Prothena Corp plc
Form 10-Q
November 12, 2013

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2013

Or

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

Commission file number: 001-35676

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

Ireland (State or other jurisdiction of incorporation or organization)	98-1111119 (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 ý 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 ý 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 ý

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

The number of ordinary shares outstanding as of October 31, 2013 was 21,856,261.

PROTHENA CORPORATION plc
Form 10Q – QUARTERLY REPORT
For the Quarter Ended September 30, 2013
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Prothena Corporation plc
Condensed Consolidated Balance Sheets
(in thousands, except share and per share data)

	September 30, 2013 (unaudited)	December 31, 2012 [1]
Assets		
Current assets:		
Cash and cash equivalents	$101,859	$124,860
Receivable from related party	54	223
Deferred tax assets	267	73
Prepaid expenses and other current assets	758	685
Total current assets	102,938	125,841
Non-current assets:		
Property and equipment, net	3,581	3,442
Deferred tax assets	678	—
Other assets	739	—
Total non-current assets	4,998	3,442
Total assets	$107,936	$129,283
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$896	$—
Accrued research and development	3,117	47
Income taxes payable	617	27
Other current liabilities	3,085	1,670
Total current liabilities	7,715	1,744
Non-current liabilities:		
Deferred rent	1,440	1,055
Total liabilities	9,155	2,799
Shareholders' equity:		
Euro deferred shares, €22 nominal value:	—	—
Authorized shares — 10,000 at September 30, 2013 and December 31, 2012		
Issued and outstanding shares — none at September 30, 2013 and December 31, 2012		
Ordinary shares, $0.01 par value:	177	177
Authorized shares — 100,000,000 at September 30, 2013 and December 31, 2012		
Issued and outstanding shares — 17,679,182 at September 30, 2013 and December 31, 2012		
Additional paid-in capital	128,891	126,652
Accumulated deficit	(30,287)	(345)
Total shareholders' equity	98,781	126,484
Total liabilities and shareholders' equity	$107,936	$129,283

[1] Amounts have been derived from the December 31, 2012 audited consolidated financial statements.
See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Revenues—related party	$171	$944	$509	$2,083
Operating expenses:				
Research and development	6,348	7,530	20,452	24,306
General and administrative	3,389	2,082	9,782	6,967
Total operating expenses	9,737	9,612	30,234	31,273
Loss from operations	(9,566)	(8,668)	(29,725)	(29,190)
Interest income	14	—	50	—
Loss before income taxes	(9,552)	(8,668)	(29,675)	(29,190)
Provision for income taxes	137	—	267	—
Net loss	$(9,689)	$(8,668)	$(29,942)	$(29,190)
Basic and diluted net loss per share	$(0.55)	$(0.60)	$(1.69)	$(2.01)
Shares used to compute basic and diluted net loss per share	17,679	14,497	17,679	14,497

See accompanying notes to condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2013	2012
Operating activities		
Net loss	$(29,942)	$(29,190)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	428	306
Share-based compensation	2,037	5,733
Deferred income taxes	(586)	—
Gain on disposal of fixed asset	(29)	—
Changes in operating assets and liabilities:		
Receivable from related party	169	—
Other assets	(73)	(23)
Accounts payable, accruals and other liabilities	5,734	(3,263)
Net cash used in operating activities	(22,262)	(26,437)
Investing activities		
Purchases of property and equipment	(567)	(274)
Proceeds from disposal of fixed asset	29	—
Net cash used in investing activities	(538)	(274)
Financing activities		
Cash paid for deferred offering costs	(117)	—
Proceeds from funding provided by Elan	—	26,711
Post separation adjustments to the funding provided by Elan	(84)	—
Net cash (used in) provided by financing activities	(201)	26,711
Net decrease in cash and cash equivalents	(23,001)	—
Cash and cash equivalents, beginning of the year	124,860	—
Cash and cash equivalents, end of the period	$101,859	$—
Supplemental cash flow information		
Cash paid for income taxes	$263	$—

See accompanying notes to condensed consolidated financial statements.

