and not as a separate entity. As a result, the Company did not have any ordinary shares outstanding prior to December 21, 2012. The calculation of basic and diluted net loss per share assumes that the 14,497,000 shares issued to Elan shareholders in connection with the separation from Elan have been outstanding for all periods presented and that the 3,182,000 shares purchased by Elan upon separation have only been outstanding since December 20, 2012.

Net loss per share was determined as follows (in thousands, except per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Numerator:				
Net loss	$(11,302)	$ (9,711)	$(20,253)	$(20,522)
Denominator:				
Weighted-average ordinary shares outstanding	17,679	14,497	17,679	14,497
Basic and diluted net loss per share	$ (0.64)	$ (0.67)	$ (1.15)	$ (1.42)

The equivalent ordinary shares not included in diluted net loss per share because their effect would be anti-dilutive are as follows (in thousands):

	June 30,	
	2013	2012
Options to purchase ordinary shares	1,836	1,096
Restricted stock units	—	328
	1,836	1,424

6. Share-Based Compensation Expense

The Prothena Corporation plc 2012 Long Term Incentive Plan

The Company's 2012 Long Term Incentive Plan ("LTIP") provides for the issuance of ordinary share-based awards, including restricted shares, restricted stock units ("RSUs"), stock options, share appreciation rights and other equity-based awards, to its employees, officers, directors and consultants. Under the LTIP, the Company is authorized to issue a total of 2,650,000 shares. During the three and six months ended June 30, 2013, the Company granted 469,500 and 1,835,500 stock options, respectively, under its LTIP. At June 30, 2013, 814,500 shares remain available for grant.

Share-based Compensation Expense

The Company estimates the fair value of share-based compensation on the date of grant using an option-pricing model. The Company uses the Black-Scholes model to value share-based compensation, excluding RSUs, which the Company models using the fair market value of its ordinary shares on the date of grant. The Black-Scholes option-pricing model determines the fair value of share-based payment awards based on the share price on the date of grant and is affected by assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to, the Company's share price, volatility over the expected life of the awards and actual and projected employee stock option exercise behaviors. Option-pricing models were developed for use in estimating the value of traded options that have no vesting or hedging restrictions and are fully transferable. Although the fair value of stock options granted by the Company is estimated by the Black-Scholes model, the estimated fair value may not be indicative of the fair value observed in a willing buyer and seller market transaction.

As share-based compensation expense recognized in the condensed consolidated financial statements is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from estimates. Forfeitures were estimated based on estimated future turnover and historical experience.

The fair value of the options granted during the three and six months ended June 30, 2013 is estimated as of the grant date using the Black-Scholes option-pricing model assuming the weighted-average assumptions listed in the following table:

	Three Months Ended June 30, 2013	Six Months Ended June 30, 2013
Expected volatility	84.5%	84.2%
Risk-free interest rate	1.7%	1.2%
Expected dividend yield	0.0%	0.0%
Expected life (in years)	6.0	6.0
Weighted average fair value	$ 5.28	$ 4.56

The following table summarizes share-based compensation expense recognized for stock options during the three and six months ended June 30, 2013 (in thousands):

	Three Months Ended June 30, 2013	Six Months Ended June 30, 2013
Research and development*	$ 226	$ 305
Selling, general and administrative	516	777
	$ 742	$ 1,082

* Includes $0.1 million of share-based compensation expense related to an option grant to a consultant.

Share-based compensation expense will continue to have an adverse impact on the Company's reported results of operations, although it will have no impact on its overall financial position. The amount of unearned share-based compensation currently estimated to be expensed from now through the year 2017 related to unvested share-based payment awards at June 30, 2013 is $6.4 million. The weighted-average period over which the unearned share-based compensation is expected to be recognized is 3.1 years. If there are any modifications or cancellations of the underlying unvested securities, the Company may be required to accelerate, increase or cancel any remaining unearned share-based compensation expense. Future share-based compensation expense and unearned share-based compensation will increase to the extent that the Company grants additional equity awards.

The following table summarizes the Company's stock option activity during the six months ended June 30, 2013 (in thousands):

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at the beginning of the year	—	$ —		
Granted	1,836	6.57		
Outstanding at the end of the period	1,836	6.57	9.6	$11,643
Vested and expected to vest at the end of the period	1,637	6.56	9.6	10,391
Vested at the end of the period	—	—	—	—

Elan's Share-based Compensation Awards

Prior to the separation and distribution of the Prothena Business on December 20, 2012, the Company's employees had received share-based compensation awards under Elan's equity compensation plans and, therefore, the following disclosures pertain to share-based compensation expense that was allocated to the Prothena Business related to Elan's share-based equity awards. Elan's equity award program provided for the issuance of stock options, RSUs and other equity awards to its employees, including employees that have directly and indirectly provided service to the Prothena Business. The share-based payment compensation expense recognized in these condensed consolidated financial statements includes all of the share-based payment expenses directly attributable to the

Prothena Business and an allocation of indirect expenses that have been deemed attributable to the Prothena Business for the three and six months ended June 30, 2012. The Company will not recognize any share-based compensation expense in relation to the existing Elan equity-based awards for periods after December 31, 2012 as its employees are not required to provide service after the separation and distribution in order to receive the benefits of the awards.

The following table summarizes share-based compensation expense recognized during the three and six months ended June 30, 2012 (in thousands):

	Three Months Ended June 30, 2012	Six Months Ended June 30, 2012
Research and development	$ 1,652	$ 5,220
General and administrative	3	5
Total direct expense	1,655	5,225
General and administrative — allocated	410	886
	$ 2,065	$ 6,111

Share-based Compensation Expense

Share-based compensation expense was measured and recognized based on estimated grant date fair values. These awards include employee stock options and RSUs, and share purchases related to the Employee Equity Purchase Plan ("EEPP"). Share-based compensation cost for stock options and ordinary shares issued under Elan's EEPP was estimated at the grant date based on each option's fair value as calculated using an option-pricing model. Share-based compensation expense for RSUs was measured based on the closing fair market value of Elan's ordinary shares on the date of grant. The value of awards expected to vest was recognized as an expense over the requisite service periods prior to the separation and distribution. Estimating the fair value of share-based awards as of the grant or vest date using an option-pricing model, such as the binomial model, was affected by Elan's share price as well as assumptions regarding a number of complex variables. These variables included, but were not limited to, the expected share price volatility over the term of the awards, risk-free interest rates, and actual and projected employee exercise behaviors.

The following table summarizes share-based compensation expense related to award type during the three and six months ended June 30, 2012 (in thousands):

	Three Months Ended June 30, 2012	Six Months Ended June 30, 2012
Restricted stock units	$ 988	$ 2,983
Stock options	667	2,242
Total direct	1,655	5,225
Total allocated	410	886
	$ 2,065	$ 6,111

The fair value of stock options was calculated using a binomial option-pricing model, taking into account the relevant terms and conditions. The binomial option-pricing model was used to estimate the fair value of Elan's stock options because it better reflects the possibility of exercise before the end of the options' respective lives. The binomial option-pricing model also integrated the possible variations in model inputs, such as risk-free interest rates and other inputs, which may change over the life of the options.

The implied volatility for traded options on Elan's shares with remaining maturities of at least one year was used to determine the expected volatility assumption required in the binomial model. The risk-free interest rate assumption was based upon the observed interest rates appropriate for the term of the stock option awards. The dividend yield assumption is based on the history and expectation of dividend payouts.

As share-based compensation expense recognized in the condensed consolidated financial statements was based on awards ultimately expected to vest, it had been reduced for estimated forfeitures. Forfeitures were estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differed from estimates.

The fair value of options granted during the three and six months ended June 30, 2012 was estimated using the binomial option-pricing model with the following weighted-average assumptions:

Variables	Assumptions
Expected volatility	60.1%
Risk-free interest rate	0.9%
Expected dividend yield	0.0%
Expected life (1)	—
Weighted average fair value	$ 6.66

(1) The expected life of options granted, as derived from the output of the binomial model, ranged from 4.9 to 6.8 years. The contractual life of the options, which is not more than 10 years from the date of grant, was used as an input into the binomial model.

7. Related Parties

Prior to December 20, 2012, the Prothena Business operated as part of Elan and not as a separate stand-alone entity. Effective December 20, 2012, the Prothena Business separated from Elan. In connection with the plan of separation, Elan acquired an 18% interest in the Company (as calculated immediately following the acquisition).

As described elsewhere in these consolidated financial statements, the results of operations of the Prothena business for the time period prior to the separation include transactions with Elan. All of the revenue recognized by the Company for the three and six months ended June 30, 2013 consisted of fees arising from R&D services provided to Elan. Additionally, the results of operations for this time period include certain costs allocated from Elan to the Company for centralized support services.

The Company has entered into certain agreements with Elan, including the Transitional Services Agreement and the R&D Services Agreement.

Transitional Services Agreement

In December 2012, the Company entered into a Transitional Services Agreement ("TSA") with Elan under which Elan will provide to the Company, and the Company will provide to Elan, specified services to help ensure an orderly transition following the separation and distribution. The services provided by Elan under the Transitional Services Agreement will include chemistry, manufacturing and controls/quality assurance, information services, IT services, facilities services, company secretarial services, finance services, legal services, compliance services and human relations services. The services provided by the Company will include finance services and product support services and assisting in reviewing proposed Elan publications related to work done at Elan prior to separation.

The Company expects that the TSA will remain in effect until the expiration of the last time period for the performance of services thereunder, which in no event shall be later than December 31, 2013.

Both the Company and Elan will be permitted to terminate the TSA (to the extent it relates to any particular transitional service) if the other party breaches any of its significant obligations under the agreement and does not cure such breach within 20 business days of receiving written notice from the other party. In addition, either party may terminate the TSA if a receiver, examiner or administrator is appointed with respect to any of the other party's assets, the other company is struck off the Register of Companies in its jurisdiction of organization or at the option of such party with respect to a particular transition service if such party is the service recipient.

The payment terms of the agreement generally provide that the Company will pay Elan for the time spent by each Elan employee providing the services, which will be calculated by the portion of the employee's time dedicated to the provision of the services, plus 40%. The time for each employee will be calculated using one of two specified rates per annum depending on the employee's wage band. Similarly, Elan will pay the Company for the time spent by each of the Company's employee providing services to Elan, which will be an agreed percentage of the employee's time, based on the cost of providing those services plus 40% and including, as applicable, any fees for any services from Elan or the Company provided by third party providers and invoiced to the recipient at cost. The services from the Company will also be calculated using one of two specified rates per annum depending on the employee's wage band.

TSA expenses recognized during the three and six months ended June 30, 2013 was $Nil and $0.5 million, respectively, of which $0.1 million was included in R&D expense and $0.4 million was included in general and administrative expense.

R&D Services Agreement

In December 2012, The Company entered into a Research and Development Services Agreement ("RDSA") with Elan pursuant to which the Company will provide certain R&D services to Elan. The RDSA will, among other things, set out the scope of the services, the consideration to be paid for the services and the general principles around ownership of intellectual property as it relates to the services. The RDSA is expected to be in effect for a period of not less than two years. Either party is entitled to terminate the RDSA at any time by notice in writing to the other party if there has been a material breach by the other party or if the other party becomes insolvent or if the other party is in breach of any of its confidentiality obligations under the agreement. The amounts earned under this RDSA are recognized as related party revenues on the Condensed Consolidated Statement of Operations.

The services provided for under the RDSA include support for the ELND005 program (which include the provision of expert advice and opinion in the areas of nonclinical safety/toxicology and pharmacology, regulatory support for nonclinical sections of pertinent documents, conducting and interpreting externally conducted nonclinical studies, and support in respect of the identification and maintenance of nonclinical expert advisors as required). These services will be substantially similar to research services performed by the Company for Elan prior to the separation and distribution. There is also a fixed monthly charge of $7,500 to account for lab space and capital equipment used by Elan.

The payment terms of the RDSA provide that Elan will pay the Company: (i) a fixed charge of $500,000 per year based on a charge for two of the Company's employees providing the services at a rate of $250,000 each per annum, (ii) if the $500,000 fixed charge has been paid in any year, a variable charge of $250,000 per year for any additional employee that provides services for such year (calculated pro rata based on the number of days the employee provides services in such year), (iii) research costs including direct overheads and (iv) a mark-up of 10% applied to the fixed charge, variable charge (if any) and research costs such that the total payment reflects a cost-plus standard.

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

This Quarterly Report on Form 10-Q, including this Management's Discussion and Analysis of Financial Condition and Results of Operations, contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements relate to future events or our future financial performance. Forward-looking statements may include words such as "may," "will," "should," "expect," "plan," "intend," "anticipate," "believe," "estimate," "predict," "potential," "continue" or other wording indicating future results or expectations. Forward-looking statements are subject to risks and uncertainties, and actual events or results may differ materially. Factors that could cause our actual results to differ materially include, but are not limited to, those discussed under "Risk Factors" in this report. We also face risks and uncertainties relating to our business including:

- our ability to obtain additional financing;
- our history of operating losses;
- our ability to successfully complete research and development of our drug candidates and the growth of the markets for those drug candidates;
- our ability to develop and commercialize products before competitors that are superior to the alternatives developed by such competitors;
- our ability to protect our patents and other intellectual property;
- loss of key employees;
- tax treatment of our separation from Elan and subsequent distribution of our ordinary shares;
- restrictions on our taking certain actions due to tax rules and covenants with Elan;
- the impact of our separation from Elan and risks relating to our ability to operate effectively as a stand-alone, publicly traded company, including, without limitation:
    - our ability to achieve benefits from our separation;
    - changes in our cost structure, management, financing and business operations;
    - growth in costs and expenses;
- our ability to maintain financial flexibility and sufficient cash, cash equivalents, and investments and other assets capable of being monetized to meet our liquidity requirements;
- disruptions in the U.S. and global capital and credit markets;
- fluctuations in foreign currency exchange rates;
- extensive government regulation;
- the volatility of our share price;
- general changes in U.S. Generally Accepted Accounting Principles;
- business disruptions caused by information technology failures; and
- the other risks and uncertainties described in Part II, Item 1, "Risk Factors."

We undertake no obligation to revise or update any forward-looking statements to reflect any event or circumstance that arises after the date of this report, or to conform such statements to actual results or changes in our expectations.

Except with respect to our trademarks, the trademarks, trade names and service marks appearing in this report are the property of their respective owners.

This discussion should be read in conjunction with the condensed consolidated financial statements and notes presented in this Quarterly Report on Form 10-Q and the consolidated financial statements and notes in our 2012 Form 10-K.

Overview

We are a clinical stage biotechnology company focused on the discovery and development of novel antibodies for the potential treatment of a broad range of diseases that involve protein misfolding or cell adhesion. We focus on the discovery and development of potential therapeutic monoclonal antibodies directed specifically to disease causing proteins. These potential therapies have a broad range of indications including AL and AA forms of amyloidosis (NEOD001), Parkinson's disease and related synucleinopathies (PRX002) and autoimmune diseases and metastatic cancers (PRX003). We initiated a Phase 1 clinical trial for NEOD001, with the first patient dosing in April 2013. The Phase 1 clinical trial of NEOD001 will evaluate safety and tolerability in AL Amyloidosis patients. We also plan to initiate

Phase 1 clinical trials for PRX002 and PRX003 in 2014 and 2015, respectively. Our strategy is to identify antibody candidates for clinical development by applying our extensive expertise in generating novel therapeutic antibodies and working with collaborators having expertise in specific animal models of disease.

We are a public limited company incorporated in Ireland. Our business, which for the period prior to the separation from Elan on December 20, 2012 we refer to as the Prothena Business, consists of a substantial portion of Elan's former drug discovery business platform, including Neotope Biosciences Limited (and its wholly-owned subsidiary Prothena Biosciences Inc) and Onclave Therapeutics Limited, each former wholly-owned subsidiaries of Elan. Our condensed consolidated financial statements included in this report for the periods prior to December 21, 2012 have been derived from Elan's historical accounting records and reflect significant allocations of direct costs and expenses. All of the allocations and estimates in these condensed consolidated financial statements are based on assumptions that we believe are reasonable. However, the condensed consolidated financial statements do not necessarily represent our financial position or results of operations had we been operating as a separate independent entity. See "Critical Accounting Policies and Estimates" below as well as Note 2 of the "Notes to the Condensed Consolidated Financial Statements" included in Item 1 of this report and in Note 2 of the "Notes to the Consolidated Financial Statements" included in Item 8 of our 2012 Form 10-K.

The Separation and Distribution

Elan's board of directors and its management team periodically assesses the optimal alignment of Elan's assets, and in particular the benefits and risks of maintaining both a late-stage products development business and an early-stage discovery business and the income statement dynamics such businesses present to the marketplace and Elan shareholders. On August 13, 2012, Elan announced that its board of directors had approved the separation of Elan and its drug discovery business into two independent, publicly traded companies: Elan and Prothena. On December 7, 2012, the Elan board of directors approved a deemed *in specie* distribution by Prothena issuing directly to the holders of Elan ordinary shares and Elan American Depository Shares, or ADS, on a pro rata basis, Prothena ordinary shares representing 99.99% of Prothena's outstanding shares (with the remaining 0.01% of Prothena's outstanding shares, which were previously issued to the original incorporators of Prothena and which we refer to as the "incorporator shares," being mandatorily redeemed by Prothena after the related demerger). On December 12, 2012, shareholders of Elan voted to approve the "*in specie* distribution" as required by Elan's Articles of Association. On December 20, 2012, each holder of Elan ordinary shares or ADSs received 1 Prothena ordinary share for every 41 Elan ordinary shares or Elan ADSs held at the close of business on the record date for the distribution, subject to certain conditions.

Immediately after the separation and distribution, a wholly-owned subsidiary of Elan acquired newly-issued ordinary shares of Prothena, representing 18% of the outstanding ordinary shares of Prothena (as calculated immediately following the acquisition), for a cash payment to Prothena of $26.0 million. Immediately after the consummation of this purchase, the incorporator shares were mandatorily redeemed by Prothena pursuant to their terms for their initial subscription price, and cancelled. Immediately following the separation and distribution and Elan's purchase of Prothena ordinary shares, Elan shareholders owned directly 82% of the outstanding ordinary shares of Prothena, and Elan owned the remaining 18%.

Basis of Presentation and Preparation of the Financial Statements

Our business consists of a substantial portion of Elan's former drug discovery business platform, including Neotope Biosciences Limited (and its wholly-owned subsidiary Prothena Biosciences Inc) and Onclave Therapeutics Limited, each former wholly-owned subsidiaries of Elan, and related tangible assets and liabilities.

Prior to December 21, 2012, the Prothena Business operated as part of Elan and not as a separate stand-alone entity. Our condensed consolidated financial statements for the three and six months ended June 30, 2012 have been prepared on a "carve-out" basis from the consolidated financial statements of Elan to represent our financial performance as if we had existed on a stand-alone basis during the three and six months ended June 30, 2012.

Prior to the separation and distribution on December 20, 2012, centralized support costs were allocated to us for the purposes of preparing the condensed consolidated financial statements based on our estimated usage of the resources. Our estimated usage of the centralized support resources was determined by estimating our portion of the most appropriate driver for each category of centralized support costs such as headcount or labor hours, depending on the nature of the costs. We believe that such allocations were made on a reasonable basis, but may not necessarily be indicative of the costs that would have been incurred if we had operated on a standalone basis. For additional information regarding the basis of preparation, refer to Note 2 of the "Notes to the Condensed Consolidated Financial Statements" included in Item 1 of this report.

Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, revenues, expenses and related disclosures. Actual results could differ from these estimates.

Carve-out of the Results of Operations, Financial Condition and Cash Flows of the Prothena Business

Prior to December 21, 2012, the Prothena Business operated as part of Elan and not as a separate stand-alone entity. Our condensed consolidated financial statements have been prepared on a "carve-out" basis from the consolidated financial statements of Elan to represent the financial position and performance of Prothena as if we had existed on a stand-alone basis during the three and six months ended June 30, 2012, and as if Financial Accounting Standards Board, or FASB, Accounting Standard Codification, or ASC, Topic 810, *Consolidation*, had been applied throughout. The condensed consolidated financial statements have been prepared in conformity with GAAP, by aggregating financial information from the components of Prothena described in Note 1 of the "Notes to Condensed Consolidated Financial Statements," included in Item 1 of this report.

The accompanying condensed consolidated financial statements include allocations of direct costs and indirect costs attributable to our operations. Indirect costs relate to certain support functions that were provided on a centralized basis within Elan. The support functions provided to us by Elan included, but were not limited to: accounting, information technology, taxation, legal, corporate strategy, investor relations, corporate governance and other professional services, employee benefit administration, including equity award and pension services, and cash and treasury management. Central support costs of our business for the three and six months ended June 30, 2012 were $2.1 million and $4.1 million, respectively. These costs have been allocated to us for the purposes of preparing the condensed consolidated financial statements based on our estimated usage of the resources. Our estimated usage of the central support resources was determined by estimating our portion of the most appropriate driver of each category of central support costs such as headcount or labor hours, depending on the nature of the costs. We believe that such allocations have been made on a reasonable basis, but may not necessarily be indicative of the costs that would have been incurred if we had operated on a standalone basis.

Recent Accounting Pronouncements

As an Emerging Growth Company under the JOBS Act, unlike other public companies, the Company is eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not Emerging Growth Companies. The Company has an extended transition period for adopting new or revised accounting standards that have different effective dates for public and private companies until such time as those standards apply to private companies. There have been no new accounting pronouncements or changes to accounting pronouncements during the six months ended June 30, 2013, as compared to the recent accounting pronouncements described in our 2012 Form 10-K, that are of significance or potential significance to us.

Results of Operations

Results for the Three and Six Months Ended June 30, 2013 and 2012

	Three Months Ended June 30,		Increase (Decrease)	
	2013	2012	$	%
	(in thousands, except percents)			
Revenues—related party	$ 167	$ 735	$ (568)	(77)%
Operating expenses:				
Research and development	8,147	8,019	128	2
General and administrative	3,212	2,427	785	32
Total operating expenses	11,359	10,446	913	9
Loss from operations	(11,192)	(9,711)	1,481	15
Interest income, net	14	—	14	nm
Loss before income taxes	(11,178)	(9,711)	1,467	15
Provision for income taxes	124	—	124	nm
Net loss	$(11,302)	$ (9,711)	1,591	16

	Six Months Ended June 30,		Increase (Decrease)	
	2013	2012	$	%
	(in thousands, except percents)			
Revenues—related party	$ 338	$ 1,139	$ (801)	(70)%
Operating expenses:				
Research and development	14,104	16,776	(2,672)	(16)
General and administrative	6,393	4,885	1,508	31
Total operating expenses	20,497	21,661	(1,164)	(5)
Loss from operations	(20,159)	(20,522)	(363)	(2)
Interest income, net	36	—	36	nm
Loss before income taxes	(20,123)	(20,522)	(399)	(2)
Provision for income taxes	130	—	130	nm
Net loss	$(20,253)	$(20,522)	(269)	(1)

nm – not meaningful

Revenue

Revenue for the three and six months ended June 30, 2013 and 2012 was comprised of fees earned from the provision of R&D services to Elan.

During the three and six months ended June 30, 2013, total revenues decreased $0.6 million and $0.8 million, or 77% and 70%, compared to the three and six months ended June 30, 2012, respectively. The decrease was primarily due to a reduction in the scope of the R&D services provided to Elan.

Operating Expenses

Total operating expenses consist of R&D expenses and general and administrative, or G&A, expenses. Operating expenses for the three and six months ended June 30, 2013 was $11.4 million and $20.5 million, respectively, compared to $10.4 million and $21.7 million for the three and six months ended June 30, 2012, respectively. R&D expenses primarily consist of employee and related expenses, costs associated with preclinical activities and regulatory operations, share-based compensation and other research costs we incurred in providing research services to Elan's ELND005 program. G&A expenses primarily consist of professional services expenses, management compensation expenses and, for the three and six months ended June 30, 2012, certain centralized support

costs that had been allocated to us by Elan based on estimated usage of resources by us. Share-based compensation expense during the three and six months ended June 30, 2012 was allocated to us by Elan. For additional information regarding the allocation of centralized G&A expenses, refer to Note 2 of the "Notes to Condensed Consolidated Financial Statements" included in Item 1 of this report and Note 1 of "Notes to the Consolidated Financial Statements" included in Item 8 of our 2012 Form 10-K.

