Prothena Corp plc
Form 10-Q
May 15, 2013
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 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 x 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 x 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 x

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

The number of ordinary shares outstanding as of April 30, 2013 was 17,679,182.

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PROTHENA CORPORATION plc

Form 10Q QUARTERLY REPORT

For the Quarter Ended March 31, 2013

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS (unaudited)

Prothena Corporation plc

Condensed Consolidated Balance Sheets

(in thousands, except par value)

	March 31, 2013 (unaudited)	December 31, 2012 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 119,563	$ 124,860
Receivable from related party	261	223
Deferred tax assets	73	73
Prepaid expenses and other current assets	894	685
Total current assets	120,791	125,841
Non-current assets:		
Property and equipment, net	3,371	3,393
Intangible assets, net	44	49
Deferred tax assets	62	
Total non-current assets	3,477	3,442
Total assets	$ 124,268	$ 129,283
Liabilities and Shareholders Equity		
Current liabilities:		
Accrued research and development	$ 2,596	$ 47
Income taxes payable	72	27
Other current liabilities	2,418	1,670
Total current liabilities	5,086	1,744
Non-current liabilities:		
Deferred rent	1,393	1,055
Total liabilities	6,479	2,799
Shareholders equity:		
Euro deferred shares, 22 nominal value:		
Authorized shares 10,000 at March 31, 2013 and December 31, 2012		
Issued and outstanding shares none at March 31, 2013 and December 31, 2012		
Ordinary shares, $0.01 par value:	177	177
Authorized shares 100,000 at March 31, 2013 and December 31, 2012		
Issued and outstanding shares 17,679 at March 31, 2013 and December 31, 2012		
Additional paid-in capital	126,908	126,652
Accumulated deficit	(9,296)	(345)
Total shareholders equity	117,789	126,484

Total liabilities and shareholders equity	$ 124,268	$ 129,283

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

See accompanying notes to Condensed Consolidated Financial Statements.

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Prothena Corporation plc

Condensed Consolidated Statements of Operations

(in thousands, except per share data)

(unaudited)

	Three Months Ended March 31,	
	2013	2012
Revenues - related party	$ 171	$ 404
Operating expenses:		
Research and development	5,957	8,757
General and administrative	3,181	2,458
Total operating expenses	9,138	11,215
Loss from operations	(8,967)	(10,811)
Interest income, net	22	
Loss before income taxes	(8,945)	(10,811)
Income taxes	6	
Net loss	$ (8,951)	$ (10,811)
Basic and diluted net loss per share	$ (0.51)	$ (0.75)
Shares used to compute basic and diluted net loss per share	17,679	14,497

See accompanying notes to Condensed Consolidated Financial Statements.

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Prothena Corporation plc

Condensed Consolidated Statements of Cash Flows

(in thousands)

(unaudited)

	Three Months Ended March 31,	
	2013	**2012**
Operating activities		
Net loss	$ (8,951)	$ (10,811)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	137	113
Share-based compensation	340	3,570
Changes in operating assets and liabilities:		
Receivable from related party	(38)	
Other assets	(271)	(32)
Accounts payable, accruals and other liabilities	3,680	(1,464)
Net cash used in operating activities	(5,103)	(8,624)
Investing activities		
Purchases of property and equipment	(110)	(137)
Net cash used in investing activities	(110)	(137)
Financing activities		
Proceeds from funding provided by Elan		8,761
Post separation adjustments to the funding provided by Elan	(84)	
Net (used in) cash provided by financing activities	(84)	8,761
Net decrease in cash and cash equivalents	(5,297)	
Cash and cash equivalents, beginning of the year	124,860	
Cash and cash equivalents, end of the period	$ 119,563	$
Supplemental cash flow information		
Cash paid for income taxes	$ 23	$

See accompanying notes to Condensed Consolidated Financial Statements.

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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 March 31, 2013, the Company had an accumulated deficit of $9.3 million and cash and cash equivalents of $119.6 million. Based on the Company s current business plans, management believes that the Company s cash and cash equivalents at March 31, 2013 will be sufficient to meet the Company s obligations for at least the next twelve months based on management s current business plans. 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 may 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 March 31, 2013, as compared to the significant accounting policies described in Note 2 of the Notes to Consolidated Financial Statements in its 2012 Form 10-K.