Notes to Condensed Consolidated Financial Statements
(unaudited)

1. Organization

Description of Business

Prothena Corporation plc (“Prothena” or the “Company”), a public limited company formed under the laws of Ireland, is a clinical stage biotechnology company focused on the discovery, development and commercialization of novel antibodies for the treatment of a broad range of diseases that involve protein misfolding or cell adhesion. The Company is focused on the discovery, development and commercialization of therapeutic monoclonal antibodies directed specifically to disease causing proteins. These product candidates have a broad range of potential indications including AL and AA forms of amyloidosis (NEOD001), Parkinson's disease and other synucleinopathies (PRX002) and inflammatory diseases and cancers (PRX003). The Company initiated a Phase 1 clinical trial for NEOD001, with the first patient dosing in April 2013. The Phase 1 clinical trial of NEOD001 is evaluating its safety and tolerability in AL amyloidosis patients. The Company also plans to initiate Phase 1 clinical trials for PRX002 and PRX003 in 2014 and 2015, respectively. 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 Onclave Therapeutics Limited (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 September 30, 2013, the Company had an accumulated deficit of $30.3 million and cash and cash equivalents of $101.9 million, respectively. Based on the Company's business plans, management believes that the Company's cash and cash equivalents at September 30, 2013 are sufficient to meet its obligations for at least the next respective 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 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. In October 2013, the Company sold an aggregate of 4,177,079 ordinary shares for net proceeds of approximately $84.7 million, after deducting the underwriting discount and estimated offering expenses, in an underwritten public offering (see Note 8 - “Subsequent Events”).

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 healthcare industry.

The Company is dependent on Boehringer Ingelheim to manufacture its clinical supplies for its therapeutic antibody programs. An inability to obtain product supply could have a material adverse impact on the Company's business, financial condition and results of operations.

2. Summary of Significant Accounting Policies

Basis of Preparation and Presentation of Financial Information

The accompanying interim condensed consolidated financial statements have been prepared in accordance with the accounting principles generally accepted in the United States of America (“GAAP”) and with the instructions for Form 10-Q and Regulation S-X. Accordingly, they do not include all of the information and notes required for complete financial statements. These interim condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto contained in the Company’s Form 10-K filed with the Securities

and Exchange Commission ("SEC") on March 29, 2013. The unaudited condensed consolidated financial statements include the accounts of the Company and its consolidated subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

The Prothena Business has historically operated as part of Elan and not as a separate stand-alone entity. Prior to the separation on December 20, 2012, the condensed consolidated financial statements of Prothena 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 the Company

had existed on a stand-alone basis and as if Financial Accounting Standards Board ("FASB") Accounting Standard Codification ("ASC") Topic 810, "Consolidation" ("ASC 810") had been applied throughout. The accompanying condensed consolidated financial statements prior to December 21, 2012 include only those assets and liabilities that management has determined are specifically identifiable to Prothena and allocations of direct costs and indirect costs attributable to the Company's operations. The indirect costs included in the Company's condensed consolidated financial statements relate to certain centralized support functions that were provided by Elan. All intragroup transactions within the Prothena Business have been eliminated in the condensed consolidated financial statements and are not disclosed.

The centralized support functions provided to the Company 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 nine months ended September 30, 2012 were $1.8 million and $5.8 million, respectively. These costs have been allocated to the Company 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 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 the Prothena Business had operated on a standalone basis.

Elan used a centralized approach to manage substantially all of its liquid resources and to finance its operations and, as a result, no separate cash accounts for Prothena were historically maintained, and debt and liquid resources maintained at the Elan group level are not included in the accompanying condensed consolidated financial statements prior to the separation. Elan has historically funded all of Prothena's operating and capital resource requirements. The parent company equity balance in the condensed consolidated financial statements constitutes Elan's investment in Prothena and represents the excess of total liabilities over total assets (or excess of total assets over total liabilities), including the netting of intercompany funding balances between Prothena and Elan. Changes in parent company equity represent Elan's net investment in Prothena, after giving effect to its net loss, contributions from Elan in the form of share-based compensation to Prothena's employees and net funding provided by Elan.

Unaudited Interim Financial Information

The accompanying interim condensed consolidated financial statements and related disclosures are unaudited, have been prepared on the same basis as the annual consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair statement of the results of operations for the periods presented. The year-end condensed balance sheet data was derived from audited financial statements, but does not include all disclosures required by Generally Accepted Accounting Principles in the United States ("GAAP"). The condensed consolidated results of operations for any interim period are not necessarily indicative of the results to be expected for the full year or for any other future year or interim period.