Research and Development Expenses

For the three months ended June 30, 2013, R&D expenses increased by $0.1 million, or 2%, as compared to the three months ended June 30, 2012 and for the six months ended June 30, 2013, R&D expenses decreased by $2.7 million, or 16%, as compared to the six months ended June 30, 2012. The decrease for the six months ended June 30, 2013 as compared to the prior year period was primarily due to decreases in share-based compensation expense, personnel costs attributable to Prothena programs and external expenses related to our NEOD001 development program, partially offset by increases in costs related to our PRX002 and PRX003 programs.

Our research activities are aimed at developing new drug products. Our development activities involve the translation of our research into potential new drugs. R&D expenses include personnel, materials, equipment and facilities costs that are allocated to clearly related R&D activities.

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete development of our product candidates. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress and expense of our drug discovery efforts and other R&D activities;
- the potential benefits of our product candidates over other therapies;
- clinical trial results; and
- the terms and timing of regulatory approvals.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or other regulatory authority were to require us to conduct clinical trials beyond those which we currently anticipate will be required for the completion of clinical development of a product candidate or if we experience significant delays in enrollment in any clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

The following table sets forth the R&D expenses for our major program (specifically, any program where an Investigational New Drug Application has been filed with the FDA), NEOD001, and other R&D expenses for the three and six months ended June 30, 2013 and 2012, and the cumulative amounts to date (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,		Cummulative to Date
	2013	2012	2013	2012	
NEOD001 (1)	$ 703	$ 1,888	$ 1,491	$ 3,841	$ 24,930
Other R&D (2)	7,444	6,131	12,613	12,935	
	$8,147	$ 8,019	$14,104	$16,776	

(1) Cumulative R&D costs to date for NEOD001 include the costs incurred from the date when the program has been separately tracked in preclinical development. Expenditures in early discovery stage are not tracked by program and accordingly have been excluded from this cumulative amount.

(2) Other R&D is comprised of preclinical development and discovery programs that have not yet resulted in an Investigational New Drug Application filing with the FDA, including PRX002 and PRX003, and research costs we incurred in providing research services to Elan's ELND005 program.

General and Administrative Expenses

For the three and six months ended June 30, 2013, G&A expenses increased by $0.8 million and $1.5 million, or 32% and 31%, respectively, compared to the three and six months ended June 30, 2012. G&A expenses consisted primarily of professional services fees (including payments to Elan under the Transitional Services Agreement), internal personnel costs and share-based compensation expense of $0.5 million and $0.8 million for the three and six months ended June 30, 2013, respectively. For the three and six months ended June 30, 2012, G&A expenses was presented on a "carve-out" basis as the Prothena Business consisted of a substantial portion of Elan's former drug discovery business platform, therefore the G&A expenses during the three and six months ended June 30, 2012 consisted of $0.3 million and $0.8 million, respectively, of direct expense incurred by the Prothena Business and $2.1 million and $4.1 million, respectively, of indirect expenses which was based on an allocation to the Prothena Business by Elan.

Taxation

Our operations were historically included in Elan's consolidated U.S. federal and state income tax returns and in returns of certain Elan foreign subsidiaries. The current and deferred tax provision calculations have been prepared as if we were a separate taxable entity during the three and six months ended June 30, 2012 and are consistent with the asset and liability method prescribed by ASC 740, *Income Taxes*. The current and deferred tax provision and the related tax disclosures are not necessarily representative of the tax provision (benefit) that may arise for the Company in the future.

The tax provision for both the three and six months ended June 30, 2013 was $0.1 million compared to $Nil for both the three and six months ended June 30, 2012. The tax provision reflects U.S. federal and state taxes and the availability of Irish tax losses.

Liquidity and Capital Resources

Overview

Prior to the separation, our operating and capital resource requirements were funded by Elan. As part of the separation and distribution, Elan made a cash investment in us of $99.0 million, which we expect to be used to fund working capital expenses and for other general corporate purposes. Additionally, a wholly-owned subsidiary of Elan made a cash payment of $26.0 million to acquire 18% of our outstanding ordinary shares (as calculated immediately following the acquisition). As of June 30, 2013, we had $112.5 million in cash and cash equivalents. Based on our current business plan, we believe such cash and cash equivalents will be sufficient to meet our obligations for at least the next twelve months.

We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development of our product candidates. Our future capital requirements will depend on numerous factors, including, without limitation, the timing of initiation, progress, results and costs of our clinical trials; the results of our research and preclinical studies; the costs of clinical manufacturing and of establishing commercial manufacturing arrangements; the costs of preparing, filing, and prosecuting patent applications and maintaining, enforcing, and defending intellectual property-related claims; the costs and timing of capital asset purchases; our ability to establish research collaborations, strategic collaborations, licensing or other arrangements; the costs to satisfy our obligations under potential future collaborations; and the timing, receipt, and amount of revenues or royalties, if any, from any approved drug candidates. In order to develop and obtain regulatory approval for our potential products we will need to raise substantial additional funds. We expect to raise any such additional funds through public or private equity or debt financings, collaborative agreements with corporate partners or other arrangements. We cannot assume that such additional financings will be available on acceptable terms, if at all, and such financings may only be available on terms dilutive to our shareholders.

Cash Flows for the Six Months Ended June 30, 2013 and 2012

The following table summarizes, for the periods indicated, selected items in our Condensed Consolidated Statements of Cash Flows (in thousands):

	Six Months Ended June 30,	
	2013	2012
Net cash used in operating activities	$(11,958)	$(18,988)
Net cash used in investing activities	(311)	(171)
Net cash (used in) provided by financing activities	(84)	19,159
Net decrease in cash and cash equivalents	$(12,353)	$ —

Cash Used in Operating Activities

Net cash used in operating activities was $12.0 million and $19.0 million during the six months ended June 30, 2013 and 2012, respectively, in each case consisting primarily of net losses (adjusted to exclude non-cash charges) and changes in working capital accounts. The decrease was primarily due to an increase in current liabilities.

Cash Used in Investing Activities

Net cash used in investing activities was $0.3 million and $0.2 million during the six months ended June 30, 2013 and 2012, respectively, consisting primarily of purchases of property and equipment.

Cash (Used in) Provided by Financing Activities

Net cash used in financing activities was $0.1 million during the six months ended June 30, 2013, consisting of the final settlement of liabilities as a result of our separation from Elan. Net cash provided by financing activities was $19.2 million during the six months ended June 30, 2012, reflecting funding provided by Elan.

Off-Balance Sheet Arrangements

At June 30, 2013, we were not a party to any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Foreign Currency Risk

Our business is primarily conducted in U.S. dollars except for our agreement with our contract manufacturer for clinical supplies. At this time, our foreign exchange risk is not material.

Interest Rate Sensitivity

Our exposure to interest rate risk is limited to our cash equivalents, which consist of accounts maintained in money market funds. We have assessed that there is no material exposure to interest rate risk given the nature of money market funds. In general, money market funds are not subject to market risk because the interest paid on such funds fluctuates with the prevailing interest rate.

In the future, we anticipate that our exposure to interest rate risk will primarily be related to our investment portfolio. We intend to invest any surplus funds in accordance with a policy approved by our board of directors which will specify the categories, allocations, and ratings of securities we may consider for investment. The primary objectives of our investment policy will be to preserve principal and maintain proper liquidity to meet our operating requirements. Our investment policy will also specify credit quality standards for our investments and limit the amount of credit exposure to any single issue, issuer or type of investment.

Credit Risk

All of our accounts receivables are due from a single customer (Elan) to whom we provide R&D services. Due to Elan's substantial financial resources, we do not believe that our credit risk is significant. As of June 30, 2013, our receivables from Elan total $0.1 million.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2013. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2013, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the three months ended June 30, 2013 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings. We may at times be involved in litigation and other legal claims in the ordinary course of business. When appropriate in management's estimation, we may record reserves in our financial statements for pending litigation and other claims.

ITEM 1A. RISK FACTORS

Investing in our ordinary shares involves a high degree of risk. Our 2012 Form 10-K includes a detailed discussion of our risk factors under the heading "Part I, Item 1A—Risk Factors." Set forth below are certain changes from the risk factors previously disclosed in our 2012 Form 10-K and 2013 First Quarter Form 10-Q. You should consider carefully the risk factors discussed in our 2012 Form 10-K, 2013 First Quarter Form 10-Q and in this report, and all other information contained in or incorporated by reference in this report before making an investment decision. If any of the risks discussed in the 2012 Form 10-K, 2013 First Quarter Report or this report actually occur, they may materially harm our business, financial condition, operating results, cash flows or growth prospects. As a result, the market price of our ordinary shares could decline, and you could lose all or part of your investment. Additional risks and uncertainties that are not yet identified or that we think are immaterial may also materially harm our business, financial condition, operating results, cash flows or growth prospects and could result in a complete loss of your investment.

Risks Relating to Our Financial Position, Our Need for Additional Capital and Our Business

We have not generated any significant third party external revenue to date, and we anticipate that we will incur losses for the foreseeable future and we may never achieve or sustain profitability.

We may not generate the cash that is necessary to finance our operations in the foreseeable future. We have not generated any significant third party external revenues to date. We have incurred losses of $20.3 million for the six months ended June 30, 2013 and $41.4 million and $29.7 million for the years ended December 31, 2012 and 2011, respectively. We expect to continue to incur substantial losses for the foreseeable future as we:

- conduct our Phase 1 clinical trial for NEOD001 and initiate additional clinical trials, if supported by the results of the Phase 1 trial;
- complete preclinical development of other product candidates and initiate clinical trials, if supported by positive preclinical data;
- pursue our early stage research and seek to identify additional drug candidates and potentially acquire rights from third parties to drug candidates through licenses, acquisitions or other means; and
- add operational, financial and management information systems and other personnel.

We must generate significant revenue to achieve and sustain profitability. Even if we succeed in discovering, developing and commercializing one or more drug candidates, we may not be able to generate sufficient revenue and we may never be able to achieve or sustain profitability.

We will require additional capital to fund our operations, and if we are unable to obtain such capital, we will be unable to successfully develop and commercialize drug candidates.

As of June 30, 2013, we had cash and cash equivalents of $112.5 million. Although we believe, based on our current business plans, that our existing cash and cash equivalents will be sufficient to meet our obligations for at least the next twelve months, we anticipate that we will require additional capital in the future in order to continue the research and development of our drug candidates. Our future capital requirements will depend on many factors that are currently unknown to us, including, without limitation:

- the timing of initiation, progress, results and costs of our clinical trials, including our Phase 1 clinical trial for NEOD001;
- the results of our research and preclinical studies;
- the costs of clinical manufacturing and of establishing commercial manufacturing arrangements;
- the costs of preparing, filing, and prosecuting patent applications and maintaining, enforcing, and defending intellectual property-related claims;
- the costs and timing of capital asset purchases;
- our ability to establish research collaborations, strategic collaborations, licensing or other arrangements;
- the costs to satisfy our obligations under potential future collaborations; and
- the timing, receipt, and amount of revenues or royalties, if any, from any approved drug candidates.

We have based our expectations relating to liquidity and capital resources on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development of our current product candidates.

We are not able to provide specific estimates of the timelines or total costs to complete the Phase 1 clinical trial for NEOD001. In the pharmaceutical industry, the research and development process is lengthy and involves a high degree of risk and uncertainty. This process is conducted in various stages and, during each stage, there is a substantial risk that potential products in our research and development pipeline will experience difficulties, delays or failures. This makes it difficult to estimate the total costs to complete the Phase 1 clinical trial or any future clinical trials for NEOD001, or any potential future drug candidates, and to estimate the anticipated completion date with any degree of accuracy, and raises concerns that attempts to provide estimates of timing may be misleading by implying a greater degree of certainty than actually exists.

In order to develop and obtain regulatory approval for our potential products we will need to raise substantial additional funds. We expect to raise any such additional funds through public or private equity or debt financings, collaborative agreements with corporate partners or other arrangements. We cannot assure you that additional funds will be available when we need them on terms that are acceptable to us, or at all. General market conditions may make it very difficult for us to seek financing from the capital markets. If we raise additional funds by issuing equity securities, substantial dilution to existing shareholders would result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business. We may be required to relinquish rights to our technologies or drug candidates or grant licenses on terms that are not favorable to us in order to raise additional funds through strategic alliances, joint ventures or licensing arrangements.

If adequate funds are not available on a timely basis, we may be required to:

- terminate or delay clinical trials or other development for one or more of our drug candidates;
- delay arrangements for activities that may be necessary to commercialize our drug candidates; or
- curtail or eliminate our drug research and development programs that are designed to identify new drug candidates; or
- cease operations.

In addition, if we do not meet our payment obligations to third parties as they come due, we may be subject to litigation claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and distract management, and may have unfavorable results that could further adversely impact our financial condition.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

See the Exhibit Index following the signature page to this Quarterly Report on Form 10-Q for a list of exhibits filed or furnished with this report, which Exhibit Index is incorporated herein by reference.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Quarterly Report on Form 10-Q to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: August 12, 2013

Prothena Corporation plc
(Registrant)

/s/ Dale B. Schenk
Dale B. Schenk
President and Chief Executive Officer

/s/ Tran B. Nguyen
Tran B. Nguyen
Chief Financial Officer

EXHIBIT INDEX

The following exhibits have been filed with this report:

Exhibit No.	Description
3.1	Amended and Restated Memorandum and Articles of Association of Prothena Corporation plc(1)
10.1#	Offer letter, dated April 18, 2013, between Prothena Biosciences Inc. and Karin L. Walker (2)
10.2	Amendment No. 1 to Tax Matters Agreement, dated June 25, 2013, by and between Elan Corporation, plc and Prothena Corporation plc
10.3†	Master Process Development and Clinical Supply Agreement, dated as of June 23, 2010, as amended August 1, 2011, by and among Elan Pharma International Limited, Neotope Biosciences limited and Boehringer Ingelheim Pharma GmbH & Co. KG
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS+	XBRL Instance Document
101.SCH+	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

(1) Filed as Exhibit 3.1 to Registrant's Annual Report on Form 10-K (for the year ended December 31, 2012) filed with the SEC on March 29, 2013, and incorporated herein by reference.
(2) Filed as Exhibit 10.1 to Registrant's Current Report on Form 8-K filed with the SEC on May 22, 2013, and incorporated herein by reference.
# Indicates management contract or compensatory plan, contract or arrangement.
† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment and this exhibit has been filed separately with the SEC.
* Exhibit 32.1 is being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall such exhibit be deemed to be incorporated by reference in any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as otherwise specifically stated in such filing.
+ XBRL information is furnished and not filed for purposes of Sections 11 and 12 of the Securities Act of 1933 and Section 18 of the Securities Exchange Act of 1934, and is not subject to liability under those sections, is not part of any registration statement or prospectus to which it relates and is not incorporated or deemed to be incorporated by reference into any registration statement, prospectus or other document.

Exhibit 10.2

AMENDMENT NO. 1 TO TAX MATTERS AGREEMENT

THIS AMENDMENT NO. 1 TO TAX MATTERS AGREEMENT (this "Amendment") is made and entered into as of June 25, 2013 by and between Elan Corporation, plc, an Irish public limited company ("Parent"), and Prothena Corporation plc, an Irish public limited company ("Prothena").

Reference is made to the Tax Matters Agreement (the "Agreement") dated as of December 20, 2012 by and between Parent and Prothena. Reference is also made to that certain representation letter (the "Prothena Representation Letter") executed and delivered by Prothena on December 20, 2012 in connection with the delivery of certain legal opinions with respect to tax matters. Capitalized terms used herein but not defined shall have the meanings assigned to such terms in the Agreement.

WHEREAS, Section 7.06 of the Agreement provides that, if there is a conflict between any provision of the Agreement and a provision in another Transaction Document, including the Prothena Representation Letter, the provision of the Agreement will control, unless specifically provided otherwise in the Agreement or in the applicable Transaction Document.

WHEREAS, for the avoidance of doubt, Parent and Prothena wish to amend the Agreement pursuant to Section 7.07(a) of the Agreement to conform certain provisions of the Agreement and the Prothena Representation Letter.

NOW, THEREFORE, for good and valuable consideration, the receipt of which is hereby acknowledged, Parent and Prothena agree as follows:

A. Amendment to the Agreement.

1. The definition of "Equity Investment" in Section 1.01 of the Agreement is hereby removed and replaced in its entirety with the following:

   "Equity Investment" means Prothena's potential issuance(s) of common shares, ordinary shares, American Depositary Receipts, ADSs and/or preferred shares to investors after the Transactions for cash in an aggregate amount not to exceed US$ 300,000,000.

2. Section 4.02(a) of the Agreement is hereby removed and replaced in its entirety with the following:

   "(a) During the Restricted Period, (i) neither Parent nor any of its Affiliates (or any officers or directors acting on behalf of Parent or any of its subsidiaries, or any Person acting with the implicit or explicit permission of any such officers or directors) shall take or fail to take any action if such action (or the failure to take such action) would (x) be inconsistent with any covenant, representation or statement made by, Parent or any of its Affiliates in the Parent Representation Letter or in any Transaction Document, or (y) prevent, or be reasonably likely to prevent, the Transactions (or any portion thereof) from qualifying for Tax-Free Treatment; and (ii) none of Prothena or any of its Affiliates (or any officers or directors acting on behalf of Prothena or any of its subsidiaries, or any Person acting with the implicit or explicit permission of any such officers or directors) shall take or fail to take any action if such action (or the failure to take such action) would (x) be inconsistent with any covenant, representation or statement made by, Prothena or any of its Affiliates in the Prothena Representation Letter or in any Transaction Document, or (y) prevent, or be reasonably likely to prevent, the Transactions (or any portion thereof) from qualifying for Tax-Free Treatment. Notwithstanding anything to the contrary in this Agreement or the Prothena Representation Letter, no issuance of shares of Prothena Capital Stock that complies with Section 4.02(b)(v) of this Agreement shall be deemed to be inconsistent with or a breach of the Prothena Representation Letter, including but not limited to Section 14 of the Prothena Representation Letter, or this Agreement, including but not limited to this Section 4.02(a)."

B. Binding Effect. This Amendment shall be legally binding and enforceable in accordance with its terms, and shall be binding upon and inure to the benefit of each of the undersigned's heirs, successors and assigns.

[Signature Page Follows]

IN WITNESS whereof this Agreement has been duly executed as a deed by the parties to it on the date set out at the beginning of this Agreement.

GIVEN UNDER THE COMMON SEAL
of **ELAN CORPORATION, PLC**
in the presence of:

/s/ Robert A. Ingram
Signature of Authorised Signatory

/s/ William F. Daniel
Signature of Director/Secretary

GIVEN UNDER THE COMMON SEAL
of **PROTHENA CORPORATION PLC**
in the presence of:

/s/ Shane Cooke
Signature of Director
Shane Cooke

/s/ Tara Nickerson
Signature of Director/Secretary
Tara Nickerson

Exhibit 10.3

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

MASTER PROCESS DEVELOPMENT
AND
CLINICAL SUPPLY AGREEMENT

This Master Process Development and Clinical Supply Agreement ("Agreement") is made by and among

ELAN Pharma International Limited "EPIL"
Treasury Building,
Dublin 2
Ireland

and

Neotope Biosciences Limited "Neotope"
Monksland
Athlone, County Westmeath
Ireland

(hereinafter collectively called "ELAN"),

and

Boehringer Ingelheim Pharma GmbH & Co. KG
Birkendorfer Straße 65
88397 Biberach an der Riss
Germany

(hereinafter called "BI Pharma")

(hereinafter BI Pharma and ELAN each shall also be called "Party" and collectively "Parties" as the case may be).

EFFECTIVE DATE: JUNE 23, 2010

TABLE OF CONTENTS

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

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Preamble

WHEREAS, EPIL and Neotope are companies engaged in the design and development of innovative drugs; and

WHEREAS, BI Pharma has know-how and expertise to develop production processes for biopharmaceuticals towards commercial scale volumes and within international regulatory requirements; and

WHEREAS, ELAN wishes to have BI Pharma, and BI Pharma has agreed to, develop high expression production cell lines and fed-batch production processes for the production of a series of ELAN's Products (as defined below) with the aim under this Agreement to produce material for preclinical and clinical testing; and

NOW THEREFORE and in consideration of the mutual covenants set forth in this Agreement, BI Pharma and ELAN hereby agree as follows:

1. Definitions

1.1 "Acceptance Criteria"

shall mean the (preliminary or final, as the case may be) Specifications of the Product for clinical use set forth in Appendix 9, accompanied by a Confirmation of Compliance and Certificate of Analysis, and review and approval by ELAN of the respective executed Batch records.

1.2 "Affiliate"

shall mean any company or entity controlled by, controlling, or under common control with a Party hereto for as long as such control exists. As used in this Section 1.2, "control" means: (a) to possess, directly or indirectly, the power to direct the management and policies of such company or entity, whether through ownership of voting securities or by contract relating to voting rights or corporate governance; or (b) direct or indirect beneficial ownership of at least fifty percent (50%) (or such lesser percentage that is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the voting share capital in such company or entity.

1.3 "Antibody"

shall mean any hybridoma, polyclonal or monoclonal antibodies specified by the [***] and/or [***], and [***]. Antibodies may be [***] or may be [***] so long as they [***]. Antibodies may be [***] comprise a portion of [***], generally containing the [***]. Examples of antibody [***]; or other [***].

1.4 "Batch"

shall mean Product from one fermentation run using the Process.

1.5 "BI Pharma Contribution"

shall mean [***] by BI Pharma and which [***].

1.6 "BI HEX® Technology"

shall mean [***].

1.7 "BI Pharma Confidential Information and Know-How"

shall mean all existing or future confidential technical or other information relating to (a) the Biberach Facility, (b) BI Pharma Technology, (c) the Process, (d) the BI Pharma Contribution, (e) BI Pharma Improvements, (f) BI Pharma Information as defined in the CDA, and/or (g) know-how for the development and manufacture of biopharmaceuticals generally, in each case (a)-(g) whether patented or not patented, including, without limitation, trade secrets, know-how, processes, concepts, experimental methods and results and business and scientific plans that are disclosed or supplied to ELAN or used in connection with the Project.

1.8 "BI Pharma Intellectual Property"

shall have the meaning set forth in Section 9.2.2.1 hereof.

1.9 "BI Pharma Technology"

shall mean the Technology developed or obtained by or on behalf of BI Pharma without the use of the ELAN Confidential Information and Know How (as defined below) or the Materials, including without limitation, the BI HEX® Technology and the Process.

1.10 "Biberach Facility"

shall mean the biotech buildings at the Biberach site of BI Pharma in Germany.

1.11 "Certificate of Analysis"

shall mean, with respect to a Batch, that complete and accurate document setting forth the measured and observable characteristics of each Batch as required by the Acceptance Criteria, as dated, executed and provided to ELAN by BI Pharma.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1.12 "Confirmation of Compliance"

shall mean BI Pharma's complete and accurate certificate, executed and delivered to ELAN in connection with each Batch of Product, confirming that such Batch of Product was manufactured according to cGMPs, the Process and applicable laws at the place of manufacturing, and setting forth any deviations therefrom and the results of final investigations thereof including a summary of environmental monitoring limit excursions for aseptic filling if applicable.

1.13 "cGMPs"

shall mean current Good Manufacturing Practice regulations as codified in: The Rules Governing Medicinal products supplied in the European Union: Volume 4—Medicinal products supplied for Human and Veterinary Use: Good Manufacturing Practice, as amended from time to time; the United States Code of Federal Regulations, title 21, parts 210, 211, 600 and 610, as amended from time to time; and the International Committee on Harmonisation and other comparable guidelines, directives or standards required by governmental authorities in the United States and the European Union.

1.14 "Collaboration Intellectual Property"

shall have the meaning set forth in Section 9.2.2.2 hereof.