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 Securities and Exchange Commission (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 Annual Report on Form 10-K, which was filed with the SEC on March 29, 2013 (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,

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including equity award and pension services, and cash and treasury management. Centralized support costs allocated to the Prothena Business for the three months ended March 31, 2012 was $2.0 million. These costs have been allocated to the Prothena Business for the purposes of preparing the Consolidated Financial Statements based on estimated usage of the resources by the Prothena Business. The estimated usage of the central support resources allocated to the Prothena Business has been determined by estimating its 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. 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.

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 full year 2013 or any future period.

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 three months ended March 31, 2013, as compared to the recent accounting pronouncements described in the Company s Annual Report on Form 10-K for the year ended December 31, 2012, that are of significance or potential significance to the Company.

3. Fair Value Measurements

Fair value is the amount at which a financial instrument could be exchanged in an arms-length transaction between informed and willing parties, other than in a forced or liquidation sale. The fair value of financial assets and liabilities is measured under a framework that establishes levels which are defined as follows: Level 1 fair value is determined from observable, quoted prices in active markets for identical assets or liabilities. Level 2 fair value is determined from quoted prices for similar items in active markets or quoted prices for identical or similar items in markets that are not active. Level 3 fair value is determined using the entity s own assumptions about the inputs that market participants would use in pricing an asset or liability.

The Company s Level 2 securities, valued using third-party pricing services, consist of $101.3 million and $103.5 million in money market funds included in cash and cash equivalents at March 31, 2013 and December 31, 2012, respectively. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, issuer credit spreads, benchmark securities, prepayment/default projections based on historical data and other observable inputs. The Company validates the prices provided by its third-party pricing services by understanding the models used, obtaining market values from other pricing services,

analyzing pricing data in certain instances and confirming those securities traded in active markets.

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The following financial assets and liabilities are not measured at fair value on the Company s Condensed Consolidated Balance Sheet at March 31, 2013, but require disclosure of their fair values: the portion of cash and cash equivalents not represented by money market funds. The estimated fair value of the Company s accounts receivable, accounts payable and accrued expenses at March 31, 2013 approximates their carrying value as reported on the Condensed Consolidated Balance Sheet. The fair values of such financial assets and liabilities are determined using the income approach based on the present value of estimated future cash flows. The fair value of all of these assets and liabilities would be categorized as Level 2 of the fair value hierarchy.

There were no significant transfers in and out of Level 1 and Level 2 fair value measurements during the three months ended March 31, 2013.

There were no other-than-temporary impairments during the three months ended March 31, 2013 and 2012.

4. Composition of Certain Balance Sheet Items

Property and Equipment

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

	March 31, 2013	December 31, 2012
Machinery and equipment	$ 5,697	$ 5,449
Leasehold improvements	1,513	1,651
	7,210	7,100
Less: accumulated depreciation and amortization	(3,839)	(3,707)
	$ 3,371	$ 3,393

Depreciation expense was $0.1 million for each of the three months ended March 31, 2013 and 2012.

Intangible Assets

Intangible assets consisted of the following at (in thousands):

	March 31, 2013	December 31, 2012
Purchased computer software	$ 85	$ 85
Less: accumulated amortization	(41)	(36)
	$ 44	$ 49

Intangible assets are amortized on a straight line basis over their expected life, which is estimated to be four years. Amortization expense was $5,000 for each of the three months ended March 31, 2013 and 2012. The estimated amortization expense for 2013 (remaining), 2014 and 2015 is $16,000, $21,000 and $7,000, respectively.

Other Current Liabilities

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

	March 31, 2013	December 31, 2012
Professional services	$ 1,221	$ 27
Payroll and related taxes	822	1,592
Other	375	51
	$ 2,418	$ 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. 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

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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 March 31,	
	2013	2012
Numerator:		
Net loss	$ (8,951)	$ (10,811)
Denominator:		
Weighted-average ordinary shares outstanding	17,679	14,497
Basic and diluted net loss per share	$ (0.51)	$ (0.75)

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

	March 31,	
	2013	2012
Options to purchase ordinary shares	1,366	1,175
Restricted stock units		326
	1,366	1,501

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, 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 months ended March 31, 2013, the Company granted 1,366,000 stock options to its employees under the Company s LTIP. At March 31, 2013, 1,284,000 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 historical experience and estimated future turnover.