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

Use of Estimates

The preparation of the condensed consolidated financial statements in conformity with 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.

Significant Accounting Policies

There have been no significant changes to the accounting policies during the three months ended September 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.

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 nonclinical 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. Except as described in the paragraph below, there have been no new accounting pronouncements or changes to accounting pronouncements during the nine months ended September 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.

In July 2013, the FASB issued a new accounting standard update on the financial statement presentation of unrecognized tax benefits. The new guidance provides that a liability related to an unrecognized tax benefit would be presented as a reduction of a deferred tax asset for a net operating loss carryforward, a similar tax loss or a tax credit carryforward if such settlement is required or expected in the event the uncertain tax position is disallowed. The new guidance becomes effective for the Company on January 1, 2015 and will be applied prospectively to unrecognized tax benefits that exist at the effective date with retrospective applications permitted. The Company is currently assessing the impact of this new guidance.

3. Fair Value Measurements

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

Level 1 ~~O~~bservable inputs such as quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2 ~~w~~hich all significant inputs are observable in the market or can be derived from observable market data. 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 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 consist of $78.6 million and $103.5 million in money market funds included in cash and cash equivalents at September 30, 2013 and December 31, 2012, respectively.

4. Composition of Certain Balance Sheet Items

Property and Equipment, net

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

	September 30, 2013	December 31, 2012
Machinery and equipment	$5,622	$5,449
Leasehold improvements	1,927	1,651
Purchased computer software	85	85
	7,634	7,185
Less: accumulated depreciation and amortization	(4,053)	(3,743)
Property and equipment, net	$3,581	$3,442

Depreciation expense was $0.1 million and $0.4 million for the three and nine months ended September 30, 2013, respectively, compared to $0.1 million and $0.3 million for the three and nine months ended September 30, 2012, respectively.

Other Current Liabilities

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

	September 30, 2013	December 31, 2012
Payroll and related expenses	$1,716	$1,592
Professional services	384	27
Deferred offering costs	493	—
Deferred rent	96	51
Other	396	—
Other current liabilities	$3,085	$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 been outstanding since December 20, 2012.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Numerator:				
Net loss	$(9,689)	$(8,668)	$(29,942)	$(29,190)
Denominator:				
Weighted-average ordinary shares outstanding	17,679	14,497	17,679	14,497
Basic and diluted net loss per share	$(0.55)	$(0.60)	$(1.69)	$(2.01)

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

	Three and Nine Months Ended September 30,	
	2013	2012
Stock options to purchase ordinary shares	1,930	1,096
Restricted stock units	—	328
Total	1,930	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 nine months ended September 30, 2013, the Company granted 99,000 and 1,934,500 stock options, respectively, under its LTIP. As of September 30, 2013, 720,000 shares remain available for grant and options to purchase 1,930,000 ordinary shares granted from the LTIP were outstanding with a weighted-average exercise price of approximately $7.16 per share.

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.

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 September 30, 2013 is $6.8 million. The weighted-average period over which the unearned share-based compensation is expected to be recognized is 2.9 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.

Share-based compensation expense recorded in these condensed consolidated financial statements for the three and nine months ended September 30, 2013 was based on awards from Prothena's LTIP granted to Prothena employees. The following table summarizes share-based compensation expense recognized for stock options during the three and nine months ended September 30, 2013 (in thousands):

	Three Months Ended September 30, 2013	Nine Months Ended September 30, 2013
Research and development[(1)]	$311	$616

Selling, general and administrative	644	1,421
Total share-based compensation expense	$955	$2,037

(1) Includes $0.1 million and $0.2 million, respectively, of share-based compensation expense for the three and nine months ended September 30, 2013 related to an option granted to a consultant.

The fair value of the options granted to employees during the three and nine months ended September 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 September 30, 2013	Nine Months Ended September 30, 2013
Expected volatility	81.0%	84.1%
Risk-free interest rate	1.8%	1.2%
Expected dividend yield	—%	—%
Expected life (in years)	6.0	6.0
Weighted average grant date fair value	$12.56	$4.97

The following table summarizes the Company's stock option activity during the nine months ended September 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	—	$—	0	$—
Granted	1,935	7.15		
Canceled	(5)	6.41		
Outstanding at the end of the period	1,930	$7.16	9.4	$25,232
Vested and expected to vest at the end of the period	1,752	$7.14	9.4	$22,932
Vested at the end of the period	—	$—	0	$—