1.15 "Confidentiality Agreement" or "CDA"

shall mean the Mutual Confidentiality Agreement between Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein, Germany, an affiliate of BI Pharma, and Elan Pharmaceuticals, Inc., 800 Gateway Boulevard, South San Francisco, California 94080, USA, an affiliate of ELAN, effective as of August 17, 2009 and attached to this Agreement as its Appendix 14.

1.16 "Deliverables"

shall mean the data, results and materials generated from the performance of the Services including Product HEX Cell Line, BI Pharma Contribution, Product, purified, semi-purified and unpurified expression products of Product HEX Cell Line, Certificate of Analysis and the like, as defined in the Project Plan.

1.17 "Effective Date"

shall mean the date of commencement of this Agreement as mentioned on the cover page above.

1.18 "ELAN Confidential Information and Know-How"

shall mean all existing or future confidential technical or other information relating to (a) the Materials, (b) plasmids for the Products and/or (c) the ELAN Technology, in each case (a) — (c) whether patented or not patented, and including, without limitation, all know-how, trade secrets, inventions, patent applications, processes, concepts, experimental methods and any other information concerning ELAN's financial situation, business plans, and its research and product designs, that are disclosed or supplied to BI Pharma in connection with the Project.

1.19 "ELAN Contribution"

shall mean [***] by ELAN and [***].

1.20 "ELAN Embodiment"

shall have the meaning set forth in Section 9.2.2.2(a) hereof.

1.21 "ELAN Intellectual Property"

shall have the meaning specified in Section 9.2.1.1 hereof.

1.22 "ELAN Technology"

shall mean (i) the Materials, including the ELAN Contribution, (ii) the Product, and any modifications, derivatives, or fragments thereof, and (iii) the Technology of ELAN developed or obtained by or on behalf of ELAN (x) prior to the Effective Date and/or (y) independent of and without the use of BI Pharma Confidential Information and Know-How.

1.23 "Improvements"

shall mean all Technology, discoveries and inventions, and all modifications, derivatives and improvements thereto or new uses thereof (whether or not protectable under patent, trademark, copyright or similar laws) that are discovered, developed or reduced to practice by BI Pharma in the performance of this Agreement.

1.24 "Knowledge"

shall mean that which a Party knows or should have known following that inquiry a reasonable person would have made in light of the facts and circumstances.

1.25 "Material"

shall mean the respective [***] as laid down in detail in the respective Project Plan, as amended from time to time by the Parties, and any know-how or data relating directly thereto and provided together with such [***] to BI Pharma by or on behalf of ELAN. "Materials" shall mean each and every Material transferred to BI Pharma under this Agreement.

1.26 "Other Improvements"

shall have the meaning set forth in Section 9.2.3.1 hereof.

1.27 "Process"

shall mean all the respective steps involved in the BI Pharma in-part proprietary and in-part non-proprietary manufacturing process using the respective Product HEX Cell Line to produce the respective Product, including, without limitation, the manufacture, testing and packaging thereof.

1.28 "Process Description"

shall mean a controlled document, approved by authorized technical and quality representatives of both Parties, that documents the general outline of the respective Process. It includes all relevant Process parameters to be met and equipment and raw materials to be used.

1.29 "Product"

shall mean the [***] set forth in the respective Project Plan, as amended from time to time, expressed from the ELAN Contribution provided to BI Pharma and formulated either as bulk drug substance or in final dosage form as drug product, as the context requires. If not specified the term Product shall include both drug substance and drug product. "Product(s)" shall mean each and every Product set forth in the respective Project Plan as amended from time to time.

1.30 "Product HEX Cell Line"

shall mean the BI Pharma Contribution genetically engineered by BI Pharma to express the respective Product through incorporation of the respective ELAN Contribution.

1.31 "Project"

shall mean the activities set forth in the respective Project Plan for a particular phase of development or production of the specific Product, including without limitation the cell line development program and process development program for the Product. "Project(s)" shall mean each and every Project to be conducted under this Agreement.

1.32 "Project Fee"

shall have the meaning specified in Section 3.1 hereof.

1.33 "Project Intellectual Property"

shall mean all intellectual property arising out of or in connection with BI Pharma's activities performed under this Agreement and specifically relating to the Product or aspects of the Process specifically relating to the Product, including without limitation the Product HEX Cell Line.

1.34 "Project Timeline"

shall have the meaning specified in Section 2.1.2 hereof.

1.35 "Project Plan"

shall have the meaning specified in Section 2.1.2 hereof.

1.36 "Project Manager"

shall have the meaning specified in Section 2.2.1 hereof.

1.37 "Project Team"

shall have the meaning specified in Section 2.2.2 hereof and at the Effective Date shall consist of the persons listed in Appendix 3. The Project Team may vary from Project to Project.

1.38 "QAA"

shall mean the Quality (Assurance) Agreement added hereto by the Parties in an exemplary version as Appendix 6, as will be adapted and executed in due time.

1.39 "Service(s)"

shall mean those certain services performed by BI Pharma under this Agreement together with the respective Appendix for the respective Project. Such Services may include (parts thereof or all of the following), but are not necessarily limited to, drug substance and drug product development/supply, analytical/cGMP/non-cGMP manufacturing/purification, upstream and downstream development services, formulation development of one or more pharmaceutical formulations of Products, and the production and storage of non-commercial quantities of such formulations for further stability testing or analysis, all as defined in the applicable Appendix specifying the details of such services and their related terms and conditions. For the avoidance of doubt, the provision of Services under this Agreement is always subject to both Parties mutual agreement and always requires certain planning time (e.g. capacity planning, etc.) for BI Pharma.

1.40 "Specification(s)"

shall mean all the tests, analytical methods and Acceptance Criteria and/or limits, and the results thereof, as applicable, agreed by the Parties, within which the respective Product has to conform to be considered acceptable by ELAN, attached hereto as Appendix 9, which may be amended from time to time for each respective Product. The Parties are in agreement, that in the first instance they will agree on preliminary specifications for the [***] or [***] scale, whichever scale will be used for initial clinical supply, which shall be fixed to final Specifications for such scale in accordance with Section 2.5.

1.41 "Steering Committee"

shall have the meaning specified in Section 2.2.3 hereof.

1.42 "Technology"

shall mean all cDNA, cell lines, cell banks, master cell banks, constructs, reagents, cell culture media, antibodies and/or other tangible materials, methods, techniques, processes, trade secrets, copyrights, know-how, data, documentation, regulatory submissions, specifications and other intellectual property of any kind (whether or not protectable under patent, trademark, copyright or similar laws).

1.43 "Transferred IP"

shall have the meaning specified in Section 9.2.2.2(c) hereof.

2. Cooperation between the Parties in the Course of a Project

2.1 Services

2.1.1 **General**

This Agreement sets forth the basic terms and conditions under which BI Pharma will provide the Services to ELAN. The Parties agree that these terms are applicable to the respective Service together with the specific Project Plan for such Service, which shall further detail this Agreement.

2.1.2 **Project Plan**

Each project plan ("Project Plan") shall be substantially of the form attached herein as Appendix 2, consecutively numbered and shall describe the subject project, the responsibilities of each of the parties with respect to such project, the Materials and any ELAN Contribution to be transferred to BI Pharma, the Deliverables and the timeline for completion of the project ("Project Timeline"). Each phase of the Project Plan shall be mutually agreed upon by the parties, shall reference this Agreement by date, title and

parties; and shall become incorporated herein upon execution by both parties. However, no Project Plan shall be deemed "executed" by or binding upon EPIL or Neotope unless it has been signed by an authorized officer of EPIL or Neotope, as the case may be. BI Pharma agrees that there shall be no deviations from the provisions of a duly-executed Project Plan and any attached protocols and quotes, or from any instructions provided by ELAN, without ELAN's prior written consent. Each Project Plan shall remain effective until the services described in it are performed or it is otherwise terminated pursuant to the terms of this Agreement.

2.1.3 **Priority**

In the event of a conflict or ambiguity between any term of this Agreement and an Appendix or Project Plan, the terms of this Agreement shall prevail. In case the Parties mutually agree that a specific Section of this Agreement shall be modified by the terms of a Project Plan (and that such term of the Project Plan shall prevail) for a specific Service, they may only do so by explicit reference to the Section of this Agreement that shall be modified.

2.1.4 **Performance of Services**

BI Pharma shall perform for ELAN the Services as specified in this Agreement and the applicable Project Plan for a specific Project and ELAN shall adhere to its obligations under this Agreement and the applicable Project Plan(s). The Services shall be performed at the Biberach Facility.

2.2 Personnel

2.2.1 **Designation of Project Manager**

Upon commencement of this Agreement and/or upon commencement of a specific Project, BI Pharma and ELAN will each appoint a Project Manager, who will coordinate and supervise the respective Project including communication of all instructions and information concerning the respective Project to the other Party. The Project Manager will serve as contact person for the other Party. Each Project Manager will be available on an agreed (monthly) basis for consultation at prearranged times during the course of the respective Project. Project Managers shall be copied on all correspondence by other Project Team members and all correspondence between the Parties. In the absence of the Project Manager, a substitute shall be appointed. Additional modes or methods of communication and decision making may be implemented with the mutual written consent of each Party. Each Party will use reasonable efforts to provide the other Party with [***] prior written notice of any change in such Party's Project Manager. Such Project Manager may be changed for each Project according to the outlined procedure.

2.2.2 **Project Team**

The Parties shall establish a Project Team consisting of the necessary disciplines and their respective Project Manager for each Project to (a) ensure the progress of the respective Project, (b) coordinate the performance of the respective Project, and (c) facilitate communication among the Parties. Each Project Team member shall have knowledge and ongoing familiarity with the respective Project and will possess the authority to make decisions on matters likely to be raised in the Project Team. Notwithstanding Section 2.2 each Party shall have the right to substitute its members of the Project Team as needed from time to time by giving written notice to the other Party due time in advance.

The Project Team shall meet in person or by means of a video conference or teleconference on a periodic basis (a) as agreed by the Project Managers within [***] after written request for such meeting by either Party, or (b) as specified in the Project Plan (Appendix 2, as amended from time to time).

The Project Team shall oversee the Projects. Prior to each meeting of the Project Team the Parties will distribute to each other written copies of all materials, data and information arising out of the conduct of their activities hereunder.

Each Party shall bear its own costs associated with such meetings and communications. It is the right of each Party to call for a Project Team meeting according to the covenants of this Section 2.2 upon written request at any time. In such case the meeting will be held at the other Party's offices (or by means of videoconference or teleconference upon suggestion of the requesting Party) at a time mutually agreed to by both Project Managers if not otherwise agreed between the Parties.

The requesting Party shall prepare minutes of the meeting which shall be circulated promptly following the meeting.

The current members of the Project Team and the Project Managers are set forth in Appendix 3 attached hereto which may be amended from time to time.

2.2.3 **Steering Committee**

The Parties shall form a Steering Committee, to which each Party will appoint [***] executive employees, including the Project Managers, all of whom shall be familiar with the respective Projects. The Steering Committee shall have general oversight and review of the activities of the Project Team.

Any issues or dispute that may arise out of or relate to this Agreement or relating to the validity, performance, construction or interpretation of this Agreement ("Dispute") shall first be submitted for resolution to the Steering Committee. The Steering Committee shall meet within [***] after receipt of a written request by one Party to the other Party. The request shall describe the Dispute and the solution which the requesting Party proposes to be decided. If a resolution to the Dispute is reached, the Steering Committee

will take action by unanimous consent of the Parties, provided, however that any substantive departure from the Project Plan shall require an amendment to the Project Plan. If the Steering Committee cannot resolve the Dispute, the Dispute shall then be addressed in accordance with Section 12.8.

The members of the Steering Committee and the names of the respective chief executive officers of the Parties are set forth in Appendix 3 attached hereto, which may be amended from time to time.

2.3 Conduct of a Project and BI Pharma's Work and Tasks

The Parties shall engage in the Projects upon the terms and conditions set forth in this Agreement. In the course of this Agreement the Parties shall perform the Projects as laid down and detailed in the applicable Project Plan and Project Timeline according to the respective Product. Upon mutual agreement by the Parties, additional manufacturing runs may be performed by BI Pharma under work plans added as amendments to the respective applicable Appendix 2.

Each Party shall fully and reasonably cooperate with the other Party to provide appropriate information and assistance to the other Party in connection with the Projects, responding in a reasonable and timely manner with respect to all reasonable requests for information and approval. Neither Party shall be liable for any delays in its performance of the Projects to the extent caused solely by the other Party's failure to provide in a reasonably timely manner any information or approval reasonably requested by the other Party.

BI Pharma shall assign a sufficient number of professionally qualified personnel to perform the Projects and shall perform its tasks under this Agreement according to the generally acceptable professional and then current industry standards and subject to terms and conditions as set forth herein, at all times in compliance in all material respects with all requirements of applicable laws and regulations. BI Pharma will use commercially reasonable efforts to achieve the estimated timelines as laid down in Appendix 2 as amended from time to time. Changes to the Project Plan including the Project Timeline, if any, shall require the written consent of both Parties.

BI Pharma shall obtain and maintain all governmental licenses and permits necessary to establish and operate the Biberach Facility for performance hereunder, including but not limited to those required by the FDA. BI Pharma shall operate the Biberach Facility in compliance with all applicable laws and regulations and BI Pharma shall promptly notify ELAN in writing if any applicable regulatory agency issues a finding that negatively affects BI Pharma's ability to perform under this Agreement.

2.4 Deliverables

BI Pharma will deliver the Deliverables laid down in detail in the respective Project Plan within the Project Timelines laid down in the respective Project Plan to ELAN or such third party as ELAN may direct. Following the completion of the activities required under a Project, BI Pharma will provide to ELAN then available Product and a summary containing manufacturing and analytical testing, including without limitation, the information and the results of the respective development phase according to the workscope as further described in the respective Project Plan (Appendix 2).

2.5 Nature of the Project

As the Products have never been produced at the [***] scale, ELAN acknowledges that the Projects are experimental in nature and that no favorable or useful results at such scale can be assured by BI Pharma. However, after [***] initial [***] or [***]-runs ([***]), the Parties shall in good faith agree on a revision (if necessary) to the preliminary specifications based on the outcome of the comparability discussions with the relevant regulatory authorities that shall then be the Specifications for subsequent runs in subsequent campaigns that shall form a basis for rejection or acceptance of the respective Product produced in any additional runs at the [***] or [***] scale under the provisions of Section 4.1, and, provided that the respective Process and the respective Product Hex Cell Line have not been materially changed (i.e. a change that is subject to the Change Control procedures of the QAA) the respective Project shall no longer be considered experimental in nature and the obligation to meet the respective Specification shall apply to all future runs at the [***] or [***] scale.

2.6 Additional Work

2.6.1 **Changes Requested by ELAN**

2.6.1.1 Change to Specifications

ELAN shall be entitled to request a change to the Specifications from time to time (which change is not the result of a requirement or mandate of a Regulatory Authority) and BI Pharma shall make and implement all such changes in accordance with the applicable Quality Agreement, ELAN's change control procedures, and a written implementation plan (including tasks, time and cost) agreed to by the Project Team. ELAN shall retain the right and responsibility for final approval of the Specifications and any changes made thereto.

2.6.1.2 Other Changes

If ELAN desires a change to the manufacturing process, the equipment design, the materials, or the suppliers of the materials with respect to any Product (which change is not the result of a requirement or mandate of a Regulatory Authority), ELAN shall

submit such change request to BI Pharma in writing. BI Pharma shall use its commercially reasonable efforts to accommodate such request within the time frame proposed by ELAN; provided, however, that BI Pharma's acceptance of such change request under this Section 2.6.1 shall not be unreasonably withheld or delayed. Any changes under this Section 2.6.1.2 shall be implemented in accordance with the applicable Quality Agreement and a written implementation plan agreed to by the Project Team.

2.6.1.3 Costs

ELAN shall reimburse BI Pharma for any agreed upon costs incurred in implementing any changes made pursuant to this Section 2.6.1; provided, however, that the costs to be reimbursed shall not exceed those set forth in budget in the written implementation plan agreed to by the Project Team and the updated Project Plan shall be set forth in an amendment to the Project Plan executed by the Parties. Costs also should be fair and reasonable and in proportion to the costs of the original work order.

2.6.2 **Changes Requested by BI Pharma**

Unless otherwise agreed to in writing by the Parties in the applicable Project Plan, BI Pharma shall not implement major changes to the manufacturing process, the Specifications with respect to any Product in any manner (which change is not the result of a requirement or mandate of a Regulatory Authority) without the prior written consent of ELAN, which consent shall not be unreasonably withheld by ELAN. Any such changes that are approved by ELAN shall be implemented in accordance with the applicable Quality Agreement (if any), and a written implementation plan agreed to by the Parties. Any such changes approved by ELAN under this Section 2.6.2 shall be at BI Pharma's sole expense unless otherwise agreed to by ELAN in writing.

2.6.3 **Changes Requested by Regulatory Authorities**

If ELAN or BI Pharma is required or mandated by applicable law or any action or request made by any other Regulatory Authority to effectuate a change to the manufacturing process, the Specifications, the materials, the suppliers of the materials or any analytical testing methods with respect to the Drug Substance or Product, BI Pharma shall make such changes. BI Pharma shall be responsible for all costs incurred in implementing a change under this Section 2.6.3 that is related to BI Pharma maintaining cGMP compliance. To the extent a change request under this Section 2.6.3 is a change other than a change related to BI Pharma maintaining cGMP compliance, ELAN shall reimburse BI Pharma for the agreed amount incurred in implementing such change request; provided, however, that all such changes made shall be subject to ELAN's prior written approval and in accordance with the applicable Quality Agreement (if any), and the written implementation plan agreed to by the Project Team and be made part of this Agreement. The amount to be reimbursed by ELAN under this Section 2.6.3 shall not exceed those set forth in the budget in the implementation plan agreed to by the Project Team and the updated Project Plan shall be set forth in an amendment to this Agreement. The amounts proposed by BI Pharma should be fair and reasonable and in proportion to the amounts set forth in the Project Plan.

2.6.4 **Change Request Review**

Each Party shall use its commercially reasonable efforts to respond in writing to the Party submitting a change request under this Section 2.6 within [***] (or such longer period as agreed in writing by the Parties) from receipt of such written change request.

2.6.5 **Analytical Support**

BI Pharma shall provide the agreed analytical support and analytical research and development for raw materials, in-process materials, intermediates, the Deliverables, cleaning, potency, controls for impurities in intermediates and the Deliverables, cGMP testing and documentation, and the like, always in accordance with to the Quality Agreement. BI Pharma shall maintain suitable written records to verify compliance with this paragraph and ELAN may audit such records as set forth in the Quality Agreement.

2.6.6 **Laboratory Notebook Records**

BI Pharma shall prepare and maintain detailed laboratory notebook records of the preparation and analysis of Deliverables. BI Pharma shall deliver to ELAN by not later than [***] following the completion of the Services under each Project Plan a final report(s) in the English language, which shall be in accordance with the template attached hereto as Appendix 8.

2.6.7 **Handling and Archiving of Documents**

Pursuant to applicable laws, the original raw data regarding the Deliverables will be stored at BI Pharma's facilities. BI Pharma will comply with all applicable laws, rules and regulations regarding handling and archiving of original raw data and other documents and shall take reasonable and customary precautions according to BI Pharma's internal standard operating procedures to prevent the loss or alteration of data relating to the Deliverables. Upon termination of this Agreement, BI Pharma will archive files relating to the Deliverables according to BI Pharma's internal standard operating procedures that BI Pharma certifies are compliant with all applicable laws, rules and regulations for the agreed periods. BI Pharma agrees to notify ELAN in writing a reasonable amount of time prior to any planned destruction of any of the above referenced documents and provide ELAN with the opportunity to control the disposition of such documents. ELAN shall bear all costs incurred by BI Pharma in complying with any such written instructions furnished by ELAN that is received within [***] of written notification of ELAN by BI Pharma.

2.6.8 **Regulatory Matters**

Elan shall have sole responsibility for all submissions and filings with any Regulatory Authority, including without limitation any IND, BLA, MAA, comparability filing or other similar filing. Notwithstanding anything contained in this Agreement to the contrary, BI Pharma shall not initiate or participate in any communications with the FDA or any other domestic or foreign governmental authority concerning the subject matter hereof unless required by law or requested to do so by ELAN, and then only upon prior consultation with ELAN. However, ELAN shall reasonably give BI Pharma the opportunity to take part in any discussions that relate to the operations performed by BI Pharma for ELAN. Moreover, ELAN shall not commit to any changes that relate to the operations performed by BI Pharma for ELAN without prior consultation with and approval by BI Pharma, such approval not to be unreasonably withheld, delayed or conditioned. If any governmental or regulatory authority conducts or gives notice to BI Pharma of its intent to conduct an inspection at BI Pharma's facilities or take any other regulatory action with respect to the Projects hereunder, BI Pharma will promptly give ELAN notice thereof, including all information and copies of correspondence pertinent thereto and will use their reasonable efforts to obtain approval for ELAN or its authorized representative to take part in the inspection, for consultation only as required and to the extent reasonably practicable.

2.6.9 **Amendments to the respective Project Plan**

Notwithstanding the provisions above, any change to the respective Project Plan shall require an addendum to the Project Plan executed by the Parties.

2.7 ELAN Confidential Information and Know-How and Material

To the extent not already transferred by ELAN, ELAN shall transfer the Material for the respective Project(s) to BI Pharma subject to the terms of this Section 2.7, and BI Pharma shall use such Material solely to conduct the respective Project in accordance with the respective Project Plan, this Agreement, or as otherwise may be agreed to by the Parties in writing. The Materials will not be used by BI Pharma in connection with any diagnosis, treatment or any activity in humans or for any use not directly related to the respective Project. BI Pharma's use of the Materials will be in compliance with all applicable federal, state and local laws and regulations in Germany. BI Pharma accepts the Materials with the knowledge that they are experimental. The Materials may not be transferred or otherwise made available, in whole or in part, by BI Pharma to any other individual, entity or institution, including institutions and entities affiliated or under contract with BI Pharma without the prior written consent of ELAN, which may be withheld by ELAN for any reason. Such consent is hereby given for quality control testing performed on a blinded basis as further discussed and agreed in the Project Team.

The Materials are the property of ELAN. It is agreed that the transfer of the Materials hereunder shall be a bailment and shall not constitute a sale of Materials or a grant, option or license of any patent or other rights except to allow BI Pharma to perform the respective Project. ELAN shall retain and have all right, title and interest in and to the Materials.

ELAN will inform BI Pharma in a timely manner about any safety issues of which ELAN becomes aware relating to the handling of the Materials and the Products (including but not limited to the ELAN Contribution), after the date of the execution of this Agreement.

BI Pharma shall at all times take reasonable measures to protect the Materials from loss or damage and in no event measures less than employed by BI Pharma in the protection of its own proprietary materials, and shall promptly notify ELAN, if at any time it believes any Materials have been damaged, lost or stolen. BI Pharma will ensure that the Materials remain free and clear of any liens or encumbrances.

THE MATERIALS HAVE BEEN GIVEN TO BI PHARMA GRATUITOUSLY AND ARE PROVIDED "AS IS" WITH NO WARRANTIES EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

ELAN and BI Pharma hereby acknowledge and agree that ELAN is providing ELAN Confidential Information and Know-How to BI Pharma for its use by BI Pharma on behalf of and for the benefit of ELAN for the purposes of this Agreement, and BI Pharma will make use thereof solely for such purposes and ELAN hereby consents to such use.

2.8 General Policy regarding BI Pharma Confidential Information and Know-How

A general policy regarding BI Pharma Confidential Information and Know-How is laid down in Appendix 5. In the event of any inconsistency between Appendix 5 and this Agreement, this Agreement shall prevail.

3. Project Fee and Payments

3.1 Project Fee

As consideration for BI Pharma's performance of the respective Project, ELAN shall pay BI Pharma the fees set forth in the payment schedule in the respective Project Plan (the "**Project Fee**") as may be amended from time to time according to the agreement of the Parties. BI Pharma's internal and out-of-pocket costs and expenses for its performance of the Projects, including without limitation, ordinary and standard raw materials, components and consumables, are included in the Project Fees. BI Pharma will inform ELAN and seek its consent in advance of including any raw materials in the Process that will cause extraordinary costs.