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The fair value of the options granted during the three months ended March 31, 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:

Variables	Assumptions
Expected volatility	84.0%
Risk-free interest rate	1.0%
Expected dividend yield	0.0%
Expected life (in years)	6.0
Weighted average fair value	$ 4.32

The following table summarizes share-based compensation expense recognized for stock options during the three months ended March 31, 2013 (in thousands):

	Expense
Research and development	$ 79
Selling, general and administrative	261
	$ 340

Share-based compensation expense will continue to have a significant 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 March 31, 2013 is $4.8 million. The weighted-average period over which the unearned share-based compensation is expected to be recognized is 3.2 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 (in thousands):

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at the beginning of the year		$		
Granted	1,366	6.29		
Outstanding at the end of the period	1,366	6.29	9.83	$ 543
Vested and expected to vest at the end of the period	1,204	6.29	9.84	476
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 months ended March 31, 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.

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The following table summarizes share-based compensation expense recognized during the three months ended March 31, 2012 (in thousands):

		Expense
Research and development expenses	direct	$ 3,568
General and administrative expenses	direct	2
Total direct expense		3,570
General and administrative expenses	allocated	476
		$ 4,046

Share-based Compensation Expense

Share-based compensation expense is 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 is 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 is 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 is 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, is affected by Elan s share price as well as assumptions regarding a number of complex variables. These variables include, but are 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 months ended March 31, 2012 (in thousands):

	Expense
RSUs	$ 1,995
Stock options	1,568
EEPP	7
Total direct	3,570
Total allocated	476
	$ 4,046

The fair value of stock options is calculated using a binomial option-pricing model and the fair value of options issued under the EEPP is calculated using the Black-Scholes option-pricing model, taking into account the relevant terms and conditions. The binomial option-pricing model is 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 integrates possible variations in model inputs, such as risk-free interest rates and other inputs, which may change over the life of the options. Options issued under the EEPP have relatively short contractual lives, or must be exercised within a short period of time after the vesting date, and the input factors identified above do not apply. Therefore, the Black-Scholes option-pricing model produces a fair value that is substantially the same as a more complex binomial option-pricing model for the EEPP.

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 is based upon 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 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.

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The fair value of options granted during the three months ended March 31, 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.

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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;

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;

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;

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;

the failure to comply with anti-kickback and false claims laws in the United States;

extensive government regulation;

the volatility of our share price;

general changes in U.S. generally accepted accounting principles and International Financial Reporting Standards as adopted by the European Union;

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.

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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 Annual Report on Form 10-K for the year ended December 31, 2012.

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 financial statements 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 financial statements are based on assumptions that we believe are reasonable. However, the 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 Consolidated Financial Statements included in Item 8 of our Annual Report on Form 10-K for the year ended December 31, 2012.

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 ADSs, 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 months ended March 31, 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 months ended March 31, 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 estimated usage of the resources by us. The estimated usage of the centralized support resources allocated to us was determined by estimating our portion of the most appropriate driver of 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.

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Critical Accounting Policies and Estimates

Management s discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with GAAP. The preparation of these 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. Set forth below are certain changes to our accounting policies that are critical to the judgments and estimates used in the preparation of our financial statements during three months ended March 31, 2013, as compared to the accounting policies that are critical to the judgments and estimates used in the preparation of our financial statements described in Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operations, in our 2012 Form 10-K.

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 months ended March 31, 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 US 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 months ended March 31, 2012 were $2.0 million. These costs have been allocated to us for the purposes of preparing the Condensed Consolidated Financial Statements based on estimated usage of the resources by us. The estimated usage of the central support resources allocated to us has been 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 three months ended March 31, 2013, as compared to the recent accounting pronouncements described in our Annual Report on Form 10-K for the year ended December 31, 2012, that are of significance or potential significance to us.

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Results of Operations

Results for the three months ended March 31, 2013 and 2012

	Three Months Ended March 31,		Increase (Decrease)	
	2013	2012	$	%
	(in thousands, except percents)			
Revenues - related party	$ 171	$ 404	$ (233)	(58)%
Operating expenses:				
Research and development	5,957	8,757	(2,800)	(32)
General and administrative	3,181	2,458	723	29
Total operating expenses	9,138	11,215	(2,077)	(19)
Loss from operations	(8,967)	(10,811)	(1,844)	(17)
Interest income, net	22		22	
Loss before income taxes	(8,945)	(10,811)	(1,866)	(17)
Income taxes	6		6	
Net loss	$ (8,951)	$ (10,811)	(1,860)	(17)

Revenue

Revenue for the three months ended March 31, 2013 and 2012 was comprised of fees earned from the provision of R&D services to Elan.

