

Prothena Corp plc
Form 10-Q
August 13, 2013
[Table of Contents](#)

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)

Edgar Filing: Prothena Corp plc - Form 10-Q

Ireland
(State or other jurisdiction of
incorporation or organization)

43-1256213
(I.R.S. Employer
Identification Number)

650 Gateway Boulevard

South San Francisco, California
(Address of principal executive offices)

94080
(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.

Table of Contents

PROTHENA CORPORATION plc

Form 10Q QUARTERLY REPORT

For the Quarter Ended June 30, 2013

TABLE OF CONTENTS

	Page
<u>PART I. FINANCIAL INFORMATION</u>	1
<u>Item 1. Financial Statements (unaudited)</u>	1
<u>Condensed Consolidated Balance Sheets as of June 30, 2013 and December 31, 2012</u>	1
<u>Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2013 and 2012</u>	2
<u>Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2013 and 2012</u>	3
<u>Notes to Condensed Consolidated Financial Statements</u>	4
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	12
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	18
<u>Item 4. Controls and Procedures</u>	18
<u>PART II. OTHER INFORMATION</u>	20
<u>Item 1. Legal Proceedings</u>	20
<u>Item 1A. Risk Factors</u>	20
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	21
<u>Item 3. Defaults Upon Senior Securities</u>	21
<u>Item 4. Mine Safety Disclosures</u>	21
<u>Item 5. Other Information</u>	21
<u>Item 6. Exhibits</u>	21
<u>SIGNATURES</u>	22
<u>EXHIBIT INDEX</u>	23

Table of Contents**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

Edgar Filing: Prothena Corp plc - Form 10-Q

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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).

Edgar Filing: Prothena Corp plc - 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.

Table of Contents

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:

Table of Contents

- 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.

Table of Contents

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.

Table of Contents

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

Table of Contents

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.

Edgar Filing: Prothena Corp plc - Form 10-Q

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.

Table of Contents

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.

Edgar Filing: Prothena Corp plc - Form 10-Q

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.

Table of Contents

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.

Table of Contents

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;

Edgar Filing: Prothena Corp plc - Form 10-Q

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

Table of Contents

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 Depositary 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

Edgar Filing: Prothena Corp plc - Form 10-Q

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.

Table of Contents

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.

Table of Contents**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

Table of Contents

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	

Edgar Filing: Prothena Corp plc - Form 10-Q

- (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.

Table of Contents***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.

Table of Contents

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

Edgar Filing: Prothena Corp plc - Form 10-Q

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.

Table of Contents

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.

Table of Contents

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:

Edgar Filing: Prothena Corp plc - Form 10-Q

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.

Table of Contents

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.

Table of Contents

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

Table of Contents**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.