If ELAN initiates multiple Projects or phases of Projects at BI Pharma and synergies can be reasonably identified, acknowledged and agreed by the Parties, the Parties shall agree to reductions in the applicable Project fees based upon cost savings resulting from such synergies. By way of example, cost savings could be obtained with increasing number of fermenter runs.

3.2 Invoicing and Payment

BI Pharma shall invoice ELAN for Project Fees according to the respective Payment Schedule in the Respective Project Plan for the respective Product.

ELAN shall make payment of all undisputed invoiced amounts [***] from the date of receipt of BI Pharma's invoice. If ELAN fails to make timely payment when due under this Agreement, interest shall accrue at [***]. All payments due under this Agreement shall be paid in Euros by wire transfer or by such other means agreed to in writing by the Parties. ELAN will provide at least twenty-four (24) hours advance notice to BI Pharma of each wire transfer to the bank account identified below or such other bank accounts as BI Pharma shall designate in writing.

Bank Name:	[***]
Bank Number	[***]
Account Number:	[***]
BIC Number:	[***]
IBAN-Code:	[***]

4. Delivery Terms of Product for Clinical Use

4.1 General

4.1.1 BI Pharma shall (a) deliver to ELAN or to a third party as directed by ELAN or, (b) at the request of ELAN, store the respective Product on a "bill and hold" basis for further processing, the agreed amounts of the respective Product produced according to the respective Project Plan in accordance with agreed upon schedules, at the prices set forth in Appendix 2. Delivery of all Products by BI Pharma shall be made [***] (Incoterms 2000). Material that is requested to be stored shall be held by BI Pharma for further processing and BI Pharma shall bill ELAN for Products held for further processing upon acceptance of the Products by ELAN, on the terms and conditions as set forth in Appendix 13. BI Pharma shall package and arrange for shipment of Products to the delivery address specified by ELAN, all in accordance with the instructions of ELAN[***]. BI Pharma shall reasonably support ELAN in the preparation and management of shipments to ELAN. Each shipment of cGMP Product will follow the criteria and contain the documents set forth in the Quality Agreement. The Parties shall cooperate reasonably to obtain all customs licenses or permits necessary to ship the Products (the evaluation of which customs licenses or permits required shall be performed by ELAN).

4.1.2 ELAN shall diligently examine Products delivered under this Agreement as soon as practicable after receipt. Notice of all claims arising out of (i) damage to or total or partial loss of Product or such other item in transit shall be given in writing to BI Pharma and the carrier or (ii) non-delivery shall be given in writing to BI Pharma within [***] after the date of receipt of the goods by ELAN. ELAN shall make a damaged Product available for inspection and shall comply with the requirements of any insurance policy covering a Product. BI Pharma shall offer ELAN all reasonable assistance, at the cost and expense of ELAN, in pursuing any claims arising out of the transportation of a Product.

4.1.3 Except as otherwise provided herein and as set forth in Section 2.5, ELAN shall have [***] from the date of delivery of a Product in order to evaluate a Product and accept or reject such delivery; provided that ELAN shall only be permitted to reject a Product if (a) BI Pharma fails to deliver a Certificate of Analysis and a Confirmation of Compliance, (b) the Product does not meet the Acceptance Criteria or (c) the Product, if intended for human use, was not manufactured in accordance with the applicable Quality Agreement, cGMPs and applicable laws at the place of manufacturing.

4.1.4 ELAN will have no obligation to accept any Product that does not meet the foregoing requirements. If ELAN determines after reviewing the relevant documentation and performing reasonable testing that any Batch does not meet such requirements, or if Product is determined by BI Pharma to be unsuitable for release, then [***]: (a) to produce a new Batch [***], including [***] manufacture of such Batch, or (b) to rework or reprocess the Batch, [***] so that the Batch can be [***] and the [***], or (c) in case [***] shall [***] for such Batch, including the [***] or, if there are no further orders of Product or [***] for any future orders, [***]. If the remedy set forth in either (a) or (b) is [***], then BI Pharma shall start the applicable work as soon as reasonably practicable, such that [***], with the goal to resupply within [***] and the closure of the respective investigation of the respective cause of the rejection. Moreover, the Parties shall take into account a possible lead time for raw materials. For the avoidance of doubt, if drug product is [***] as provided above, then [***] obligations set forth above shall [***] therein.

4.1.5 In the event ELAN rejects a Product for failure to meet Acceptance Criteria, BI Pharma shall have the right to sample and retest the Product, which shall be done as soon as practicable. In the event of a discrepancy between ELAN's and BI Pharma's test results such that one Party's results fall within the Acceptance Criteria and the other Party's test results fall outside the Acceptance Criteria, or there exists a dispute over whether such failure is due (in whole or in part) to acts or omissions of ELAN or any third party after delivery, the Parties shall cause a testing laboratory agreeable to both Parties to perform comparative tests and/or analyses on samples of the alleged defective Product. The testing laboratory's

results shall be in writing and shall be final and binding save for manifest error on the face of its report. Unless otherwise agreed to by the Parties in writing, the costs associated with such testing and review shall be borne by the Party against whom the testing laboratory rules. The testing laboratory shall be required to enter into written undertakings of confidentiality no less burdensome than set forth or referred to by this Agreement.

4.2 Access to Facility

Upon reasonable notice ELAN and its duly authorized representatives [***] will — upon BI Pharma's agreement regarding timing and specific manufacturing areas, which shall not be unreasonably withheld or delayed — have reasonable access to BI Pharma's facilities used to manufacture the respective Product, during operating hours and during active manufacturing of the respective Product, to inspect the facility and manufacturing process to ascertain compliance by BI Pharma with the requirements of cGMP, the Acceptance Criteria, the Quality Agreement, and applicable [***] law in a manner that is customary in the biopharmaceutical contract manufacturing business.

4.3 Recall

ELAN shall have the sole discretion to withdraw or recall any Products, and shall be responsible for directing all administrative and regulatory actions relating thereto. In the event that ELAN withdraws or removes any Products manufactured and supplied by BI Pharma, BI Pharma shall cooperate with ELAN as reasonably requested in connection with any such withdrawal or removal, including complying with all applicable laws and regulations. [***].

5. Ownership and Use of Project Data and Cell Banks

5.1 Project Data

(a) BI Pharma shall carry out the respective Project and provide ELAN with a summary containing the respective results from manufacturing and analytical release and also shall provide ELAN with summary report with results on the various stages of cell line development and process development;

(b) BI Pharma shall supply ELAN with data, results and information required to comply with any request of any applicable regulatory body or to comply with such regulatory body's requirement; and

(c) BI Pharma shall prepare the draft chemistry, manufacturing and controls section of any regulatory filing supporting the clinical development or application for marketing approval of the respective Product for [***]. ELAN shall review, finalize and approve the chemistry, manufacturing and controls section of any regulatory filing drafted by BI Pharma. BI Pharma shall timely perform a final

review of the chemistry, manufacturing and controls section of any such regulatory filing for accuracy of content of such section prior to filing by ELAN with the relevant regulatory authorities. ELAN may use the same information as provided [***] for filing in other jurisdictions, in which regulatory approval is sought for which ELAN gives BI Pharma prior written notice. Certain trade secret information may be provided by BI Pharma via DMF or similar filing (e.g. to a notified body) directly to the respective authorities.

(d) For the avoidance of doubt, subject to ELAN's confidentiality obligations hereunder and without affecting the ownership of Improvements as set forth in Section 9, all reports generated as a result of the BI Pharma's performance under this Agreement and delivered to ELAN by BI Pharma under this Agreement and all regulatory filings and approvals for the respective Product will be [***].

5.2 Use of the Process

Except as set forth in this Agreement, the Process shall not be used by ELAN outside the scope of this Agreement.

The BI Pharma Contribution or cells derived therefrom contain transcription units with heterologous genetic elements, e.g. fluorescent proteins, promoters, selection markers, which use is limited to the manufacture of the Product. Any use outside of this Agreement, e.g. isolation, amplification, use of those elements may affect BI Pharma's and/or third party rights.

5.3 Licenses

BI Pharma hereby grants to ELAN a [***] license under BI Pharma Technology and the BI Pharma Confidential Information and Know-How to [***] according to the terms and conditions for the use of BI Pharma Confidential Information and Know-How by ELAN as laid down in Appendix 4.

6. Basic Terms for Commercial Manufacture

Exemplary, non-binding terms regarding the commercial manufacture of the Products are laid down in Appendix 7. The parties shall negotiate and agree to terms that are commercially reasonable given the nature of the Product (for example, applicable clinical indication and market), including without limitation terms relating to scale, minimum purchase obligations, minimum runs, rolling forecasts and costs.

7. Representations, Warranties and Indemnification

7.1 Mutual Representations, Warranties and Covenants

Each Party hereby represents, warrants and covenants to the other Party as follows:

a. it is a corporation duly organized and validly existing under the laws of the state or other jurisdiction of incorporation or formation;

b. the execution, delivery and performance of this Agreement by such Party has been duly authorized by all requisite corporate action;

c. it has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder.

7.2 ELAN Warranties

ELAN hereby warrants that:

a. ELAN has the right to provide the ELAN Confidential Information and Know-How;

b. ELAN is not aware of any special or unusual hazards involved in handling the Materials and/or Products of which it has failed to inform BI Pharma; and that it will inform BI Pharma of any changes related thereto after the date of execution of this Agreement; and

c. ELAN has full corporate authority to enter into this Agreement and the Agreement is binding upon ELAN in accordance with its terms; and

d. as of the Effective Date and as of the effective date of any Project Plan, except as may be otherwise indicated in the applicable Project Plan, it [***] is or would [***] and ELAN will promptly notify BI Pharma, in such manner as to [***] should it become aware of [***].

7.3 BI Pharma Warranties

BI Pharma hereby warrants that:

a. BI Pharma is entitled to use the Biberach Facility and BI Pharma Confidential Information and Know-How, for the purposes set forth in this Agreement;

b. it shall perform its tasks under this Agreement according to [***] subject to terms and conditions as set forth herein, at all times in compliance in all material respects with all requirements of applicable laws and regulations, and [***] perform the Services as set forth in the applicable Project Plan;

c. BI Pharma at the Effective Date is not aware of any special or unusual hazards that would arise as a result of its carrying out of the Projects as planned;

d. BI Pharma has full corporate authority to enter into this Agreement and the Agreement is binding upon BI Pharma in accordance with its terms;

e. BI Pharma has the right, without restriction, to grant the licenses granted under this Agreement;

f. all Product that is required to be produced to cGMP standards will, at the time of delivery to ELAN, (a) have been manufactured in accordance with such cGMP requirements and all other laws applicable at the place of manufacture, the Process Description [***] the Quality Agreement, and the Acceptance Criteria, and (b) not be adulterated or misbranded under the United States Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321 et seq., as amended from time to time, or any comparable laws, rules or regulations applicable at the place of manufacture;

g. it has not been debarred, nor is it subject to a pending debarment, and that it will not use in any capacity in connection with the services under this Agreement any person, who has been debarred pursuant to section 306 of the FDCA, 21 U.S.C. § 335a, or who is the subject of a conviction described in such section. BI Pharma agrees to notify ELAN in writing [***] if BI Pharma or any person who is performing Services is debarred or is the subject of a conviction described in section 306, or if any action, suit, claim, investigation, or proceeding is [***] relating to the debarment or conviction of BI Pharma or any person performing services under this Agreement;

h. to the best of its Knowledge at the Effective Date its [***] by BI Pharma, ELAN or a [***], does not [***] and it will promptly notify ELAN in writing should it become aware of any [***], that would be [***]; and

i. as of the Effective Date no [***] by a third party with relation to [***], or any part or component thereof.

For avoidance of doubt, all [***] that might result from the representations and warranties under this Section 7.3 are always subject to [***].

7.4 Process for Defense of Infringement

Subject to each Party's indemnification obligations, in the event that there occurs a Claim (as defined below), the Parties shall follow the following procedures with respect to the defense of the Claim:

a. BI Pharma agrees that if a third party threatens or asserts any claim or files any lawsuit (a "Claim"), claiming that [***] manufacture and production of the Products [***], BI Pharma will promptly and timely inform ELAN of such Claim, and [***] shall have the first right, and [***], to negotiate, litigate and/or settle any such Claim, and shall defend any such Claim, provided, that [***] shall have the right to fully participate in the litigation, negotiation and settlement of all such Claims.

b. ELAN agrees that in the event of a third party Claim that [***] for manufacture and production of the Products [***], ELAN will promptly and timely inform BI Pharma of such Claim, and [***] shall have the sole right, and shall pay all costs associated therewith, to negotiate, litigate and/or settle any such Claim, and shall defend any such Claim, provided, that [***] shall have the right to fully participate in the litigation, negotiation and settlement of all such Claims, to the extent such Claims relate to the Services.

c. The Parties will keep each other informed about such negotiation or litigation at all times, including all material events related thereto, and in the event that the amounts paid or to be paid by a Party in settlement of any such Claim or group of related or unrelated Claims appear reasonably likely to exceed, individually or in the aggregate, such Party's indemnification obligations, or any contemplated settlement would place any obligations or restrictions upon the other Party, then such Party shall immediately inform such other Party.

d. A Party shall not be responsible to pay for any costs of any settlement by the other Party of any Claim(s) that exceed such other Party's indemnification obligations or be bound by any obligations or restrictions agreed to by such other Party in any such settlement, without the prior written consent of such Party, [***].

e. In the case that [***] decides not to negotiate, litigate or settle any Claim, [***] shall have the right to negotiate, litigate and settle any such Claim, and, provided that [***] decides to pursue such negotiation, litigation or settlement, [***] will provide all commercially reasonable cooperation to [***] such that [***] may appropriately defend such Claims.

7.5 Enforcement of Collaboration Intellectual Property

a. [***] shall have the first right (but not the obligation), [***] to enforce the Collaboration Intellectual Property other than Transferred IP; provided, however, that (i) [***] shall have the right to join such proceeding at any time at its own expense, and (ii) [***] shall not admit the invalidity or unenforceability of any Collaboration Intellectual Property without [***] prior written consent. [***] shall keep [***] reasonably informed prior to and during any such enforcement. [***] shall assist [***], upon request and at [***] expense in taking any action to enforce such Collaboration Intellectual Property and shall join in any such action if deemed to be a necessary party. [***] shall incur [***] as a consequence of such litigation or any unfavorable decision resulting therefrom, including any decision holding any of such Collaboration Intellectual Property invalid, not infringed or unenforceable. In the case that [***] decides not to enforce such Collaboration Intellectual Property, [***] shall have the right to enforce such Collaboration Intellectual Property [***] and [***] will provide all commercially reasonable cooperation to [***].

b. [***] shall have the sole right (but not the obligation), [***], to enforce the Transferred IP; provided, however, that (i) [***] shall not admit the invalidity or unenforceability of any Transferred IP without [***] prior written consent. [***] shall keep [***] reasonably informed prior to and during any such enforcement. [***] shall assist [***], upon request and at [***] expense in taking any action to enforce such Transferred IP and shall join in any such action if deemed to be a necessary party. [***] shall incur [***] as a consequence of such litigation or any unfavorable decision resulting therefrom, including any decision holding any of the Transferred IP invalid, not infringed or unenforceable. In the case that [***] decides not to enforce such Transferred IP, to the extent such Transferred IP relates to manufacturing Technology developed by [***], [***] shall have the right to enforce such Transferred IP [***] and [***] will provide all commercially reasonable cooperation to [***].

c. All monies recovered upon the final judgment or settlement of any action under 7.5(a) or (b) shall be used first to reimburse the costs and expenses (including reasonable attorneys' fees and costs) of [***], and thereafter [***].

7.6 Disclaimer of Warranties

EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, WITH RESPECT TO ANY INTELLECTUAL PROPERTY, TECHNOLOGY, RIGHTS, RESULTS OF THE PROJECTS; THE DELIVERABLES OR OTHER SUBJECT MATTER OF THIS AGREEMENT OR THAT THE PROJECTS WILL RESULT IN A COMMERCIALLY-VIABLE PROCESS, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

8. Liability, Limitations, Indemnification and Insurance

8.1 General

BI Pharma has no knowledge or awareness of or control over the manner in which ELAN intends to use the results of the Projects, the Products or the Deliverables, if any, obtained in the Projects and in particular does not know or control how ELAN intends to use such Products or results in clinical studies.

BI Pharma and ELAN hereby agree that the terms of the limitation of liability and indemnification that shall apply to this Agreement shall be as set forth hereinafter in this Agreement.

8.2 Liability

8.2.1 **No Liability for Consequential Damages**

Under no circumstance shall [***] be entitled to incidental, indirect or consequential damages arising in connection with any default or breach of [***] obligations (whether or not [***] has been advised of the possibility of such damages), but — for the avoidance of doubt — the [***] indemnification obligations of [***] shall not be considered incidental, indirect, consequential or special damages.

8.2.2 **[***] Liability**

[***] shall be legally liable in case of negligent or wilful breach of its representations and warranties and/or covenants set forth in this Agreement. Provided however, that the foregoing shall not apply if and as far as such cases are due to the negligence or wilful misconduct of [***].

[***] liability above shall be subject to the following limitations:

(i) In the case of gross negligent acts or omissions of [***] and/or its Affiliates to an amount up to [***], and

(ii) In the case of other negligent acts or omissions of [***] and/or its Affiliates to an amount up to [***].

For the avoidance of doubt, the foregoing limitations shall (i) not apply in cases of wilful misconduct of [***] or its Affiliates and where a limitation is not possible according to mandatory laws, and (ii) shall also be applicable to cases where [***] has an indemnification and hold harmless obligation.

8.2.3 **[***] Liability**

[***] shall be legally liable (i) in case of negligent or wilful breach of its representations and warranties and/or covenants set forth in this Agreement; and (ii) [***]. Provided however, that the foregoing shall not apply if and as far as such cases are due to the negligence or wilful misconduct of [***].

8.3 Insurance

Each of BI Pharma and ELAN each represent, warrant and covenant that it has and shall maintain during the term of this Agreement and for a period of five (5) years thereafter, comprehensive general liability insurance including products coverage in amounts, which are reasonable and customary in the pharmaceutical industry for companies of comparable size and activities at their respective place of business. Such product liability insurance shall insure against all mandatory liability, including liability for personal injury, physical injury and property damage. Upon a Party's written request the other Party shall within three (3) weeks provide the requesting Party with a written confirmation of the existence of such insurance. BI Pharma and ELAN may opt to self insure in order to meet the obligations of this Section.

8.4 Indemnification

8.4.1 **[***] Indemnity**

[***] shall indemnify, defend and hold harmless, [***], its directors, officers, employees and agents and affiliates, from and against any and all liability, damage, loss, cost (including reasonable attorneys' fees) and expense resulting from claims of any kind and character by any third party (including, without limitation, employees or agents of [***]) with respect to Products [***] pursuant to this Agreement or the use of the [***]. Notwithstanding the foregoing, [***] and its directors, officers, employees, and agents shall not be entitled to indemnification under this Section against any claim if and to the extent (a) [***] is liable according to Section 8.2.2 and (b) any accident at [***] which may arise in the course of [***] hereunder unless the same is caused by [***].

8.4.2 **[***] Indemnity**

[***] shall indemnify, defend and hold harmless, [***], its directors, officers, employees and agents and affiliates, from and against any and all liability, damage, loss, cost (including reasonable attorneys' fees) and expense resulting from claims of any kind and character by any third party (including, without limitation, employees or agents of [***]) with respect to [***] work performed hereunder to the extent [***] is liable according to Section 8.2.2.

8.4.3 **Indemnification Procedures**

A Party (the "Indemnitee") which intends to claim indemnification under this Section 8.4 shall promptly notify the other Party (the "Indemnitor") in writing of any action, claim or other matter in respect of which the Indemnitee or any of its directors, officers or employees intend to claim such indemnification; provided, however, that the failure to provide such notice within a reasonable period of time shall not relieve the Indemnitor of any of its obligations hereunder except to the extent the Indemnitor is prejudiced by such failure. The Indemnitee and its directors, officers or employees and agents shall cooperate fully with the Indemnitor and its legal representatives in the investigation, negotiations, compromise, settlement and defense of any action, claim or other matter covered by this indemnification, at the Indemnitor's sole cost and expense. The Indemnitor shall be in charge of and control of any such investigation, negotiation, compromise, settlement and defense and shall have the right to select counsel with respect thereto. In no event shall the Indemnitee compromise or settle any such matter without the prior written consent of the Indemnitor, which shall not be bound by any such compromise or settlement absent its prior written consent. In no event shall the Indemnitor compromise or settle any such matter for anything other than the payment of money without the prior written consent of the Indemnitee, which shall not be bound by any such compromise or settlement absent its prior written consent. The Indemnitee shall have the right, but not the obligation, to be represented by counsel of its own selection and at its own cost and expense.

9. Intellectual Property

9.1 Existing Intellectual Property Rights

9.1.1 BI Pharma hereby acknowledges that ELAN is the owner of ELAN Confidential Information and Know-How and the ELAN Technology and BI Pharma shall acquire no rights, title or interest whatsoever in or to any of ELAN Confidential Information and Know-How or ELAN Technology, except as specifically provided for in this Agreement.

9.1.2 ELAN hereby acknowledges that BI Pharma is the owner of BI Pharma Confidential Information and Know-How and the BI Pharma Technology and ELAN shall acquire no rights, title or interest whatsoever in or to any of BI Pharma Confidential Information and Know-How or BI Pharma Technology, except as specifically provided for in this Agreement. BI Pharma hereby grants to ELAN and ELAN hereby accepts [***] license to use BI Pharma Technology, BI Pharma Contribution and BI Pharma Confidential Information and Know-How solely to (i) [***] Products for [***] purposes; and (ii) [***] Products for [***]. BI Pharma shall have no right to [***] to manufacture Products except for the benefit of ELAN.

9.1.3 ELAN hereby grants to BI Pharma and BI Pharma hereby accepts for the purpose of this Agreement a [***], license to use ELAN Confidential Information and Know-How and ELAN Technology solely to develop the Process and to manufacture the Products for clinical purposes under this Agreement.

9.2 New Intellectual Property and Project Results

9.2.1 **ELAN Improvements**

9.2.1.1 Improvements that (i) [***], and (ii) [***], and (iii) [***] will be [***].

9.2.1.2 ELAN hereby grants to BI Pharma and BI Pharma hereby accepts for the purpose of pursuing the Projects under this Agreement a non-exclusive, non-sub-licensable (except to BI Pharma affiliates), royalty-free, license to use the ELAN Intellectual Property solely to develop the Process, and to use the Process solely for the manufacturing of the Products for clinical purposes in accordance with this Agreement.

9.2.2 **BI Pharma Improvements**

9.2.2.1 Improvements that (i) [***], and (ii) [***], and (iii) [***] will be [***].

9.2.2.2 Improvements that (i) [***], and (ii) [***].

(a) If either Party wishes to file a patent application on [***] the Parties shall reasonably cooperate in the preparation, filing, prosecution and maintenance of such patent application. [***] shall control patent prosecution and maintenance thereof and [***]. [***].

(b) [***] reasonably apprised of the status of the Collaboration Intellectual Property, and at the request of [***] shall copy its designated patent counsel on all prosecution correspondence with Patent Offices and provide it a reasonable opportunity to comment thereon. [***] designated patent counsel with respect to the prosecution of any claims in such Collaboration Intellectual Property relating to [***] and shall reasonably cooperate to effect the filing of one or more separate, divisional or continuation applications to [***].

(c) If a patent grants or issues [***]; or (ii) a patent application [***] and (iii) neither such [***]. Thereafter, [***] shall control patent prosecution and maintenance thereof and shall pay all costs associated therewith. [***], and at the request [***] shall copy its designated patent counsel on all prosecution correspondence with Patent Offices and provide it a reasonable opportunity to comment thereon. [***].

9.2.2.3 BI Pharma hereby grants and agrees to grant to ELAN a [***] license to BI Pharma's interest under all [***] solely to [***] the Products [***]. ELAN hereby grants and agrees to grant to BI Pharma [***] license to ELAN's interest under all [***] ELAN [***]; provided, however, that [***].