Total revenues decreased $0.2 million, or 58%, in the three months ended March 31, 2013 compared to the three months ended March 31, 2012, primarily as a result of 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. For the three months ended March 31, 2013 and 2012, total operating expenses were $9.1 million and $11.2 million, 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 months ended March 31, 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 months ended March 31, 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 Annual Report on Form 10-K for the year ended December 31, 2012.

Research and Development Expenses

R&D expenses decreased by $2.8 million, or 32%, in the three months ended March 31, 2013 compared to the three months ended March 31, 2012. The decrease 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

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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 months ended March 31, 2013 and 2012, and the cumulative amounts to date (in thousands):

	Three Months Ended March 31,		Cummulative to Date
	2013	2012	
NEOD001 (1)	$ 788	$ 1,953	$ 24,227
Other R&D (2)	5,169	6,804	
	$ 5,957	$ 8,757	

(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

G&A expenses increased by $0.7 million, or 29% in the three months ended March 31, 2013 compared to the three months ended March 31, 2012. For the three months ended March 31, 2013, G&A expenses consisted primarily of professional services fees (including payments to Elan under the Transitional Services Agreement), internal personnel costs and $0.3 million in share-based compensation expense. For the three months ended March 31, 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 this period consisted of $0.5 million of direct expense incurred by the Prothena Business and $2.0 million of indirect expenses which was based on an allocation to the Prothena Business by Elan. Generally, we anticipate that our G&A expenses will change in concert with changes in our R&D activities.

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 months ended March 31, 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 the three months ended March 31, 2013 and 2012 was $6,000 and nil, respectively. 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 March 31, 2013, we had $119.6 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

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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 may 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 Three Months Ended March 31, 2013 and 2012

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

	Three Months Ended March 31,	
	2013	**2012**
Net cash used in operating activities	$ (5,103)	$ (8,624)
Net cash used in investing activities	(110)	(137)
Net cash (used in) provided by financing activities	(84)	8,761
Net decrease in cash and cash equivalents	$ (5,297)	$

Cash Used in Operating Activities

Net cash used in operating activities was $5.1 million and $8.6 million during the three months ended March 31, 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 a decrease in R&D expense, partially offset by an increase in G&A expense.

Cash Used in Investing Activities

Net cash used in investing activities was $0.1 million during the three months ended March 31, 2013 and 2012, consisting 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 three months ended March 31, 2013, consisted of the final settlement of liabilities as a result of our separation from Elan. Net cash provided by financing activities was $8.8 million during the three months ended March 31, 2012, reflecting funding provided by Elan.

Off-Balance Sheet Arrangements

At March 31, 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.

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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.

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 March 31, 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 March 31, 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 quarter ended March 31, 2013 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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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 Annual Report on Form 10-K for the year ended December 31, 2012 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 Annual Report on Form 10-K. You should consider carefully the risk factors discussed in our Annual Report on Form 10-K and in this quarterly report on Form 10-Q, 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 Annual Report on Form 10-K 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. Except with respect to our trademarks, the trademarks, trade names and service marks appearing in this report are the property of their respective owners.

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, 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 $9.0 million for the three months ended March 31, 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 March 31, 2013, we had cash and cash equivalents of $119.6 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.

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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.

Risks Related to the Discovery, Development and Regulatory Approval of Drug Candidates

Our success is largely dependent on the success of our research and development programs, which are at an early stage. Our drug candidates are still in early stages of development and we have only one drug candidate in clinical trials. We may not be able to successfully discover, develop, obtain regulatory approval for or commercialize any drug candidates.

The success of our business depends substantially upon our ability to discover, develop, obtain regulatory approval for and commercialize our drug candidates successfully. Our research and development programs are prone to the significant and likely risks of failure inherent in drug development. We intend to continue to invest most of our time and financial resources in our research and development programs. Although we have initiated one Phase 1 clinical trial for NEOD001, there is no assurance that this clinical trial will support further development of this drug candidate. In addition, we currently do not, and may never, have any other drug candidates in clinical trials, and we have not identified drug candidates for many of our research programs.