9.2.3 **Other Improvements**

9.2.3.1 Any Improvements that are not [***] shall be defined as "Other Improvements" and shall be [***] by [***], with [***]. Any Other Improvements shall be listed on Appendix 10, hereto, which shall be amended from time to time upon the creation of any additional Other Improvements. For the avoidance of doubt, know-how pertaining to [***] provided, that, notwithstanding the foregoing, BI Pharma may not [***] without ELAN's prior written consent, which shall not be unreasonably withheld, provided, however, that it shall not be unreasonable to withhold consent for [***].

9.2.3.2 [***] hereby grants and agrees to grant to [***] license to [***] under all Other Improvements developed, conceived or reduced to practice in the performance of this Agreement to [***].

9.2.4 **Patent Procedures**

9.2.4.1 The Parties shall meet and confer in good faith with regard to (i) establishment and implementation of efforts to pursue patent protection for the [***], including, but not limited to, [***] (ii) patent strategy, if a Party reasonably believes [***]("Combination IP"), to determine whether and how to prosecute such Combination IP. If [***] elects

not to pursue, or intends to abandon or not to file or maintain any patent or patent application in any jurisdiction, reasonable notice of which shall be given to [***], [***] shall be entitled to pursue or maintain such patent or patent application related to Project Intellectual Property, as applicable, and [***] agrees to [***] all right, title and interest it may have to such items of intellectual property.

9.2.4.2 The Parties shall be obligated to acquire the [***] shall be borne by the Party that [***] following the [***], provided, that [***] shall have the right to [***], provided, in the event that any such invention is subject to the licenses granted by [***] to [***] hereunder, then not less than [***] prior to notifying [***], [***] shall offer to [***] the right to [***] and, if accepted by [***] within the [***] prior to the intended notification date (or such later date if extended), [***] shall [***], and [***] shall [***] under the [***]. If pursuant to this Agreement, [***] is obliged to [***], [***] shall submit to [***] any draft to determine such [***], or any draft to agree with [***] under the [***] prior to submitting such determination or proposal to [***]. [***] will not unreasonably withhold its consent to such determination or agreement. [***] will not be responsible for any other obligation of [***] under the [***] except as expressly provided by this Agreement.

9.2.4.3 Subject to the terms and conditions contained in this Agreement and except as expressly set forth otherwise in Sections 9.2.1-9.2.3: (i) [***] shall be responsible for filing, prosecution and maintenance of patent applications and patents granted or generated under this Agreement and owned by [***]; (ii) [***] shall be responsible for filing, prosecution and maintenance of patent applications and patents granted or generated under this Agreement and owned by [***]. [***] shall be [***] responsible for filing, prosecution and maintenance of patent applications and patents granted or generated under this Agreement and [***]; (iii) BI Pharma shall keep ELAN and ELAN shall keep BI Pharma reasonably informed about prosecution of any patent applications and maintenance of any patents generated under this Agreement; and (iv) each Party shall provide reasonable assistance to the other Party for any action which may be necessary [***] contemplated by this Section 9.2.4.3.

10. Confidentiality

Exchange of confidential information by the Parties shall be subject to the terms and conditions of the Confidentiality Agreement; provided, however, the Parties hereby agree that the Confidentiality Agreement shall apply to any (i) BI Pharma Confidential Information and Know-How disclosed by BI Pharma to ELAN; (ii) ELAN Confidential Information and Know-How disclosed by ELAN to BI Pharma; and (iii) any information generated by either party in connection with this Agreement for a period of [***] following the termination or earlier expiration of this Agreement. For the avoidance of doubt, (i) the Disclosing Party with respect to ELAN Intellectual Property and Transferred IP and any information or document or data explicitly set forth herein as being the property of ELAN shall be ELAN; and (ii) the Disclosing Party with respect to BI Pharma Intellectual Property and Collaboration Intellectual Property other than Transferred IP shall be BI Pharma.

Nothing in this Agreement or the Confidentiality Agreement shall be construed to restrict the Parties from disclosing any information as required by mandatory law or court order or other governmental order or request, provided in each case the Party requested to make such disclosure shall timely inform the other Party and use all reasonable efforts to limit the disclosure and maintain the confidentiality of such information to the extent possible, if it comprises BI Pharma Confidential Information and Know-How or ELAN Confidential Information and Know-How. In addition, the Party proposing to make such disclosure shall permit the other Party to attempt to limit such disclosure by appropriate legal means.

Notwithstanding any provisions set forth in the Confidentiality Agreement to the contrary, a Party may make such disclosures of the other Party's Confidential Information and Know-How, to governmental entities to the extent reasonably necessary in connection with pursuit of intellectual property procurement and protection, development and commercialization activities related to the Products, and applications and approvals to use and sell the Products. Moreover, upon BI Pharma's prior written approval, which shall not be unreasonably withheld or delayed, ELAN may disclose BI Pharma Confidential Information and Know-How to entities with whom ELAN has (or may have in the future) a marketing and/or development collaboration for the Products and who have a specific need to know such information and who are bound by reasonable obligations of confidentiality and restrictions on use.

11. Term and Termination

11.1 Term

This Agreement shall take effect as of the Effective Date and shall continue until terminated.

11.2 Right to Terminate a Specific Project

11.2.1 Except as set forth below, ELAN in its sole discretion may terminate a specific Project upon [***] prior written notice to BI Pharma. However, this shall not apply to specific tasks that require a specific firm order period (for example, development activities, which require a certain lead time or firmly ordered clinical supply runs).

In case of a deletion or a delay of a [***] or [***] campaign the following provision will apply:

11.2.2 If BI Pharma gets notice in writing of a deletion or a delay of a [***] or [***] campaign [***] in advance of [***] cancellation fee will occur with the exception of [***].

11.2.3 In case of a cancellation less than [***] prior to the [***] will be charged to ELAN if the slot cannot be used for another project. Such fee will include the raw materials. Long lead items such as [***] will be outlined in the work scope and cost estimate separately.

11.2.4 Provided that BI Pharma shall have first followed the dispute resolution procedures set forth in Section 12.8, BI Pharma may terminate a specific Project upon [***] prior written notice to ELAN if at any stage of a Project:

(i) BI Pharma reasonably believes it will not be possible to carry out a specific Project for scientific or technical reasons or

(ii) the Parties cannot agree on any material changes or amendments to the scope of the respective Project Plan of this Agreement pursuant to Section 2.6.

11.3 Termination of this Agreement

This Agreement may be terminated by ELAN by written notice to BI Pharma with a notice period of [***].

11.4 Termination of this Agreement for Material Breach

This Agreement may be terminated at once by written notice by either Party, if the other Party breaches this Agreement in any material manner and shall have failed to remedy such default within [***] after written notice thereof from the terminating Party, provided that the terminating party shall have first followed the dispute resolution procedures set forth in Section 12.8, and provided further that BI Pharma shall continue to provide transitionary services [***]. However, in case of an adjudication by a court of or agreement by the Parties about a material breach by ELAN, ELAN shall [***].

11.5 Effect of Termination

11.5.1 In the event of termination as set forth in Section 11.2, [***] BI Pharma shall [***] For the avoidance of doubt, this Section shall not apply to [***]. The same shall be outlined in the Project Plan.

11.5.2 Upon the termination of this Agreement or a specific Project by either Party at the request of ELAN, BI Pharma shall [***] at ELAN's request to ELAN or a party nominated by ELAN at ELAN's cost and shall promptly return all ELAN Confidential Information and Know-How to ELAN; except for a copy and/or sample of each material for documentation purposes only. Except for the foregoing, BI Pharma's responsibility to [***] after expiration or termination of the respective Project or this Agreement. At the request of ELAN, BI Pharma shall ship all investments and raw material purchased in the course of the Project and paid by ELAN to ELAN.

11.5.3 Technology Transfer

Upon (i) termination by either Party or during the notice period regarding termination of this Agreement or a Project, (ii) at any time at ELAN's sole discretion during the pendency of this Agreement or a Project or (iii) on approaching expiry of this Agreement, ELAN may by written notice to BI Pharma seek assistance from BI Pharma with respect to the transfer to another manufacturer ("CMO") of the [***] and any associated Technology solely for the purpose of manufacturing Product ("Technology Transfer"). Following BI Pharma's receipt of such notice, the Parties will establish, in good faith, a schedule and plan to enable a knowledgeable manufacturer to continue manufacture of Product consistent with then current industry standards for effecting such transfer and BI Pharma will thereafter co-operate with ELAN in implementing such plan. However, it is understood by ELAN that BI Pharma cannot guarantee that such Technology Transfer will lead to the successful implementation of the process at ELAN or its named CMO.

11.5.3.1 As part of the Technology Transfer, BI Pharma will (i) transfer to the manufacturer or ELAN, as ELAN directs, all Technology, know-how and information necessary for performing the Process by a party skilled in the art of biotechnology processing (ii) make available for collection, subject to any regulatory obligations, all [***] generated pursuant to the this Agreement and the Projects up to the date of termination or expiry, i.e. batch records, development reports and production process documentation, and (iii) transfer, or if transfer cannot reasonably be performed, make available, to ELAN and its Affiliates and licensees and any applicable regulatory agencies, all other documentation reasonably necessary for clinical testing and commercialization of the Product.

11.5.3.2 The obligations on BI Pharma in respect of the Technology Transfer shall be exercisable by ELAN within a period beginning [***] prior to the date of termination or expiry (whichever is the earlier) and ending [***] after the date of termination or expiry (whichever is the earlier).

11.5.3.3 The foregoing Technology Transfer shall be limited capacitywise to [***] full time equivalents (FTE) for [***] working days, which may be used in the period set forth above. Thereafter, ELAN shall pay [***] and all other costs shall be charged as agreed.

11.5.3.4 ELAN shall enter into a written sublicense and confidentiality agreement with the CMO containing terms [***] and shall be responsible for any for any breach of the provisions of this Agreement by the CMO.

11.5.3.5 ELAN shall pay to BI Pharma a fee for the Technology Transfer in an amount of [***] Euro (Euro [***]) if a total of less than [***] runs of clinical supply ("Clinical Campaign") has taken place, which fee shall be [***] that has taken place and been paid for by ELAN for the specific Project.

11.5.4 In case of an adjudication by a court of or agreement by the Parties about a material breach by ELAN and except to the extent required to make use of the Technology Transfer:

11.5.4.1 ELAN shall promptly return all BI Pharma Confidential Information and Know-How to BI Pharma, except for a single copy and/or sample for documentation purposes only; and

11.5.4.2 all licenses granted by BI Pharma under this Agreement shall be null and void and ELAN shall not be entitled to further use BI Pharma Confidential Information and Know-How.

11.5.5 Surviving Provisions:

As far as not expressly set forth in this Agreement the following provisions of this Agreement shall survive the termination or expiration of this Agreement: 1, 5, 6, 7, 8, 9, 10, 11, 12.

12. Miscellaneous

12.1 Force Majeure

Neither Party shall be in breach of this Agreement if there is any failure of performance under this Agreement (except for payment of any amounts due hereunder) occasioned by any act of God, fire, act of government or state, war, civil commotion, insurrection, embargo, prevention from or hindrance in obtaining energy or other utilities, labour disputes of whatever nature or any other reason beyond the control of either Party.

12.2 Conflict

In case of a conflict between this Agreement and any of its Appendices, including any applicable Project Plan, this Agreement shall prevail, except as expressly determined differently in an amendment to this Agreement. For the avoidance of doubt, any modification to or amendment of the Specifications shall only be effective upon and amendment of this Agreement.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

12.3 Publicity

No press release or other form of publicity regarding a Project or this Agreement shall be permitted by either Party to be published unless both Parties have indicated their consent to the form of the release in writing. Nothing in this Section shall prevent the Parties from disclosing this Agreement, if and as far as required by applicable laws, rules or regulations. However, the disclosing Party shall inform the other Party well in advance whenever reasonably possible and shall provide the opportunity to comment on such required disclosure (e.g. under SEC rules).

12.4 Notices

Any notice required or permitted to be given hereunder by either Party shall be in writing and shall be (i) delivered personally, (ii) sent by registered mail, return receipt requested, postage prepaid or (iii) delivered by facsimile with immediate confirmation of receipt, to the addresses or facsimile numbers set forth below:

If to BI Pharma:
Boehringer Ingelheim Pharma GmbH & Co. KG
Birkendorfer Straße 65
88397 Biberach an der Riss
Germany
Attention: [***]
Fax: [***]

If to EPIL:
Elan Pharma International Limited
Treasury Building
Lower Grand Canal Street
Dublin 2
Ireland
Attention: Secretary
Fax: [***]

With a copy to:
Elan Pharmaceuticals, Inc.
800 Gateway Boulevard
South San Francisco, CA 94080
USA
Attention: Sr. VP Legal
Fax: [***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

If to Neotope:
Neotope Biosciences Limited
Monksland
Athlone, County Westmeath Ireland
Attention: Director
Fax: [***]

With a copy to:
Neotope Biosciences, a division of Elan
Pharmaceuticals, Inc.
650 Gateway Boulevard
South San Francisco, CA 94080
USA
Attention: Legal Counsel
Fax: [***]

12.5 Applicable Law and Jurisdiction

This Agreement shall be exclusively governed by and construed in accordance with the laws of [***] without regard to its conflict of laws provisions.

The Parties agree that all disputes that may not be resolved amicably between the Parties arising out of or in connection with this Agreement shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce ("ICC") by [***] appointed in accordance with said rules. The exclusive place of arbitration shall be [***] and the proceedings shall be conducted in the English language.

In such arbitration, the arbitrators shall apply the [***]. The award for arbitration shall be final and binding and may be enforced in any court of competent jurisdiction against BI Pharma or ELAN.

The Parties further agree that

(a) except as may be otherwise required by law, neither Party, its witnesses, or the arbitrators may disclose the existence, content, results of the arbitration hereunder without prior written consent of both Parties; and

(b) neither Party shall be required to [***] except as permitted or required pursuant to [***]; and

(c) [***]; and

(d) no arbitrator shall be an employee, director or shareholder of either Party or any of their affiliated companies but each shall have experience in the pharmaceutical industry. The chairman shall [***].

12.6 Waiver

No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition or of any other term, provision or condition of this Agreement.

12.7 Severability

If any provision of this Agreement is held to be invalid or unenforceable by a court of competent jurisdiction all other provisions shall continue in full force and effect. The Parties hereby agree to attempt to substitute for any invalid or unenforceable provision a valid and enforceable provision which achieves to the greatest extent possible the economic legal and commercial objectives of the invalid or unenforceable provision.

12.8 Dispute Resolution

If the Dispute is not resolved by the Steering Committee, then before resorting to litigation, unless emergency relief is required by either Party when either Party shall be free to resort to litigation, the Parties shall use their reasonable efforts to negotiate in good faith and settle amicably the Dispute. If the Dispute cannot be settled through negotiations by appropriate representatives of each of the Parties, either Party may give to the other a notice in writing (a "Dispute Notice"). Within [***] of the Dispute Notice being given the Parties shall each refer the Dispute to their respective Chief Executive Officers who shall meet in order to attempt to resolve the dispute. If within [***] of the Dispute Notice (i) the Dispute is not settled by agreement in writing between the Parties or (ii) the Parties have failed to discuss the Dispute or use good faith negotiations, the Dispute may be submitted to and finally be settled by the competent court. Nothing in this Agreement shall prohibit (nor force) the Parties to submit to any other dispute resolution forums as they may between themselves subsequently agree.

12.9 Assignment

This Agreement shall be binding upon the successors and assigns of the Parties and the name of a Party appearing herein shall be deemed to include the names of its successors and assigns provided always that nothing herein shall permit any assignment by either Party. However, BI Pharma may assign this Agreement to its Affiliates, and ELAN may assign this Agreement in its entirety or one or more specific Project Plans to its Affiliates or to a third party in connection with the transfer or sale of all or substantially all of the assets relating to the subject matter of this Agreement or the subject Project Plans, or in the event of a change in control, merger, acquisition, consolidation or similar transaction, provided, that the Parties agree that the activities under this Agreement shall be performed at the Biberach Facility, subject to Section 11.5.3.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the Effective Date.

Dublin, June 24, 2010

ELAN Pharma International Limited

/s/ William Daniel

Biberach, June 23, 2010

Boehringer Ingelheim Pharma GmbH & Co. KG

ppa.

/s/ Uwe Buecheler
Dr. Uwe Buecheler
SVP Biopharmaceuticals

ppa.

/s/ Hans Michelberger
Dr. Hans Michelberger
VP Legal Germany

Athlone, June 24, 2010

Neotope Biosciences Limited

/s/ William Daniel

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

List of Appendices:

Appendix 1:	not applicable
Appendix 2:	Project Plan including Project Timeline, Payment Schedule and ELAN Materials
Appendix 3:	Members of the Project Team & Steering Committee
Appendix 4:	Draft Conditions for Use of BI HEX® Cell Line
Appendix 5:	General Policy regarding BI Pharma Confidential Information and Know-How
Appendix 6:	Quality Assurance Agreement
Appendix 7:	7.1 Development of Commercial Process and 7.2 Basic Terms for Commercial Manufacture
Appendix 8:	BI Pharma Template for Final Report(s)
Appendix 9:	Specifications, incl. shipping and packing instructions agreed by the Parties (to be attached upon agreement of the Parties)
Appendix 10:	Other Improvements
Appendix 11:	Certain BI Pharma patents and patent applications relating to and/or describing the "BI Pharma Contribution"
Appendix 12:	Certain ELAN patents and patent applications relating to and/or describing the "ELAN Contribution"
Appendix 13:	Bill and Hold Provisions
Appendix 14:	Mutual Confidentiality Agreement

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Appendix 2

Project Plan including Project Timeline, Payment Schedule and ELAN Materials

for

[***] Antibody

Cell Line Development BI HEX®

Process Development

Drug Product manufacturing

Supply of clinical grade product

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1. [no text for this level]

1.1. Development of BIP high expression cell line [***]

Time frame: [***]
Total cost: [***]

1.2. Development of BIP high expression cell line [***]

Cell Transfection and Screening

[***]

Time frame: [***]
Total cost: [***]

[***]

1.3. Adaptation of analytical testing

Establish Analytical and QC Test Methods

[***]

Time frame: [***]
Total cost: [***]

[***]

Documentation and Progress Reporting of Cell Transfections

[***]

1.4. Material Produced from Stable Transfectant Pools

[***]

Time frame: [***]
Total cost: [***]

1.5. Development of BIP high expression cell line [***]

[***]

Time frame: [***]
Total cost: [***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Documentation and Progress Reporting of [***]

[***]

1.6. Deliverables

Elan → BIP

[***]

BIP → Elan

[***]

2. Drug Substance Manufacturing

[***]

2.1. Antibody Function Assay(s)

[***]

Time frame:	[***]
Total cost:	[***]

2.2. Application and Fixation of platform process at [80 L] scale

[***]

Time frame:	[***]
Total cost:	[***]

2.3. Consolidation of a scaleable process at [***] scale

[***]

Time frame:	[***]
Cost per run incl. filling:	[***]
Total cost [***]:	[***]

[***]

2.4. Explorative stability testing of Drug Product (DP) out of [***] scale

[***]

Analytical methods for stability testing	DS	DP
[***]		

[***]

Time frame:	[***]
Cost per lot:	[***]
Total Cost [***]:	[***]

2.5. Establishing of a Master Cell Bank (MCB)

[***]

Time frame:	[***]
Total cost:	[***]

2.6. Scale-up and GMP manufacturing at [***] or [***] scale

[***]

2.6.1. Ordering of long lead chromatography material (resins) for downstream process at [***] or [***] scale

[***]

Time frame:	[***]	
Scale:	[***]	[***]
Cost estimate:	[***]	[***]

2.6.2. Scale-up to pilot scale [***] or [***]

[***]

2.6.3. Manufacturing of [***] material for supply of clinical trials

2.6.3.1 Manufacturing scale [***]

¡ Production assumptions: [***]

Time frame:	[***]
Cost per [***] run:	[***]
Total cost [***] campaign [***]:	[***]

Additional runs at [***] scale for clinical supply can be manufactured at a campaign basis of [***] runs.

or

2.6.3.2 Manufacturing scale [***]

¡ Production assumptions: [***]

Time frame:	[***]
Cost per [***] run:	[***]
Total cost [***] campaign: [***]:	[***]

Additional runs at [***] scale for clinical supply can be manufactured at a campaign basis of [***] runs.

2.7. Analytical Characterization of Pre-Clinical and Clinical Batches

[***]

Analytical methods for release testing	DS	DP
[***]		

2.7.1. Stability program of Bulk Drug Substance

[***]

Time frame:	[***]
Cost [***]: [***]	[***]

2.7.2. Virus removal validation

[***]

Time frame:	[***]
Total cost:	[***]

2.7.3. DNA removal validation

[***]

Time frame:	[***]
Total cost:	[***]

2.8. Establishing CMC part for IND filing

[***]

Time frame:	[***]
Total cost:	[***]

2.9. Deliverables

[***]

Drug Product Section in addition to the Vendor Evaluation A and B

3. Drug Product Manufacturing and DP Stability Studies

[***]

3.1. Confirm Filling Performance Under Scaleable Process Conditions

[***]

Time frame:	[***]
Total cost:	[***]

[***]

3.2. Manufacturing of one liquid fill into vials under GMP conditions at technical scale

[***]

Time frame:	[***]
Total cost one fill:	[***]

[***]

3.3. Stability testing of Drug Product

(Material out of [***] scale)

[***]

Time frame:	[***]
Cost per lot:	[***]

[***]

3.4. Comparability testing of BDS and DP

[***]

Time frame:	[***]
Total cost:	[***]

[***]

3.5. Deliverables

[***]

Project Timeline

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

4. Cost of services

No.	Work package	Total Cost
1.	**Cell Line Development**	
	[***]	
2.	**Drug Substance Manufacturing**	
	[***]	
3.	**Drug Product Manufacturing and DP Stability Studies**	
	[***]	

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Appendix 3

Members of the Project Team & Steering Committee

Steering Committee

ELAN	Boehringer Ingelheim
[***]	[***]

Project Team

ELAN	Boehringer Ingelheim
[***]	[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Appendix 4

Draft Conditions for Use of BI HEX® Cell Line

If the Customer receives a license to manufacture or have manufactured any Product by using the [***] cell line (hereinafter called "BI HEX® Cell Line") or any cells derived thereof, the following terms and conditions shall be part of the license grant:

1. Grant:

Subject to the adherence of the Customer to the agreements entered into with BOEHRINGER INGELHEIM and to the provisions set forth in Section 2 and 3 below, BOEHRINGER INGELHEIM grants to Customer an [***] to use the BI HEX® Cell Line modified specifically for Customer during the development of the manufacturing process to produce the Product (hereinafter the "Cell Line")

- only to the extent necessary, and
- for the sole purpose, and
- to the extent incorporating BOEHRINGER INGELHEIM Technology

to [***] the Product [***] using the Cell Line. Any sublicense shall be in line with the scope of the license as set forth in the relevant agreement.

[***]

2. Milestone-payments:

[***]

It is understood that the milestone payments are only due once a milestone has been reached by using the Cell Line and manufacture of clinical trial material has not occurred at BOEHRINGER INGELHEIM.

For the avoidance of doubt, no milestone payments have to be paid if BOEHRINGER INGELHEIM is engaged with the manufacture of the respective Product for clinical trials and commercial Product.

3. Royalties:

If a third party, other than BOEHRINGER INGELHEIM and / or its Affiliates manufactures the Product for commercial use, a royalty of [***] shall be paid to BOEHRINGER INGELHEIM. If BOEHRINGER INGELHEIM and / or its Affiliates will manufacture the Product for an initial term of [***] royalty payments will occur during the contract term and thereafter.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

4. Terms

The license according to Section 1 shall last until expiration of the last valid patent claim in a respective territory or for a period of [***] after first commercialization of the Product whichever term is longer. Payments according to Sections 2 and 3 shall not be affected.

5. Warranty:

Any license (e.g. BI HEX® Cell Line, Cell Line, Technology, etc.) is granted in the condition "as it is" without any warranty of any kind, express or implied.