Before obtaining regulatory approvals for the commercial sale of any drug candidate for a target indication, we must demonstrate with substantial evidence gathered in well-controlled clinical trials, and, with respect to approval in the United States, to the satisfaction of the United

States Food and Drug Administration, or FDA, or, with respect to approval in other countries, similar regulatory authorities in those countries, that the drug candidate is safe and effective for use for that target indication. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain, and subject to unanticipated delays. Despite our efforts, our drug candidates may not:

offer improvement over existing, comparable drugs;

be proven safe and effective in clinical trials; or

meet applicable regulatory standards.

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Positive results in preclinical studies of a drug candidate may not be predictive of similar results in humans during clinical trials, and promising results from early clinical trials of a drug candidate may not be replicated in later clinical trials. Interim results of a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in early-stage development. Accordingly, the results from completed preclinical studies and clinical trials for our drug candidates may not be predictive of the results we may obtain in later stage trials or studies. Our preclinical studies or clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials, or to discontinue clinical trials altogether.

Furthermore, we have not marketed, distributed or sold any drugs. Our success will, in addition to the factors discussed above, depend on the successful commercialization of drug candidates, which may require:

- obtaining and maintaining commercial manufacturing arrangements with third-party manufacturers;
- collaborating with pharmaceutical companies or contract sales organizations to market and sell any approved drug; or
- acceptance of any approved drug in the medical community and by patients and third-party payors.

Many of these factors are beyond our control. We do not expect any of our drug candidates to be commercially available for at least seven years and some or all may never become commercially available. Accordingly, we may never generate revenues through the sale of products.

If clinical trials for our drug candidates are prolonged, delayed, suspended or terminated, we may be unable to commercialize our drug candidates on a timely basis, which would require us to incur additional costs and delay our receipt of any revenue from potential product sales.

We cannot predict whether we will encounter problems with our Phase 1 clinical trial for NEOD001 or any future clinical trials that will cause us or any regulatory authority to delay or suspend those clinical trials or delay the analysis of data derived from them. A number of events, including any of the following, could delay the completion of our planned clinical trials and negatively impact our ability to obtain regulatory approval for, and to market and sell, a particular drug candidate:

- conditions imposed on us by the FDA or any foreign regulatory authority regarding the scope or design of our clinical trials;
- delays in obtaining, or our inability to obtain, required approvals from institutional review boards, or IRBs, or other reviewing entities at clinical sites selected for participation in our clinical trials;
- insufficient supply or deficient quality of our drug candidates or other materials necessary to conduct our clinical trials;
- delays in obtaining regulatory agency agreement for the conduct of our clinical trials;
- lower than anticipated enrollment and retention rate of subjects in clinical trials for a variety of reasons, including size of patient population, nature of trial protocol, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications;
- serious and unexpected drug-related side effects experienced by patients in clinical trials; or

failure of our third-party contractors to meet their contractual obligations to us in a timely manner.

Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated by us, the FDA, the IRBs at the sites where the IRBs are overseeing a trial, or a data safety monitoring board, or DSMB, overseeing the clinical trial at issue, or other regulatory authorities due to a number of factors, including:

failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;

inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;

varying interpretation of data by the FDA or similar foreign regulatory authorities;

failure to achieve primary or secondary endpoints or other failure to demonstrate efficacy;

unforeseen safety issues; or

lack of adequate funding to continue the clinical trial.

Additionally, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the cost, timing or successful completion of a clinical trial.

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We do not know whether our clinical trials will be conducted as planned, will need to be restructured or will be completed on schedule, if at all. Delays in our clinical trials will result in increased development costs for our drug candidates. In addition, if we experience delays in the completion of, or if we terminate, any of our clinical trials, the commercial prospects for our drug candidates may be harmed and our ability to generate product revenues will be jeopardized. Furthermore, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a drug candidate.

If a successful product liability or clinical trial claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, we could incur substantial liability.

The use of our drug candidates in clinical trials and the sale of any products for which we obtain marketing approval will expose us to the risk of product liability and clinical trial liability claims. Product liability claims might be brought against us by consumers, health care providers or others selling or otherwise coming into contact with our products. Clinical trial liability claims may be filed against us for damages suffered by clinical trial subjects or their families. If we cannot successfully defend ourselves against product liability claims, we could incur substantial liabilities. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand for any approved drug candidates;
- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- distraction of management s attention;
- substantial monetary awards to patients or other claimants;
- loss of revenues; or
- the inability to successfully commercialize any approved drug candidates.

We currently have clinical trial liability insurance coverage for our Phase 1 clinical trial of NEOD001 with a $10.0 million annual aggregate coverage limit; however, our insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for any of our drug candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain this product liability insurance on commercially reasonable terms. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

Risks Related to Our Dependence on Third Parties

We rely on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet established deadlines for the completion of any such clinical trials.

We do not have the ability to independently conduct clinical trials for our drug candidates, and we rely on third parties, such as consultants, contract research organizations, medical institutions, and clinical investigators, to perform this function. Our reliance on these third parties for clinical development activities results in reduced control over these activities. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. Although we have and will enter into agreements with these third parties, we will be responsible for confirming that our clinical trials are conducted in accordance with their general investigational plans and protocols. Moreover, the FDA requires us to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities and requirements. To date, we believe our consultants, contract research organizations and other similar entities with which we are working have performed well; however, if these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be required to replace them. Although we believe that there are a number of other third-party contractors we could engage to continue these activities, it may result in a delay of our planned clinical trials. Accordingly, we may be delayed in obtaining regulatory approvals for our drug candidates and may be delayed in our efforts to successfully develop our drug candidates.

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We anticipate continued reliance on third-party manufacturers if we are successful in obtaining marketing approval from the FDA and other regulatory agencies for any of our drug candidates.

To date, our drug candidates have been manufactured in small quantities for preclinical and clinical testing by third-party manufacturers. If the FDA or other regulatory agencies approve any of our drug candidates for commercial sale, we expect that we would continue to rely, at least initially, on third-party manufacturers to produce commercial quantities of approved drug candidates. These manufacturers may not be able to successfully increase the manufacturing capacity for any approved drug candidates in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. If third-party manufacturers are unable to successfully increase the manufacturing capacity for a drug candidate, or we are unable to establish our own manufacturing capabilities, the commercial launch of any approved products may be delayed or there may be a shortage in supply, which in turn could have a material adverse effect on our business.

Risks Related to Our Ordinary Shares

A trading market may not develop to provide you with adequate liquidity for our ordinary shares. In addition, the market price of our shares may fluctuate widely.

Our ordinary shares have been traded on The NASDAQ Global Market since December 21, 2012; however, there can be no assurance that an active trading market for our ordinary shares will develop or be sustained in the future. We cannot predict the prices at which our ordinary shares may trade at. The market price of our ordinary shares may fluctuate widely, depending upon many factors, some of which may be beyond our control, including:

our ability to obtain financing as needed;

progress in and results from our clinical trials, including our Phase 1 clinical trial of NEOD001;

failure or delays in advancing our preclinical drug candidates or other drug candidates we may develop in the future, into clinical trials;

results of clinical trials conducted by others on drugs that would compete with our drug candidates;

issues in manufacturing our drug candidates;

regulatory developments or enforcement in the United States and foreign countries;

developments or disputes concerning patents or other proprietary rights;

introduction of technological innovations or new commercial products by our competitors;

changes in estimates or recommendations by securities analysts, if any, who cover our company;

public concern over our drug candidates;

litigation;

future sales of our ordinary shares;

general market conditions;

changes in the structure of healthcare payment systems;

failure of any of our drug candidates, if approved, to achieve commercial success;

economic and other external factors or other disasters or crises;

period-to-period fluctuations in our financial results;

overall fluctuations in U.S. equity markets;

the sale of our shares by some shareholders, who received shares through the separation, because our business profile and market capitalization may not fit their investment objectives;

our quarterly or annual results, or those of other companies in our industry;

announcements by us or our competitors of significant acquisitions or dispositions;

the operating and share price performance of other comparable companies;

investor perception of our company and the drug development industry;

natural or environmental disasters that investors believe may affect us; or

fluctuations in the budget of federal, state and local governmental entities around the world.

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These and other external factors may cause the market price and demand for our ordinary shares to fluctuate substantially, which may limit or prevent investors from readily selling their ordinary shares and may otherwise negatively affect the liquidity of our ordinary shares. In particular, stock markets in general have experienced volatility that has often been unrelated to the operating performance of a particular company. These broad market fluctuations may adversely affect the trading price of our ordinary shares. In the past, when the market price of a stock has been volatile, some holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our shareholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management.

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.

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ITEM 6. EXHIBITS

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)
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.

* 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.

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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: May 15, 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

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