6. Liability:

Except for willful misconduct, for which there shall be no limitation, the liability and / or indemnification obligation of BOEHRINGER INGELHEIM is limited, as further specified below:

In case of third party claims regarding patent infringements relating to the BI HEX® Cell Line, [***].

Any and all liability and / or indemnification obligations of BOEHRINGER INGELHEIM for consequential, incidental or special damages are excluded.

In case of any direct damages of the Customer, BOEHRINGER INGELHEIM's liability is limited to the [***].

Furthermore, the Customer will indemnify and hold harmless BOEHRINGER INGELHEIM against any third party claims.

BOEHRINGER INGELHEIM will [***] under an agreement with Customer, such limitation shall only apply to the extent BOEHRINGER INGELHEIM is, at the effective date of the agreement with Customer, to the best of its knowledge, not aware of any third party rights that will affect BOEHRINGER INGELHEIM's s work under such agreement.

7. Governing law and Jurisdiction of the license:

[***] and competent court for [***], No reference to conflict of laws provisions.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Appendix 5

General Policy regarding BI Pharma Confidential Information and Know-How

BI Pharma represents a bench mark in Biopharmaceuticals and has to keep certain trade secrets to maintain its leading position in this technology

As a consequence the following policy has been issued:

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Appendix 6

Exemplary Non-Binding Terms for

Quality (Assurance) Agreement

on the

Manufacturing of [*fill in name*] Drug Substance and Drug Product

for Clinical Trials Phase(s) [*fill in*]

between

[*fill in Client name and address*]

(hereinafter called "CLIENT")

and

Boehringer Ingelheim Pharma GmbH & Co. KG
Birkendorfer Str. 65
88397 Biberach an der Riss
Germany
(hereinafter called "BIP").

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Table of Contents

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

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1. General

1.1. Purpose / Contents of this Agreement

The purpose of this Quality Agreement is to define the roles and responsibilities between CLIENT and BIP to establish quality requirements for [fill in name] Drug Product manufacturing for clinical trials phase(s) [fill in].

BIP is responsible for manufacturing of Product.

1.2. Main Agreement and this Quality Agreement

This Quality Agreement is intended to be an integral part and Appendix of the Main Agreement as defined herein.

2. Definitions

2.1. General

Unless otherwise defined in this Agreement the definitions of the Main Agreement shall apply also to this Agreement.

2.2. Agreement or Quality Agreement

shall mean this quality agreement by and between the Parties.

2.3. cGMP

means current Good Manufacturing Practices

2.4. CoC

means Confirmation of Conformance, confirming that the Product was manufactured according cGMP-rules and Product related deviations / investigations including environmental monitoring are finalized.

2.5. Critical Raw Materials

means Product-specific Raw Materials defined in Appendix 4

2.6. Drug Product

means the final dosage form containing the Drug Substance formulated with excipients.

2.7. Drug Substance

means the active ingredient that is subsequently formulated with excipients and used to produce the Drug Product.

2.8. IPC

means In Process Control.

2.9. Lot Genealogy

means a scheme depicting the origins of a biopharmaceutical batch (Drug Substance or Drug Product) taking into consideration specific operations like splitting and pooling.

2.10. Main Agreement

means the Clinical Supply Agreement dated as of [fill in date]

2.11. OoS

means Out of Specification.

2.12. Party/Parties

shall mean CLIENT and/or BIP as the circumstance requires.

2.13. Process

means a single operation or a number of operations involved in the preparation of the Product.

2.14. Product

shall mean [fill in name] Drug Substance or Drug Product

2.15. Raw Materials

means all materials including Critical Raw Materials used to manufacture the Product. Packaging Raw Materials and Consumables, which are not present in the Drug Product are excluded

2.16. Regulatory Relevant Changes

means changes with a potential impact on Product quality or regulatory commitments.

2.17. Significant Deviation

means a deviation with a potential impact on Product quality or regulatory documents.

2.18. Specifications

means a list of tests and acceptance criteria, with which the Product or materials used or obtained during manufacturing Process have to conform. Specifications for the manufacturer's release of Drug Substance and Drug Product are attached as Appendix 3 to this Quality Agreement.

3. Effective Date

This Agreement becomes effective at the date of the last signature.

4. Confidentiality

The provisions of the Main Agreement apply.

5. Applicable Regulations

The Parties shall ensure that the Product is manufactured and quality controlled in compliance with the technical information provided by CLIENT, the current GMP rules and local law and regulations applicable at the site of the corresponding activities.

6. Subcontracting

Any subcontracting, related to the activities described later in this Agreement, requires the prior approval of CLIENT and a contractual agreement between BIP and the respective subcontractor.

7. Others

7.1. Facilities and Equipment

For all manufacturing, testing, packaging, storage, equipment and facilities, as applicable, BIP will operate according to written, approved procedures for equipment qualification, preventative maintenance, instrument calibration, computer validation and cleaning, including revalidation requirements.

BIP is responsible for maintaining records of equipment usage, cleaning and any maintenance / calibration performed.

7.2. Raw Materials

CLIENT is responsible for the safe and secure shipment of any Raw Materials that CLIENT provides to BIP. CLIENT must provide Material Safety Data Sheets (MSDS) and shall insure that for Raw Materials released by CLIENT Quality Assurance, BIP receives the necessary documentation of the material release.

If BIP provides or procures Raw Materials as part of their contracted services, BIP will obtain those from a qualified or specified manufacturer. BIP will ensure that a Certificate of Analysis or equivalent is obtained with each lot of Raw Material purchased. Specifications for Critical Raw Materials (Appendix 4) will be agreed to by CLIENT.

BIP will store all Raw Materials and CLIENT Product in a secure location under appropriate conditions.

7.3. Change Control

BIP will have a Change Control Procedure in place to address changes to BIP's systems, facilities, Processes and Master Batch Records. BIP will provide CLIENT with Process Descriptions containing all relevant information necessary for IND and / or IMPD submission. The Process Descriptions will be subject to BIP's Change Control Procedure and will reflect regulatory relevant changes to BIP's Processes and procedures relating to CLIENT Product. BIP's Quality Assurance Unit will approve Master Batch Records and insure all information is in accordance with the Process Descriptions approved by CLIENT. Changes in Master Batch Records that are significant enough to require a change in the corresponding Process Description will trigger a Process Description Change and approval by CLIENT prior to an Master Batch Record change. Requested Changes shall be communicated to the other Party using the Change Permit Form (Appendix 5).

7.4. Deviation Handling

BIP will maintain a documented system for handling Deviations, Deviation Investigations, Out-of-Specification Results and Corrective Actions. CLIENT must approve in writing any Significant Deviation from BIP's internal Specifications or standard operating procedures affecting CLIENT Product, such approval shall not be unreasonably withheld or delayed.

BIP will provide additional information that CLIENT deems necessary to support the conclusions of the investigation. It is the responsibility of BIP to ensure that all Deviations are investigated, documented, and approved prior to release of a Product lot.

7.5. Production Systems

Manufacture of clinical batches of Product will be done at BIP's pharmaceutical manufacturing facility and will occur on a campaign basis. BIP will use procedures for manufacturing and control of Product set forth in the Master Batch Records according to Process Descriptions approved by CLIENT. BIP's Quality Assurance organisation will review the completed documentation and confirm that all activities were carried out in accordance with Process instructions and cGMPs.

7.6. Laboratory Control Systems

BIP will notify CLIENT of all confirmed OOS results and corresponding investigations as soon as possible. Each investigation will be reviewed and approved by BIP's designated Quality Assurance personnel. BIP will forward all documentation relating to investigations regarding confirmed OOS results for CLIENT's approval prior to batch release at BIP.

8. Product Release and Documentation

8.1. Manufacturer's Release by BIP

BIP shall be responsible for release of Product batches to CLIENT (manufacturer's release) confirming that each Batch supplied is in full accordance with the relevant Specifications. CLIENT and BIP will mutually approve in writing all IPC, manufacturer's release and stability Specifications for Product. Manufacturer's release Specifications for Drug Substance and Drug Product are defined in Appendix 3.

BIP shall prepare a Confirmation of cGMP Compliance (CoC) and a Certificate of Analysis (CoA) for each lot of Product. BIP shall provide CLIENT with a release documentation package for each lot of Product consisting of CoC, CoA, Lot Genealogy and a Deviation summary. The release documentation package shall be provided to CLIENT prior to BIP shipment of any lot, unless otherwise mutually agreed.

8.2. Final Release by CLIENT

CLIENT shall be responsible for the final release of the Product based on BIP's release documentation and their review of BIP's Batch Records. Upon reasonable request BIP shall provide CLIENT on-site access for review of the executed Batch Records. CLIENT is permitted to perform one on-site Batch Record Review per campaign with mutually agreed upon timing and schedule. The team conducting such on-site Batch Record Reviews should consist of not more than [***] persons belonging to CLIENT that are bound to confidentiality and non-use obligations as between the parties.

8.3. Shipment and Quarantine Shipment

BIP shall insure that the transport packaging and the shipping documentation of the Product is in accordance with the shipment instructions (if any) set forth in the corresponding Main Agreement. The shipment of Product to CLIENT or its contractual partners, post manufacturer's release at BIP, is CLIENT's sole responsibility ([***] conditions).

Product may be shipped exceptionally to CLIENT prior to BIP's manufacturer's release. As a prerequisite CLIENT must provide BIP with an "Authorisation for shipment under quarantine" (Appendix 2) signed by the quality organisation of CLIENT.

8.4. Documentation and Sample Retention

BIP shall be responsible for ensuring that all relevant data is recorded according to the requirements of cGMP and their internal SOPs and retained in a secure and retrievable manner. At the end of BIP's retention period, the data may be returned to CLIENT but must not be destroyed without the written prior agreement from CLIENT. BIP is responsible for sampling and storing reserve samples under controlled conditions as agreed to by the Parties.

9. Audits / Inspections / Contacts

9.1. Audits by CLIENT

CLIENT shall be entitled to audit all areas on the BIP facility relevant for the contracted service during normal business hours. CLIENT shall give BIP at least [***] prior written notice on its audit. One routine audit with mutually agreed upon timing and schedule is permitted per year. The audit team should consist of not more than [***].

Should in a given year no manufacture of Product take place no audit shall be conducted. BIP allows CLIENT to observe operations related to Product manufacturing and testing provided BIP's other customer's confidentiality is respected. A written response including expected time lines for corrective actions to all audit findings that require corrective actions will be provided by BIP following receipt of the audit report.

9.2. Inspections by Regulatory Agencies

BIP agrees to inform CLIENT in advance as soon as reasonably possible of any inspections by Regulatory Agencies related to the Product and about any observations with potential influence on the quality of the Product.

9.3. Regulatory Agency Contacts

Any observations, reports or warning letters from a regulatory agency resulting from an inspection that directly affect an CLIENT Product will be communicated to CLIENT by BIP as soon as reasonably possible after BIP's receipt of the observations, warning letters and reports.

Prior to making any commitment to a regulatory agency regarding an CLIENT Product as a result of a regulatory inspection of BIP each Party must obtain the other Party's review and approval of the proposed commitment.

BIP will provide a list or copies of all documents directly related to an CLIENT Product shared with a regulatory agency during any inspection.

BIP shall be entitled to attend teleconferences and meetings between CLIENT and Regulatory Agencies where there are specific agenda items regarding BIP activities and Facilities.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

10. Complaint Handling

CLIENT will be responsible for handling and evaluating customer complaints with respect to the manufacture, testing, stability, safety, effectiveness and packaging of Product. If a complaint relates to the activities or Processes carried out or controlled by BIP, BIP will be notified by CLIENT and will investigate and evaluate the complaint. BIP will notify CLIENT of the results of a complaint inspection and evaluation in writing within a time period jointly agreed upon. CLIENT shall be responsible for the final reply to the complainant.

11. Recalls

Product recalls will be the responsibility of CLIENT. All communications to the regulatory agencies will be the sole responsibility of CLIENT. CLIENT will notify BIP prior to approaching any regulatory agencies in connection with a Product recall.

12. Inconsistencies between Agreements

This Agreement and its annexes supplement the Main Agreement. Provided any inconsistencies exist between this Agreement and the Main Agreement, the latter shall prevail.

13. Amendments or Supplements

Any amendment or supplement to this Agreement shall be documented and approved in writing by both Parties.

14. Communications/List of Contact Persons

Any and all communication shall take place by and through the contact persons named by the Parties. The current list of contact persons is attached hereto as

Appendix 1 and shall be updated as necessary via amendment to this Agreement.

List of Appendices

Appendix 1: List of Contact Persons

Appendix 2: Authorization for Shipment under Quarantine

Appendix 3: Manufacturer's Release Specifications

Appendix 4: List of Critical Raw Materials

Appendix 5: Change Permit Form

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Signatures

Agreed by the Parties through their authorized signatories:-

CLIENT

Date / Signature

Date / Signature

Boehringer Ingelheim Pharma GmbH & Co. KG (BIP)

Date / Signature (Dr. Hans Michelberger, VP Legal Germany)

Date / Signature (Dr. Gerd Benirschke, VP Quality & Compliance)

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Appendix 1

List of Contact Persons

Contact for	Function	BIP	CLIENT
• Scale-up / GMP-Manufacturing		[***]	Name e-mail: Tel.:
• Analytics	QC	[***]	Name e-mail: Tel.:
• Batch Release	Local QP	[***]	Name e-mail: Tel.:
• Quality Assurance	QA	[***]	Name e-mail: Tel.:

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Appendix 2

Authorisation for Shipment under Quarantine

General Information

Product Name:

Manufacturing stage: Drug Substance ☐
Drug Product ☐

Batch no:

Quantity:

Order no:

Estimated release date:

CLIENT Approval

CLIENT herewith confirms that the above mentioned material will not be used in humans until it has been fully released by BOEHRINGER INGELHEIM and CLIENT Quality Operations.

CLIENT Quality Assurance
(Date / Signature)

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Appendix 3

Manufacturer's Release Specifications

Drug Product

Test methods and acceptance criteria for [*fill in name*] Drug Product for manufacturer's release

Test Method	Document #	Acceptance Criteria

Drug Substance

Test methods and acceptance criteria for *[fill in name]* Drug Substance for manufacturer's release

Test Method	Document #	Acceptance Criteria

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Appendix 4

List of Critical Raw Materials

		Acceptance Criteria
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		
13		
14		

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Appendix 5

CHANGE PERMIT FORM

Part A — Change Request

Organization Requesting the Change:

☐ **BOEHRINGER INGELHEIM**
☐ **CLIENT**

Name & Title of Requesting Individual:

Date of Submission:

Product / Material:

☐ **[*fill in name*]**
☐ **Raw Material**
☐ **Other:**_____

Description of Proposed Change:

☐ **Process / Material Change with Document Impact**
☐ **Document Change(s) only**
☐ **New Document(s)**
☐ **Other:**_____

Impacted Document(s):

Document Number	Title	Revision (From / To)
_____	_____	
_____/ _____		
_____	_____	
_____/ _____		
_____	_____	
_____/ _____		

Reason for Change and Supporting Documentation:

☐ **Environmental, Health & Safety**
☐ **Quality Improvement**
☐ **Adjustment to requirements of pharmacopoeia**
☐ **Cost Savings**
☐ **Other:** _____

Attachments:

☐ **Final Draft**
☐ **List of Changes**
☐ **Other:**_____

Comments:

QA Signature / Date:

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Appendix 5

CHANGE PERMIT FORM, continued

Part B — Change Review and Determination

Date of Receipt: _____
(Signature of QA Representative and Date)

Regulatory Impact Assessment (determined by CLIENT):

☐ **Major** ☐ **Minor** ☐ **None**

QA Approval of proposed Changes:

Herewith CLIENT agrees with the aforementioned Change(s) and the implementation at BOEHRINGER INGELHEIM

_____
(Signature of QA Representative and Date)

➢ **Return signed Change Permit Form to BOEHRINGER INGELHEIM QA**

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Appendix 7.1

Development of Commercial Process

Non-Binding Proposal

by Boehringer Ingelheim Pharma GmbH & Co. KG (BIP)

for

[***] Antibody

Development of Commercial Process

Clinical Supply for Phase II and III

Process Validation

Regulatory Filing

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1. Development of a Commercial Process at Small Scale and Fixation at [***] Scale

1.1. Establishing and Characterization of a Working Cell Bank (WCB)

¡ [***]

Time frame: [***]
Total Cost: [***]

1.2. Limit of In Vitro Cell Age (LCA) Study

[***]

Time frame: [***]
Total Cost: [***]

1.3. Development of a Commercial Process on the Basis of BIP's Platform Process

[***]

Time frame: [***]
Total Cost: [***]

1.4. Development and Establishing of a Commercial Liquid Formulation

[***]

Time frame: [***]
Total Cost: [***]

1.5. Establishing of Filling Process at Technical Scale

[***]

Time frame: [***]
Total Cost: [***]

1.6. Consolidation of Fermentation and Purification Process Format at [***] Scale

¡ [***]

Time frame: [***]
Cost per run: [***]
Total Cost: [***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1.7. Validation of Analytical Methods

[***]

Time frame:	[***]
Total Cost:	[***]

1.8. Explorative Stability Testing of Drug Product (out of [***] scale)

[***]

Time frame:	[***]
Cost one lot:	[***]

[***]

2. Scale-up to [***] Scale

2.1. Ordering of Long Lead Material (Chromatography Resins)

[***]

Time frame:	[***]
Scale:	[***]
Cost estimate:	[***]

[***]

2.2. Manufacturing of [***] GMP Runs for Clinical Supply

¡ [***]

Time frame:	[***]
Cost per [***] run:	[***]
Total Cost:	[***]

[***]

2.3. Stability Testing of Bulk Drug Substance (out of [2,000 L] scale)

[***]

Time frame:	[***]
Cost one lot:	[***]

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

2.4. Filling of Drug Product for Clinical Supply at Technical Scale

[***]

Time frame:	[***]
Total Cost:	[***]

2.5. Filling and Qualification of Reference Standard

[***]

Time frame:	[***]
Total Cost:	[***]

3. Scale-up to Commercial Scale [***]

3.1. Ordering of Long Lead Material (Chromatography Resins)

[***]

Time frame:	[***]
Scale:	[***]
Cost estimate:	[***]

3.2. Manufacturing of One (1) Scale-up Transfer Run

[***]

Time frame:	[***]
Total Cost:	[***]

3.3. Stability Testing of Bulk Drug Substance (out of [***] Transfer Run)

[***]

Time frame:	[***]
Cost one lot:	[***]
[***]	

3.4. Purchase of Dedicated Drug Product Filling Equipment

Time frame:	[***]
Rough cost estimate	[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

3.5. Establishing of Filling Process at Commercial Scale

¡ [***]

Time frame:	[***]
Rough cost estimate	[***]

4. Validation of Commercial Process at [***] Scale

4.1. Manufacturing of [***] Conformance Runs

¡ [***]

Time frame:	[***]
Cost per [***] run:	[***]
Total Cost:	[***]

4.2. Filling of [***] Drug Product Lots at Commercial Scale

Assumptions:

Vial size:	[***]
Concentration:	[***]
Fill volume:	[***]
Dose per vial:	[***]
Batch Size:	[***]

[***]

Time frame:	[***]
Cost per lot:	[***]
Total Cost:	[***]

[***]

4.3. Stability Testing of Drug Product (out of [***] Conformance Runs)

[***]

Time frame:	[***]
Cost one lot:	[***]
[***]	

4.4. Virus Removal Validation – [***] scale

[***]

Assumption:

[***]

Time frame:	[***]
Total Cost:	[***]

4.5. DNA Removal Validation – [***] Scale

[***]

Time frame:	[***]
Total Cost:	[***]

4.6. Comparability Testing

[***]

4.7. Process Characterization

[***]

4.8. Process Validation and Establishing of CMC Package ready for FDA/EMA Submission

Time frame:	[***]
Total Cost:	[***]

Project Timeline

[***]

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5. Cost of services

No.	Work package	Total Cost
1.	**Development of a Commercial Process at Small Scale and Fixation of Process at [***] Scale**	
2.	**Scale-up to [***] Scale**	
3.	**Scale-up to Commercial Scale [***]**	
4.	**Validation of Commercial Process at [***] Scale**	

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Appendix 7.2

Basic Terms for Commercial Manufacture

Non-Binding Proposal

by Boehringer Ingelheim Pharma GmbH & Co. KG (BIP)

for

[***] Antibody

Provisions for a Commercial Supply

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1. Provisions for a commercial supply

(to be negotiated between the parties; based on current process assumptions)

1) Term of Supply Agreement:

Minimum of 5 years after the later of (i) first product launch or (ii) delivery of Drug Product from first [***] commercial GMP run under condition of supply agreement.

2) Basic production assumptions:
[***]

3) Maximum Contract Capacity:

The reservation of contract capacity needed is subject for further discussion and has to be committed by Elan and BIP when the Parties intend to conclude a commercial supply agreement. As an assumption for the proposal a capacity request of [***] runs at [***] has been considered. (Subject for further discussion)

4) Minimum Contract Purchase Obligation:

The annual minimum purchase obligation during commercial supply term shall be an amount of [***] bulk drug substance which will be comparable to approx. [***] runs considering the above stated production assumptions (minimum purchase obligation to be agreed upon).

5) Final Product:

On Elan's request BIP will also offer contract services to manufacture Final Product, including sterile liquid filling in vial or syringe, inspection, manufacturer's release and bulk packaging (unlabeled vials/syringes in a labeled container).
The manufacturing of Finished Product which includes labeling and packaging has to be discussed separately.

6) Price Formula Bulk Drug Substance:

Price estimate for Bulk Drug Substance is based on the basic production assumptions and the total amount of product ordered per year within the range of the agreed upon capacity reservation.

Based on the basic production assumption (see section 2 above) and on the assumption of a capacity request for min. [***] (equivalent to [***] runs at [***] scale) a commercial supply price at [***] per gram Bulk Drug Substance could be expected.

The commercial supply price does include all raw materials, and services including analytical testing and manufacturer's release.

Minimum starts of a single campaign should be at least 5 runs.
The commercial product price would be valid until the end of 2012 and may be increased by BIP at the beginning of a calendar year (for the first time effective January 01, 2013) by [***] percent per year.

If the basic production assumptions change during the term of the transfer agreement and / or after scale-up of the process to commercial scale [***], the price for Drug Substance will be recalculated for commercial supply on the basis of the actual basic production assumptions of the [***] conformance lots for process validation and regulatory filing.

7) Price Formula Drug Product:

For price calculation for Drug Product the following assumptions have been made which have to be confirmed by Elan:

Drug Product:	Liquid Vial
Vial size:	[***]
Concentration:	[***]
Fill volume:	[***]
Dose per vial:	[***]
Batch Size:	[***]

Based on the assumptions as set forth above a commercial supply price of Euro [***] per vial for sterile liquid filling services can be offered.

The commercial supply price does include inspection, primary packaging material and manufacturer's release testing of filled vials. The price does not include active ingredient. In addition a filling loss of [***] has to be considered.

On request of Elan services for secondary packaging have to be discussed separately.

8) Rolling Forecast:

Drug Substance:

[***] prior to the first delivery date of product under the Supply Agreement, Elan shall provide to BIP a rolling forecast for the next [***].
[***]

Drug Product:

[***] prior to the first delivery date of Drug Product under the Supply Agreement, Elan shall provide to BIP a rolling forecast for the next [***].

The forecast for the first [***]. The forecast for [***].

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

BI Report No. DVR
File: XXXXX Cell Line Development_Report_final
Date: Oct. 26th, 2009
Page 1 of 1

Cell Line Development Report
XXXXX (YYYY)

Report ID No.	[***]
Report Title	[***]
Version No.	[***]
Project	[***]
Date of Origin	[***]
Authors	[***]
Company & Department	[***]

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Development Report:
[***] Upstream

Report ID No.	[***]
Project	[***]
Report Title	[***]
Version No.	[***]
Date of Origin	[***]
Authors	[***]
Company & Department	[***]

Remark (*adjust wording as needed*): "Upstream" means all manufacturing process steps where cell cultures are involved, starting from cell bank vials and initial cell cultivation to (and including) harvest up to the Cell-free Culture Fluid containing the Product (named "CCF" hereafter).

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Development Report:
Downstream

Report ID No.	[***]
Project	[***]
Report Title	[***]
Version No.	[***]
Date of Origin	[***]
Authors	[***]
Company & Department	[***]

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Appendix 9:

Specifications, incl. shipping and packing instructions agreed by the Parties (to be attached upon agreement of the Parties)

To be attached upon agreement of the Parties.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Appendix 10

Other Improvements

Product Hex Cell Line

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Appendix 11

Certain BI Pharma patents and patent applications relating to and/or describing the "BI Pharma Contribution"

Element / Technology	BI Pharma Patent / Publication / Application	Envisaged patent term
[***]		

BI Pharma uses [***].

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Appendix 12

Certain ELAN patents and patent applications relating to and/or describing the "ELAN Contribution"

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Appendix 13

Bill and Hold Provisions

1. BI Pharma shall be entitled to invoice ELAN for Product held on a bill and hold basis when such Product has been accepted by ELAN.
2. BI Pharma shall store such Product under agreed conditions as set forth in applicable written standard operating procedures pertaining to the storage of similar items by BI Pharma on its own behalf or, in the alternative, pursuant to written agreement of the Parties.
3. ELAN shall arrange for insurance for the Product stored at BI Pharma. Provided that BI Pharma has complied with the requirements of cGMP and any applicable standard operating procedures, including any storage procedures agreed by the Parties, BI Pharma shall not be liable for deterioration in Product. BI Pharma be liable for deterioration of or other damage to the Product that result from its gross negligent failure to comply with the requirements of cGMP and any applicable standard operating procedures, including any storage procedures agreed by the Parties.

MUTUAL CONFIDENTIALITY AGREEMENT

This Mutual Confidentiality Agreement (the "Agreement") is made as of August [17], 2009 (the "Effective Date"), by and between Boehringer Ingelheim International GmbH with an address of Binger Strasse 173, 55216 Ingelheim am Rhein, Germany ("Boehringer") and Elan Pharmaceuticals, Inc., a Delaware corporation with an address of 800 Gateway Boulevard, South San Francisco, California 94080, USA ("Elan").

Elan and Boehringer (each a "party," and collectively, the "parties") desire to provide each other with confidential and proprietary information for the purpose of evaluating a potential business and/or scientific relationship with each other concerning the pharmaceutical development of monoclonal antibody(ies) (the "Purpose").

The parties recognize that protection of such information is important to the continued success of each of their businesses. Accordingly, in reliance upon and in consideration of the following undertakings, the parties agree as follows:

1. DEFINITIONS

The following words have these meanings in this Agreement:

"*Affiliate*" means any corporation or other entity that controls, is controlled by, or is under common control with, a party hereto. An entity shall be regarded as in control of another corporation or entity if it owns or directly or indirectly controls more than 50% of the voting securities or other ownership interest of the other corporation or entity.

"*Disclosing Party*" means the party disclosing Information hereunder.

"*Information*" means any information of a confidential or proprietary nature connected with the business of either party, or any of its or their suppliers or customers, or its Affiliates, that has been or will be disclosed by or on behalf of one party to the other in any form. For the purposes of this Agreement, Information of Boehringer shall particularly include but is not limited to cell line development, process development and manufacturing of biopharmaceuticals. However, oral communications shall be protected as Information under this Agreement only if summarized in a writing marked "Confidential" and delivered to the Recipient within thirty (30) days after the disclosure.

"*Recipient*" means the party receiving Information hereunder.

2. USE AND NONDISCLOSURE

2.1 A confidential relationship with respect to the Information will be established between the parties as of the Effective Date and each Recipient will:

(a) not disclose or release, and will take all reasonable precautions, using at least the highest degree of care that the Recipient uses to protect its own confidential and

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

proprietary information and in no event less than reasonable care, to prevent disclosure or release of, the disclosing Party's Information to any third party, except with the prior, written authorization and consent of an authorized representative of the Disclosing Party. Each Recipient will limit internal dissemination of the Disclosing Party's Information to those officers, employees, Affiliates and consultants, who have been made aware that the Disclosing Party's Information is confidential, who are bound under written obligations of confidentiality substantially similar to those contained herein, and to whom disclosure is necessary for the Purpose. Each Recipient will be responsible for any actions by its officers, employees, Affiliates and consultants that constitute a breach of this Agreement;

(b) only use the Disclosing Party's Information to the extent required to accomplish the Purpose and for no other reason; and

(c) not reproduce or distribute the Disclosing Party's Information in any form, in whole or in part, except as required to accomplish the Purpose. Without limiting the foregoing, each Recipient agrees that it shall not use Disclosing Party's Information to make any materials or reproduce all or parts of any experimental information disclosed hereunder. Further, Recipient agrees that it shall not use Disclosing Party's Information for any purpose or in any manner that would constitute a violation of any laws or regulations, including, without limitation, the export control laws of the United States.

If Information is communicated via internet mail, use of internet mail encryption technology is compulsory.

2.2 All Information of a Disclosing Party obtained under this Agreement will be considered the Disclosing Party's Information and is subject to the obligations hereunder; provided however, that such obligations shall not apply to the extent that competent written evidence proves that such Information:

(a) Was lawfully in Recipient's possession prior to the date of disclosure;

(b) Becomes public or available to the public through no act or omission of the Recipient amounting to a breach hereof;

(c) Was lawfully obtained by the Recipient from a third party in lawful possession of such Information and under no obligation of confidentiality with respect thereto;

(d) Is required to be disclosed by law, regulation, rule, act or order of any governmental authority or agency, in which case the Recipient will give the Disclosing Party as much advance notice of the proposed disclosure as is practical (including a copy of any written request or order), disclose only that information required to comply with the legal requirement, and will cooperate with the

Disclosing Party at Disclosing Party's expense if it chooses to make any effort to limit or prevent such disclosure via a protective order or otherwise, provided, however, such disclosure shall not relieve the Recipient of its other obligations contained herein; or

(e) Was independently invented or developed by or on behalf of the Recipient by those who did not have access to or benefit from the Information.

2.3 All rights in the Information of the Disclosing Party, including without limitation, the right to apply for intellectual property rights in its own name, are and shall remain vested exclusively in the Disclosing Party and the Recipient shall not apply for such rights.

3. TERM AND TERMINATION

The term of this Agreement is two (2) years from the Effective Date; provided, however, that the Recipient agrees to use reasonable efforts to protect and preserve the confidential status of the Information acquired hereunder for ten (10) years from the expiration date hereof and that the Recipient's obligations of non-use under this Agreement shall last indefinitely. Promptly upon the Disclosing Party's written request, all tangible Information of the Disclosing Party acquired by the Recipient, including all whole or partial copies thereof shall, at the Disclosing Party's sole option, be returned to the Disclosing Party or destroyed, and all other embodiments and derivatives thereof shall be destroyed, except that the Recipient may retain one (1) copy of Information in its confidential files solely for the purposes of verifying compliance with the terms of this Agreement.

4. REMEDIES

The parties agree that remedies at law for breach of this Agreement by the Recipient may be inadequate and that a Disclosing Party that believes it has been injured shall be entitled, in addition to any other rights it might have, to seek injunctive relief.

5. MISCELLANEOUS

5.1 **No Further Obligations**. Nothing contained in this Agreement shall be construed, by implication or otherwise, as an obligation upon either party to negotiate or enter into any further agreement or arrangement relating to any of the Information or as a grant of any right or license by either party for the other to use its Information or intellectual property other than for the Purpose.

5.2 **Severability**. If any provision of this Agreement is declared void or unenforceable, such provision shall be deemed modified to the extent necessary to allow enforcement, and all other portions of this Agreement shall remain in full force and effect.

5.3 **Integration**. This Agreement contains the entire and complete agreement between the parties with respect to the subject matter hereof, and supersedes all prior oral and/or written agreements with respect to the subject matter hereof. Any changes to this Agreement must be in writing and signed by both parties.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

5.4 **Assignment**. This Agreement may not be assigned or otherwise transferred by any party without the prior written consent of the other party, which shall not be unreasonably withheld, conditioned or delayed, except that either party may, without prior notice or consent, assign this Agreement and/or the rights and obligations hereunder to an Affiliate, or to a third party in connection with the transferor sale of all or substantially all of its business related to the subject matter of this Agreement, or in the event of a change in control, merger, acquisition, consolidation or similar transaction. Any purported assignment or transfer in violation of this section shall be void. This Agreement shall be binding upon and inure to the benefit of the successors, permitted assigns and legal representatives of the parties.

5.5 **Governing Law**. This Agreement shall be governed by and construed in accordance with the laws of England, as such laws are applied to contracts entered into and to be performed within such jurisdiction. Place of venue is the competent courts in London, England.

5.6 **Execution**. This Agreement and any related amendments may be executed by facsimile and in one or more counterparts, each of which shall be deemed an original and all of which together shall constitute one document.

5.7 **Securities Law Compliance**. Recipient is aware of the restrictions imposed by U.S. law on the purchase or sale of securities by any person who has received material, non-public information relating to the issuer of such securities and on the communication of such information to any other person when it is reasonably foreseeable that such other person is likely to purchase or sell such securities in reliance upon that information.

Elan hereby agrees that if it intends to provide Information to Boehringer that Elan knows or, after diligent review, has reason to assume may be listed on the Commerce Control List or the Chemical Weapons Convention Schedules of Chemicals, both contained within the U.S. Export Administration Regulations, (hereinafter "Controlled Technology"), that Elan shall notify promptly Boehringer of such knowledge or assumption as soon as possible prior to such intended disclosure. In order for Boehringer to take any appropriate precautionary actions before receipt of such Controlled Technology and to ensure compliance with U.S. export laws, Elan shall, before providing the Controlled Technology:

(a) identify all Information that may be Controlled Technology; and

(b) inform Boehringer, to the extent known to Elan, where the Controlled Technology is listed on the Commerce Control List or the Chemical Weapons Convention Schedules of Chemicals and what restrictions apply to the export or disclosure of the Controlled Technology under U.S. law.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Elan further agrees to cooperate with Boehringer by providing upon request information and other assistance necessary for the export classification, export documentation and export licensing, if required, for the Controlled Technology under U.S. export laws. In any event, Elan hereby agrees that it will not disclose Controlled Technology to BOEHRINGER without the express prior consent of Boehringer.

5.8 **No Warranty**. ALL INFORMATION IS PROVIDED BY DISCLOSING PARTY "AS IS" AND WITHOUT ANY WARRANTY, EXPRESS, IMPLIED, OR OTHERWISE, INCLUDING WITHOUT LIMITATION ANY WARRANTIES REGARDING ITS ACCURACY, COMPLETENESS, PERFORMANCE, OR NONINFRINGEMENT OF THIRD PARTY RIGHTS, OR ITS MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

Accepted and Agreed as of the Effective Date, and executed by:

Elan Pharmaceuticals, Inc.	Boehringer Ingelheim International GmbH ppa. i. V.
By: /s/ Guriq Basi	By: /s/ Prof. Werner /s/ M. Mauer
Name: Guriq Basi	Name: Prof. Werner M.Mauer
Title: VP, Extramural Research	Title: authorized signatories

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Appendix 2A: Project Plan — [***]

AMENDED AND RESTATED [***] PROJECT PLAN

Antibody Description: [***]

Pertinent Elan Party: Onclave Therapeutics Limited

Treasury Building

Lower Grand Canal Street

Dublin 2

Ireland

("Onclave")

Scope: Expansion and modification to include additional drug product manufacturing and formulation activities

Cell Line Development BI HEX®

Process Development

Drug Product manufacturing

Supply of clinical grade product

WHEREAS, Elan Pharma International Limited, Treasury Building, Dublin 2, Ireland, ("EPIL"), Neotope Biosciences Limited, a private limited company incorporated under the laws of Ireland with offices at Monksland, Athlone, County Westmeath, Ireland ("Neotope") and Boehringer Ingelheim Pharma GmbH & Co. KG, Birkendorfer Str. 65, 88397 Biberach an der Riss, Germany ("BI Pharma") have previously entered into a Master Process Development and Clinical Supply Agreement effective as of June 23, 2010 (the "Agreement");

WHEREAS, Neotope and BI Pharma have incorporated Appendix 2 – Part I, Project Plan, Antibody Description: [***], Version of February 18, 2011 into the Agreement with retroactive effect as of June 23, 2010.

WHEREAS, BI Pharma and Neotope are parties to the Appendix 2 – Part I, Project Plan, Antibody Description: [***] effective June 23, 2010 ("[***] Project Plan").

WHEREAS, EPIL, Neotope and BI Pharma have mutually amended the Agreement by Amendment No. 1, effective as of August 1, 2011, to cover the provision of cell line development services for multiple antibodies, permit separate Project Plans for separate antibody projects and to include a template for future Project Plans, and in such Amendment No. 1 have renamed "Appendix 2-Part I, Project Plan, Antibody Description: [***] to "Appendix 2A: Project Plan [***].

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

WHEREAS, as described in a notice of assignment from Neotope to BI Pharma dated May 17, 2012, attached hereto as Schedule 1, Neotope assigned all of its assets relating to the [***] Project Plan, including the [***] Project Plan itself, to Onclave and provided new invoicing and notice instructions.

WHEREAS, Onclave and BI Pharma now mutually desire to amend and restate the [***] Project Plan to replace the content of the [***] Project Plan with the content set forth below.

This Amended and Restated Appendix 2B – [***] Project Plan shall incorporate the terms of the Agreement, and shall become effective as of August 1, 2012.

NOW, THEREFORE, Onclave and BI Pharma agree as follows:

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Table of contents

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

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1. Cell Line Development

Boehringer Ingelheim's proprietary high expression system (BI HEX®) enables fast-track generation of high-producer cell lines leading to high-titer processes for production of therapeutic proteins from CHO cells, thus shortening the time-to-clinic. BI HEX® represents an integrated platform which combines state-of-the-art technologies including BIP proprietary expression vectors for stable and high-level product expression, a fast-track cell line generation concept entirely free of serum and a generic screening platform including BIP media and feed compositions. Early assessment of cell line stability and initial characterization of product quality according to our paradigm "Do it right the first time" are key to our success.

Cell Line Development BI HEX®

[***]

1.1. Development of BIP high expression cell line [***]

[***]

Time frame:	[***]		
Total cost:	[***]	[***]	
Payment schedule:	[***]	[***]	**invoiced**

1.2. Development of BIP high expression cell line [***]

Cell Transfection and Screening

[***]

Time frame:	[***]		
Total cost:	[***]	[***]	
Payment schedule:	[***]	[***]	**invoiced**

- [***]

1.3. Adaptation of analytical testing

Establish Analytical and QC Test Methods

[***]

Time frame:	[***]	
Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Documentation and Progress Reporting of Cell Transfections

[***]

1.4. Material Produced from Stable Transfectant Pools

[***]

Time frame:	[***]		
Total cost:	[***]	[***]	
Payment schedule:	[***]	[***]	**invoiced**

1.5. Development of BIP high expression cell line [***]

[***]

Time frame:	[***]		
Total cost:	[***]	[***]	
Payment schedule:	[***]	[***]	**invoiced**

Documentation and Progress Reporting of [***]

[***]

1.6. Supply of [***]

Assumptions:

- [***]

Time frame:	[***]		
Total cost:	[***]	[***]	
Payment schedule:	[***]	[***]	**invoiced**

1.7. Deliverables

Elan → BIP

[***]

BIP → Elan

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

2. Drug Substance Manufacturing

[***]

]

2.1. Application and Fixation of platform process at [***] scale

- [***]

Time frame:	[***]		
Total cost:	[***]	[***]	
Payment schedule:	[***]	[***]	**invoiced**

2.2. Consolidation of a scaleable process at [***] scale

- [***]

Time frame:	[***]	
Cost per run incl. filling:	[***]	[***]
Total cost [***]:	[***]	[***]
Payment schedule:	[***]	[***]

[***]

2.3. Freeze Thaw Study Drug Substance in Bags

- [***]

Time frame:	[***]	
Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

2.4. Freeze Thaw Study [***] in Bags

- [***]

Estimated time frame:	[***]	
Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

2.5. Additional Efforts for Analytical Testing of [***] Material

[***]

Time frame:	[***]	
Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

2.6. Filling of Reference Standard for [***]

Filling assumptions:

- [***]

Time frame:	[***]	
Total cost:	[***]	[***]
Payment schedule:	[***]	

2.7. Explorative stability testing of Drug Product (DP) out of [***] scale

[***]

Analytical methods for stability testing	**DS**	**DP**
[***]		

[***]

Time frame:	[***]	
Cost per lot:	[***]	[***]
Total cost [***]:	[***]	[***]
Payment schedule:	[***]	[***]
	[***]	[***]
	[***]	[***]
	[***]	[***]

[***]

2.8. Explorative stability testing of intermediate bulk out of [***] scale

[***]

Time frame:	[***]	
Cost per lot up to [***]:	[***]	[***]
Total cost [***]:	[***]	[***]
Payment schedule:	[***]	[***]

[***]

Time frame:	[***]	
Cost per lot:	[***]	[***]
Total cost [***]:	[***]	[***]
	[***]	[***]
	[***]	[***]

2.9. Establishing of a Master Cell Bank (MCB)

[***]

Time frame:	[***]	
Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

2.10. Scale-up and GAO manufacturing at [***] scale

[***]

2.10.1. Ordering of long lead chromatography material (resins) for downstream process at [***] scale

[***]

Chromatography material	Amount
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

Time frame:	[***]	[***]
Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

2.10.2. Scale-up to pilot scale [***] and Manufacturing of clinical material

[***]

Time frame:	[***]	
Cost per [***] run:	[***]	[***]
Total cost [***] campaign [***]:	[***]	[***]
Payment schedule:	[***]	[***]
Payment schedule:	[***]	[***]

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

2.11. Analytical Characterization of Pre-Clinical and Clinical Batches

[***]

Analytical methods for release testing		DS	DP
	[***]		

2.11.1. Stability program of Bulk Drug Substance

[***]

Time frame:	[***]	
Cost per lot:	[***]	[***]
Total cost [***]:	[***]	[***]
Payment schedule:	[***]	[***]
	[***]	[***]
	[***]	[***]
	[***]	[***]

[***]

2.11.2. Virus removal validation

[***]

Time frame:	[***]	
Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

2.11.3. DNA removal validation

[***]

Time frame:	[***]	
Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

2.12. Establishing CMC part for IND filing

[***]

Time frame:	[***]	
Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

2.13. Deliverables

[***]

3. Drug Product Manufacturing and DP Stability Studies

[***]

3.1. Initial Preformulation studies

— [***]

Time frame:	[***]		
Total cost:	[***]	[***]	
Payment schedule:	[***]	[***]	**invoiced**

3.2. Confirm Filling Performance Under Scaleable Process Conditions

[***]

Time frame:	[***]	
Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

[***]

3.3. Manufacturing of one liquid fill into vials under GMP conditions at technical scale

[***]

Time frame:	[***]	
Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

[***]

3.4. Efforts for Change to [***] Vial

— [***]

Time frame:	[***]	
Total cost:		[***]
Payment schedule:	[***]	[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

3.5. Stability testing of Drug Product

(Material out of [***] scale)

[***]

Time frame:	[***]	
Cost per lot:	[***]	[***]
Total cost [***]:	[***]	[***]
Payment schedule:	[***]	[***]
	[***]	[***]
	[***]	[***]

[***]

3.6. Filling and Qualification of Reference Standard [***]

[***]

Time frame:	[***]	
Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

3.7. Comparability Testing including Characterization Studies

[***]

Analytical methods for comparability testing
[***]

[***]

Time frame:	[***]	
Total cost Comparabilty Testing (3.6.):	[***]	[***]
Total cost [***] (2.5.)	[***]	[***]
Payment schedule for 2.5. and 3.6.:	[***]	[***]

[***]

3.8. Deliverables

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

4. Additional work packages/supportive data

[***]

Time frame:	[***]	
Price estimate:	[***]	[***]
Payment schedule:	[***]	[***]

[***]

Time frame:	[***]	
Price estimate:	[***]	[***]
Payment schedule:	[***]	[***]

5. Additional work packages: Adaptation of Formulation

[***]

Filling of cGMP Material for Use in Clinical Studies

[***]

Time frame:	[***]	
Cost estimate:	[***]	[***]
Payment schedule:	[***]	[***]

5.1. Stability Studies of Bulk Drug Substance (optional) and Drug Product (Material out of [***] scale)

[***]

5.1.1. <u>Drug Product</u>:

[***]

Time frame:	[***]	
Cost per lot:	[***]	[***]
Total cost [***]:	[***]	[***]
Payment schedule:	[***]	[***]
	[***]	[***]
	[***]	[***]

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

5.2. Comparability testing to support regulatory requirements

[***]

Time frame:	[***]	
Payment schedule:	[***]	[***]

5.3. Adaptation of analytical methods due to formulation adaptation

[***]

Time frame:	[***]	
Total cost [***] formulation:		[***]
Total cost [***] formulation:		[***]
Payment schedule:	[***]	[***]

5.4. Update of CMC part for IND filing

[***]

Time frame:	[***]	
Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1. Updated Project Plan

[***]

2. Payment Schedule and Invoicing and Notice Instructions

All invoices for service fees and pass-through expenses incurred after the Amendment Effective Date shall be sent by email to:

[***]

With a copy to:

[***]

All notices to Onclave regarding this [***] Project Plan shall be sent to:

Onclave Therapeutics Limited
Treasury Building
Lower Grand Canal Street
Dublin 2
Ireland
Fax: [***]
Attention: [***]

	Work package	Price	Date of	Status
1	**Cell Line Development**			
	[***]			
2	**Drug Substance Manufacturing**			
	[***]			
3	**Drug Product Manufacturing and DP Stability Studies**			
	[***]			
4	**Additional work packages / supportive data**			
	[***]			
5	**Additional work packages / supportive data**			
	[***]			

3. Commercial Outlook

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

IN WITNESS WHEREOF, the Parties have caused this Amended and Restated Project PlanAppendix 2—Part I to be executed and effective as of June 23, 2010.

ONCLAVE THERAPEUTICS LIMITED

By: /s/ William F. Daniel
William F. Daniel
Title: Director
Date: 11 December 2012

BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG
ppa.

By: /s/ Alois Konrad
Alois Konrad
Title: VP Business and Contracts
Date: 10 December 2012

ppa.

By: /s/ Hans Michelberger
Dr. Hans Michelberger
Title: VP Legal Germany
Date: 10 December 2012

Exhibits: Schedule 1—Notice of Assignment

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Schedule I

THIS NOTICE OF ASSIGNMENT Is dated as of May 17, 2012.

TO: BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG, with offices at Birkendorfer Straße 65, 88397 Biberach an der Riss, Germany ("BI Pharma")

BY: NEOTOPE BIOSCIENCES LIMITED, a private limited company incorporated under the laws of Ireland with offices at Treasury Building, Lower Grand Canal Street, Dublin 2, Ireland ("Neotope").

INTRODUCTION

Neotope and BI Pharma are parties to that certain Project Plan A-1 Agreement titled Appendix 2—Part I of the Master Process Development and Clinical Supply Agreement dated as of June 23, 2010 (such agreement, as amended or modified from time to time, the "Agreement").

Neotope has assigned all of its rights, obligations and liabilities pursuant to or under the Agreement to Onclave Therapeutics Limited, an Irish private limited company and an affiliate of Neotope ("Onclave") formerly known as Elan Science Six Limited ("ESSL") In accordance with that certain Intellectual Property License and Contribution Agreement, dated as of January 1, 2012, between ESSL and Neotope (the "Assignment").

NOTICE OF ASSIGNMENT

Neotope herby notifies BI Pharma of the Assignment. The Assignment became effective as of January 1, 2012 (the "Closing Date").

BI Pharma shall invoice Neotope for all service fees and pass-through expenses incurred up to and including the Closing Date.

All invoices for service fees and pass-through expenses incurred after the Closing Date shall be sent to:

Accounts Payable
Elan Pharmaceuticals, Inc., on behalf of Onclave Therapeutics Limited
P.O. Box 2208
South San Francisco, CA 94083-2208

Or by email to [***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

With a copy to:

Neotope Biosciences, a division of Elan Pharmaceuticals, Inc.
650 Gateway Boulevard
South San Francisco, CA 94080
Attention: Guriq Basi

Or by email to [***]

All future notices regarding the Agreement should be to ONCLAVE as follows:

To ONCLAVE:

Onclave Therapeutics Limited
Treasury Building
Lower Grand Canal Street
Dublin 2
Ireland
Fax: [***]
Attention: [***]

And a copy to:

Neotope Biosciences, a division of Elan Pharmaceuticals, Inc.
650 Gateway Boulevard
South San Francisco, CA 94080
Fax: [***]
Attention: Legal Counsel

Onclave, along with its collaborator, Neotope Biosciences, a division of Elan Pharmaceuticals, Inc., will be working with you going forward. Your current scientific contacts will continue to work with you on behalf of Onclave.

EXECUTED on the date first written above.

NEOTOPE BIOSCIENCES LIMITED

By: /s/ William F. Daniel
Name: William F. Daniel
Title: Director

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Appendix 2B: Project Plan – [***]

AMENDED AND RESTATED [***] PROJECT PLAN

Antibody Description: [***]

[***]

[***]

Pertinent ELAN Party: Neotope Biosciences Limited

Scope – Part I: Section 1 – [***]

Scope – Part II: [***]

Section 2 – Drug Substance Manufacturing

Section 3 – Drug Product Manufacturing

Section 4 – Additional Supportive Work Packages

Cell Line Development BI HEX®

Process Development

Manufacturing of Drug Product

Supply of Clinical Grade Product

Version of October 1, 2012

WHEREAS, Elan Pharma International Limited, Treasury Building, Dublin 2, Ireland, ("EPIL"), Neotope Biosciences Limited, a private limited company incorporated under the laws of Ireland with offices at Monksland, Athlone, County Westmeath, Ireland ("Neotope") and Boehringer

Ingelheim Pharma GmbH & Co. KG, Birkendorfer Str. 65, 88397 Biberach an der Riss, Germany ("BI Pharma") have previously entered into a Master Process Development and Clinical Supply Agreement effective as of June 23, 2010 (the "Agreement");

WHEREAS, BI Pharma, EPIL and Neotope are parties to Agreement.

WHEREAS, BI Pharma and Neotope are parties to the Appendix 2B – Programme A, Project Plan, Antibody Description: [***] effective August 1, 2011 ("[***] Project Plan").

WHEREAS, EPIL, Neotope and BI Pharma have mutually amended the Master Agreement by Amendment No 1, effective as of August 1, 2011 to cover the provision of cell line development services for multiple antibodies, permit separate Project Plans for separate antibody projects and to include a template for future Project Plans.

WHEREAS, all assets relating to the [***] Project Plan, and the Project Plan itself, remain with Neotope and have not been assigned to Onclave Therapeutics Limited.

WHEREAS, Neotope and BI Pharma now mutually desire to amend and restate the [***] Project Plan to replace the content of the [***] Project Plan with the content set forth below.

This Amended and Restated Appendix 2B – [***] Project Plan shall be incorporated into the Agreement, shall itself incorporate the terms of the Agreement, and shall become effective as of May 1, 2012.

NOW, THEREFORE, Neotope and BI Pharma agree as follows:

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Table of Contents

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1. Programme A – [***]

1.1 [***]

[***]

Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

1.2 [***]

[***]

Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

[***]

1.3 [***]

[***]

Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

1.4 [***]

[***]

Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

[***]

1.5 [***]

[***]

Total cost per [***]:	[***]	[***]
Payment schedule:	[***]	[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1.6 [***]

[***]

Time frame:	[***]	
Total cost per [***]:	[***]	[***]
Payment schedule:	[***]	[***]

1.7 [***]

[***]

1.7.1 [***]

[***]

Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

1.8 Adaptation and Phase I Validation of analytical testing [***]

[***]

Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

[***]

1.9 Deliverables Elan Deliverables

[***]

BIP Deliverables

[***]

2. Drug Substance Manufacturing

[***]

2.1 Application and Fixation of platform process at [***] scale

[***]

Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

2.2 Consolidation of a Scaleable Process at [***] Scale

[***]

Cost per run incl. filling:	[***]	[***]
Total cost [***]:	[***]	[***]
Payment schedule:	[***]	[***]

[***]

2.3 Freeze Thaw Study Drug Substance in Bags

[***]

Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

2.4 Filling of Reference Standard for [***]

[***]

Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

2.5 Explorative stability testing of Drug Product (DP) out of [80 L] scale

[***]

Analytical methods for stability testing	DS	DP
[***]		

[***]

Cost per lot:	[***]	[***]
Total cost [***]:	[***]	[***]
Payment schedule:	[***]	[***]
	[***]	[***]
	[***]	[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

2.6 Establishing of a Master Cell Bank (MCB)

[***]

Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

2.7 Production of cGMP Material for Use in Clinical Studies

[***]

2.7.1 Ordering of long lead chromatography material (resins) for downstream process at [***] scale

[***]

Scale:	[***]	[***]
Cost estimate:	[***]	[***]
Payment schedule:	[***]	[***]

[***]

2.7.2 Manufacturing of Material for Supply of Clinical Trials

[***]

2.7.2.1 Manufacturing scale [***]

[***]

Cost per [***]:	[***]	[***]
Total cost [***]:	[***]	[***]
Payment schedule:	[***]	[***]
Payment schedule:	[***]	[***]

[***]

2.8 Analytical Characterization of Pre-Clinical and Clinical Batches

[***]

Analytical methods for release testing	DS	DP
[***]		

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

2.8.1 Stability program of Bulk Drug Substance

[***]

Cost per lot:	[***]	[***]
Total cost [***]:	[***]	[***]
Payment schedule:	[***]	[***]
	[***]	[***]
	[***]	[***]
	[***]	[***]

[***]

2.8.2 Virus removal validation

[***]

Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

2.8.3 Optional Work Package: DNA removal validation

[***]

Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

2.9 Establishing CMC part for IND filing

[***]

Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

2.10 Deliverables

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

3. Drug Product Manufacturing and DP Stability Studies

[***]

3.1 Full Formulation Development [***] Program

[***]

Price:	[***]

3.2 Finalisation of [***] Process

[***]

Time frame [***]:	[***]
Price:	[***]

3.3 Manufacturing of [***] into vials under GMP conditions at technical scale

[***]

Time frame:	[***]	
Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

[***]

3.4 Stability testing of Drug Product (Material out of [***] scale)

[***]

Cost per lot:	[***]	[***]
Total cost [***]:	[***]	[***]
Payment schedule:	[***]	[***]
	[***]	[***]
	[***]	[***]
	[***]	[***]

[***]

3.5 Filling and Qualification of Reference Standard ([***])

[***]

Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

3.6 Comparability Testing including Characterization Studies

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

[***]

[***]

Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

3.7 Deliverables

[***]

4. Additional supportive work packages

[***]

5. Price Overview and billing plan

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

IN WITNESS WHEREOF, the Parties have caused this Amended and Restated Appendix 2B

- Programme A to the Master Agreement to be executed and effective as of May 1, 2012.

NEOTOPE BIOSCIENCES LIMITED

By: /s/ William F. Daniel

Name: William F. Daniel
Title: Director

Date: 11 December 2012

BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG

ppa.

By: /s/ Alois Konrad
Name:Alois Konrad
Title: VP Business & Contracts

ppa.

By: /s/ Hans Michelberger
Name: Dr. Hans Michelberger
Title: VP Legal Germany

Date: 10 Dec. 2012

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Appendix 2B-2: [***] Project Plan — [***]

[***]

Neotope Biosciences Limited ("Neotope"), **Elan Pharma International Limited** ("EPIL") and **Boehringer Ingelheim Pharma GmbH & Co. KG** ("BI Pharma") entered into a Master Process Development and Clinical Supply Agreement effective June 23, 2010 (the "Original MSA").

WHEREAS, EPIL, Neotope and BI Pharma have mutually amended the Master Agreement by Amendment No 1, effective as of August 1, 2011 to cover the provision of cell line development services for multiple antibodies, permit separate Project Plans for separate antibody projects and to include a template for future Project Plans; and

WHEREAS, EPIL's rights and obligations under the Neotope MSA have been assigned to Neotope in connection with the demerger from Elan Corporation plc effective December 20, 2012 and as confirmed by EPIL in the letter dated May 22, 2013, which is attached hereto (the "Assignment").

WHEREAS, in light of the Assignment, Neotope and BI Pharma are, from the date of the Assignment, the only parties to the Original MSA, which shall, therefore, in the future be referred to as the "Neotope MSA"; and

NOW, THEREFORE, Neotope and BI Pharma agree as follows:

This Appendix 2B-2 — [***] Project Plan — [***] shall be incorporated into the Neotope MSA, shall itself incorporate the terms of the Neotope MSA, and shall be effective retroactively as of January 1, 2013.

I. [***] PROJECT PLAN: [***]

Prerequisites:

- [***]

Activity:

- [***]

Time frame:	[***]
Price Services:	[***]
Price equipment:	[***]
Total Price:	[***]
Date of invoice	[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

II. ANTIBODY DESCRIPTION: [***]

Scope – [***]

Time frame:	[***]
Price:	[***]

For the avoidance of doubt, no GMP product will be delivered before the parties will have concluded a Quality Agreement.

24, June 2013	Biberach, 14 June 2013	
NEOTOPE BIOSCIENCES LIMITED	**BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG**	
	i.v.	ppa.
/s/ Tara Nickerson	/s/ Dieter Wolf	/s/ Hans Michelberger
Tara Nickerson, Secretary	D. Wolf	Dr. Hans Michelberger

Attachment: Assignment

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Attachment

Dr. Uwe Buecheler
Boehringer Ingelheim Pharma GbH & Co. KG
Birkendorfer Strasse 65
88397 Biberach an der Riss
Germany

22 May 2013

Via Fax: +49 7351-54-98049

Re: Master Process Development and Clinical Supply Agreement by and among Elan Pharma International Limited ("EPIL") , Neotope Biosciences Limited ("Neotope") and Boehringer Ingelheim Pharma GmbH & Co. KG effective June 23, 2010 (the "Agreement")

Dear Dr. Buecheler,

EPIL hereby confirms that EPIL's rights and obligations under the Agreement have been assigned to Neotope in connection with the demerger from Elan Corporation plc., effective December 20, 2012.

Yours sincerely,

William Daniel
Director

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Appendix 2C: Project Plan – [***]

Antibody Description: [***]

(up to [***] candidates)

Scope – [***]

Scope – [***]

Section 3 – Drug Substance Manufacturing
Section 4 – Drug Product Manufacturing and DP Stability Studies

Neotope Biosciences Limited ("Neotope"), Elan Pharma International Limited ("EPIL") and Boehringer Ingelheim Pharma GmbH & Co. KG ("BI Pharma") entered into a Master Process Development and Clinical Supply Agreement effective June 23, 2010 (the "Original MSA").

WHEREAS, EPIL, Neotope and BI Pharma have mutually amended the Master Agreement by Amendment No 1, effective as of August 1, 2011 to cover the provision of cell line development services for multiple antibodies, permit separate Project Plans for separate antibody projects and to include a template for future Project Plans; and

WHEREAS, EPIL's rights and obligations under the Neotope MSA have been assigned to Neotope in connection with the demerger from Elan Corporation plc effective December 20, 2012 and as confirmed by EPIL in the letter dated May 22, 2013, which is attached hereto (the "Assignment").

WHEREAS, in light of the Assignment Neotope and BI Pharma are, from the date of the Assignment, the only parties to the Original MSA, which shall, therefore, in the future be referred to as the "Neotope MSA"; and

NOW, THEREFORE, Neotope and BI Pharma agree as follows:

This Appendix 2C – [***] Project Plan shall be incorporated into the Neotope MSA, shall itself incorporate the terms of the Neotope MSA, and shall be effective as of October 1, 2012.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

PROPOSAL#!
BY BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG
BIRKENDORFER STR 65
88397 BIBERACH AN DER RIß
(BIP)

FOR

NOETOPE

[***]

EARLY SUPPORT ON CANDIDATE ASSESSMENT

CELL LINE DEVELOPMENT

PROCESS DEVELOPMENT

MANUFACTURING OF
CLINICAL GRADE MATERIAL

Version of April 15, 2013

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Table of Contents

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1. Early Support on Candidate Assessment

[***]

Time frame:	[***]	
Total costs 1 candidate:	[***]	[***]
Costs for each additional candidate handled in parallel (up to [10] candidates in total):	[***]	[***]
Payment schedule:	[***]	[***]

[***]

Time frame:	[***]	
Total costs 1 candidate:	[***]	[***]
Costs for each additional candidate handled in parallel (up to [***] candidates in total):	[***]	[***]
Payment schedule:	[***]	[***]

Additional comments:

[***]

2. Cell Line Development

2.1. [***]

[***]

Time frame:	[***]	
Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

2.2. [***]

[***]

Time frame:	[***]	
Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

2.3. [***]

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Time frame:	[***]	
Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

2.4. [***]

[***]

Time frame:	[***]	
Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

[***]

2.5. [***]

[***]

Time frame:	[***]	
Total cost per [***]:	[***]	[***]
Payment schedule:	[***]	[***]

2.6. [***]

[***]

Time frame:	[***]	
Total cost per [***]:	[***]	[***]
Payment schedule:	[***]	[***]

2.7. [***]

[***]

2.7.1. [***]

- [***]

Time frame:	[***]	
Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

2.8. Adaptation and Phase I Validation of Analytical Testing [***]

[***]

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Time frame:	[***]	
Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

[***]

2.9. Deliverables

Neotope Deliverables

[***]

BIP Deliverables

[***]

3. Drug Substance Manufacturing

[***]

3.1. Application and Fixation of Platform Process at [***] Scale

- [***]

Time frame:	[***]	
Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

3.2. Consolidation of a Scaleable Process at [***] Scale

- [***]

Time frame:	[***]	
Cost per run incl. filling:	[***]	[***]
Total cost [***]:	[***]	[***]
Payment schedule:	[***]	[***]

[***]

3.3. Freeze Thaw Study Drug Substance in Bags

- [***]

Time frame:	[***]	
Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

3.4. Filling of Reference Standard for [***]

Filling assumptions:

- [***]

Time frame:	[***]	
Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

3.5. Explorative Stability Testing of Drug Product (DP) out of [***] Scale

[***]

Analytical methods for stability testing	DS	DP
[***]		

[***]

Time frame:	[***]	
Cost per lot:	[***]	[***]
Total cost [***]:	[***]	[***]
Payment schedule:	[***]	[***]
	[***]	[***]
	[***]	[***]
	[***]	[***]

[***]

3.6. Establishing of a Master Cell Bank (MCB)

- [***]

Time frame:	[***]	
Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

3.7. Production of cGMP Material for Use in Clinical Studies

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

3.7.1. Orderingof long lead Chromatography Material (resins) for downstream Process at [***] or [***] Scale

[***]

Time frame:	[***]		
Scale:	[***]	[***]	[***]
Cost estimate:	[***]	[***]	[***]
Payment schedule:	[***]	[***]	[***]

3.7.2. Manufacturingof Material for Supply of Clinical Trials

[***]

3.7.2.1. Manufacturing Scale [***]

Production assumptions:

[***]

Time frame:	[***]	
Cost per [***] run:	[***]	[***]
[***]:		
Payment schedule:	[***]	[***]

3.8. AnalyticalCharacterization of Pre-Clinical and Clinical Batches

[***]

Analytical methods for release testing	DS	DP
[***]		

3.8.1. StabilityProgram of Bulk Drug Substance

[***]

Time frame:	[***]	
Cost per lot:	[***]	[***]
Total cost [***]:	[***]	[***]
Payment schedule:	[***]	[***]
	[***]	[***]
	[***]	[***]
	[***]	[***]

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

3.8.2. Virus Removal Validation

[***]

Time frame:	[***]	
Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

3.8.3. Optional Work Package: DNA Removal Validation

[***]

Time frame:	[***]	
Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

3.9. Establishing CMC Part for IND Filing

[***]

Time frame:	[***]	
Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

3.10. Deliverables

[***]

4. Drug Product Manufacturing and DP Stability Studies

[***]

4.1. Full Formulation Development [***] Program

[***]

Time frame:	[***]	
Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

4.2. Finalisation of [***] Process

[***]

Time frame:	[***]	
Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

4.3. Manufacturing of [***] under GMP Conditions at Technical Scale

[***]

Filling assumptions:

- [***]

Time frame:	[***]	
Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

[***]

4.4. Stability Testing of Drug Product (Material out of [***] or [***] Scale)

[***]

Time frame:	[***]	
Cost per lot:	[***]	[***]
Total cost [***]:	[***]	[***]
Payment schedule:	[***]	[***]
	[***]	[***]
	[***]	[***]
	[***]	[***]

[***]

4.5. Filling and Qualification of Reference Standard [***]

[***]

Filling assumptions:

- [***]

Time frame:	[***]	
Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

4.6. Comparability Testing including Characterization Studies

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Analytical methods for comparability testing

[***]

[***]

Time frame:	[***]	
Total cost:	[***]	[***]
Payment schedule:	[***]	[***]

4.7. Deliverables

[***]

5. Price Overview

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

IN WITNESS WHEREOF, the Parties have caused this Appendix 2C – [***] Project Plan to be executed and effective as of October 1, 2012.

For the avoidance of doubt, no GMP product will be delivered before the parties will have concluded a Quality Agreement.

South San Francisco, 26 June 2013	Biberach, 14 June 2013
NEOTOPE BIOSCIENCES LIMITED	**BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG**
	ppa. ppa.
/s/ Jane Hickson, Secretary	/s/ Dieter. Wolf /s/ Hans Michelberger
	D. Wolf Dr. Hans Michelberger

Attachment: Assignment

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Attachment

Assignment

[PDF ATTACHMENT]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Dr. Uwe Buecheler
Boehringer Ingelheim Pharma GbH & Co. KG
Birkendorfer Strasse 65
88397 Biberach an der Riss
Germany

22 May 2013

Via Fax: +49 7351-54-98049

Re: **Master Process Development and Clinical Supply Agreement by and among Elan Pharma International Limited ("EPIL"), Neotope Biosciences Limited ("Neotope") and Boehringer Ingelheim Pharma GmbH & Co. KG effective June 23, 2010 (the "Agreement")**

Dear Dr. Buecheler,

EPIL hereby confirms that EPIL's rights and obligations under the Agreement have been assigned to Neotope in connection with the demerger from Elan Corporation plc., effective December 20, 2012.

Yours sincerely,

/s/ William Daniel
William Daniel
Director

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

AMENDMENT NUMBER ONE
(the "Amendment No 1")

to the

MASTER PROCESS DEVELOPMENT AND CLINICAL SUPPLY AGREEMENT

This Amendment No 1 is made as of August 1, 2011 (the "Amendment No 1 Effective Date") by and between **Neotope Biosciences Limited**, a private limited company incorporated under the laws of Ireland with offices at Monksland, Athlone, County Westmeath, Ireland ("Neotope"), **ELAN Pharma International Limited**, a private limited company incorporated under the laws of Ireland with offices at Monksland, Athlone, County Westmeath, Ireland ("EPIL"), (Neotope and EPIL hereinafter collectively called "ELAN") and **Boehringer Ingelheim Pharma GmbH & Co. KG** with offices at Birkendorfer Straße 65, 88397 Biberach an der Riß, Germany ("BI Pharma").

RECITALS

A. WHEREAS, ELAN and BI Pharma have previously entered into a Master Process Development and Clinical Supply Agreement effective as of June 23, 2010 (the "Agreement");

B. WHEREAS, ELAN and BI Pharma mutually desire to amend the Agreement as set forth below to provide cell line development services for multiple Antibodies, only some of which may be selected for further process development and clinical supply;

NOW THEREFORE, ELAN and BI Pharma agree as follows, effective as of the Amendment No 1 Effective Date:

TERMS AND CONDITIONS

1. Section 1.31 of the Agreement shall be amended to read as follows:

   "Project" shall mean the activities set forth in the respective Project Plan for a particular phase or phases of development or production of the specific Product, the scope of which Project may be limited to one or more of the cell line development program, the process development program, the product manufacturing program and the clinical supply program. **"Project(s)"** shall mean each and every Project to be conducted under this Agreement."

2. The first two sentences of Section 2.1.2 of the Agreement shall be amended to read as follows:

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

"Each project plan ("Project Plan") shall be substantially of the form attached herein as Appendix 2 commensurate with the scope of the Project, uniquely coded and shall describe the subject Project, the responsibilities of the Parties with respect to such Project, the Materials and any ELAN Contribution to be transferred to BI Pharma, the Deliverables and the timeline for completion of the Project ("Project Timeline"). Each Project Plan shall be mutually agreed upon by the Parties, shall reference this Agreement by date, title and Parties; and shall become incorporated herein upon execution by both Parties."

The following last sentence shall be added to Section 2.1.2 of the Agreement:

"For the avoidance of doubt, each Project Plan will be numbered by consecutive numbers (i.e. "Appendix 2A", "Appendix 2B", etc.).

3. Each Appendix 2 of the Agreement shall be amended to include a cover page substantially of the form attached hereto as Exhibit A and a signature page substantially of the form attached hereto as Exhibit B.

4. The existing Appendix 2 of the Agreement currently entitled "Appendix 2 — Part I Project Plan Antibody Description: [***]" shall be amended to be entitled "Appendix 2A: Project Plan — [***]".

5. Except as modified herein, the Agreement remains in full force and effect and is hereby incorporated by this reference. Capitalized terms not otherwise defined herein shall have the meanings contained in the Agreement.

Accepted and Agreed:

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

NEOTOPE BIOSCIENCES LIMITED

By: /s/ William Daniel
Name: William Daniel
Title: Director

Date: 15th September 2011

BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG

By: /s/ Dieter Wolf
Name: Dr. Dieter Wolf
Title: Global Dept. Business & Contracts

ELAN PHARMA INTERNATIONAL LIMITED

By: /s/ William Daniel
Name: William Daniel
Title: Director
Date: 15th September 2011

By: /s/ Andreas Felder
Name: Dr. Andreas Felder
Title: Head of Legal Germany/Team Biberach
Date: September 14, 2011

Exhibits:

Exhibit A: Cover Page
Exhibit B: Signature Page

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT A

Appendix 2 Cover Page

Appendix 2 — [*insert unique code*]

PROJECT PLAN

Antibody Description: _____

Pertinent ELAN Party: _____

Scope: [e.g., [***]]_____

[Pertinent ELAN Party] and Boehringer Ingelheim Pharma GmbH & Co. KG ("BI Pharma") entered into a Master Process Development and Clinical Supply Agreement effective June 23, 2010 and amended August 1, 2011 (the "Master Agreement"). This Appendix 2-[Unique Code] shall be incorporated into the Master Agreement and become effective as of [Pertinent Project Plan Effective Date].

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT B

Appendix 2 Signature Page

IN WITNESS WHEREOF, the Parties have caused this Appendix 2 —[Unique Code] to the Master Agreement to be executed and effective as of [Pertinent Project Plan Effective Date].

[pertinent ELAN entity]	**BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG**
By: _____	By: _____
Name:	Name:
Title:	Title:
Date: _____	Date: _____
	By: _____
	Name:
	Title:
	Date: _____

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Dale B. Schenk, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Prothena Corporation plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a–15(e) and 15d–15(e)) 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) 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

(c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

August 12, 2013

/s/ Dale B. Schenk
Dale B. Schenk
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Tran B. Nguyen, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Prothena Corporation plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a–15(e) and 15d–15(e)) 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) 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

(c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

August 12, 2013

/s/ Tran B. Nguyen
Tran B. Nguyen
Chief Financial Officer
(Principal Accounting and Financial Officer)

Exhibit 32.1

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

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Dale B. Schenk, President and Chief Executive Officer of Prothena Corporation plc (the "Company") and Tran B. Nguyen, Chief Financial Officer of the Company, each hereby certify that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2013, to which this Certification is attached as Exhibit 32.1 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

August 12, 2013

/s/ Dale B. Schenk
Dale B. Schenk
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Tran B. Nguyen
Tran B. Nguyen
Chief Financial Officer
(Principal Accounting and Financial Officer)

A signed original of this written statement required by Rule 13a-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350 has been provided to the Registrant and will be retained by the Registrant and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933 or the Securities Exchange Act of 1934 (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.