Elan's Share-based Compensation Awards

Prior to the separation and distribution of the Prothena Business on December 20, 2012, the Company's employees had received share-based compensation awards under Elan's equity compensation plans and, therefore, the following disclosures pertain to share-based compensation expense that was allocated to the Prothena Business related to Elan's share-based equity awards. Elan's equity award program provided for the issuance of stock options, RSUs and other equity awards to its employees, including employees that have directly and indirectly provided service to the Prothena Business. The share-based payment compensation expense recognized in these condensed consolidated financial statements includes all of the share-based payment expenses directly attributable to the Prothena Business and an allocation of indirect expenses that have been deemed attributable to the Prothena Business for the three and nine months ended September 30, 2012. The Company will not recognize any share-based compensation expense going forward in relation to the existing Elan equity-based awards as its employees are not required to provide service after the separation and distribution in order to receive the benefits of the awards.

Share-based compensation expense recorded in these condensed consolidated financial statements for the three and nine months ended September 30, 2012 was allocated to the Company based on awards from Elan equity plans granted to Elan employees who have, directly or indirectly, provided services to the Company.

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

	Three Months Ended September 30, 2012	Nine Months Ended September 30, 2012
Research and development	$508	$5,728
General and administrative	—	5
Total direct expense	508	5,733
General and administrative — allocated	314	1,200
	$822	$6,933

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 nine months ended September 30, 2012 (in thousands):

	Three Months Ended September 30, 2012	Nine Months Ended September 30, 2012
Restricted stock units	$286	$3,269
Stock options	222	2,464
Total direct	508	5,733
Shared-based compensation expense-allocated	314	1,200
	$822	$6,933

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

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

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

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

	Nine Months Ended September 30, 2012

Expected volatility	60.1	%
Risk-free interest rate	0.9	%
Expected dividend yield	—	%
Expected life [(1)]	0	
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 separation, a wholly owned subsidiary of Elan acquired an 18% interest in the Company (as calculated immediately following the acquisition).

As described elsewhere in these condensed 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 nine months ended September 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, as amended in March 2013, 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 technology services, facilities services, company secretarial services, finance services, legal services, compliance services and human resources 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) with 15 days' notice with respect to services provided by the other party or 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.

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

TSA expenses recognized during the three and nine months ended September 30, 2013 were $nil and $0.5 million, respectively, of which $0.1 million was included in R&D expenses and 0.4 million was included in G&A expenses.

R&D Services Agreement

In December 2012, as amended in March 2013, 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 does, 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 has a term of 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 an

uncured 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 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 are substantially similar to research services performed by the Company for Elan prior to the separation and distribution.

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. There is also a fixed monthly charge of $7,500 to account for lab space and capital equipment used by Elan, for so long as Elan uses such lab space and capital equipment.

8. Subsequent Events

October 2013 Equity Offering

In October 2013, the Company closed its underwritten public offering of 5,910,000 of its ordinary shares at an offering price of $22.00 per ordinary share consisting of 3,500,000 ordinary shares issued and sold by the Company and 2,410,000 ordinary shares sold by Janssen Pharmaceutical, a wholly-owned subsidiary of Johnson & Johnson, as selling shareholder. Net proceeds to the Company for the 3,500,000 ordinary shares sold were approximately $70.8 million, after deducting underwriting discounts of $5.4 million and estimated offering costs of $0.8 million. The Company did not receive any proceeds from the sale of ordinary shares by the selling shareholder.

In connection with this offering, the Company granted the underwriters the right to subscribe for and purchase, as applicable, up to an additional 886,500 ordinary shares, consisting of the subscription from the Company of 677,079 ordinary shares and the purchase from the selling shareholder of 209,421 ordinary shares. In October 2013, the underwriters exercised such right to subscribe for and purchase an aggregate of 886,500 ordinary shares, pursuant to which the Company issued and sold 677,079 ordinary shares and received net proceeds of approximately $13.9 million, after deducting the underwriting discount of approximately $1.0 million, and the selling shareholder sold 209,421 ordinary shares, which represented its remaining shareholding in the Company.

As of September 30, 2013 deferred offering costs of $0.7 million are classified as non-current assets on the balance sheet and upon closing of this offering, such costs will be recorded as an offset to the proceeds and recorded in additional paid in capital on the balance sheet.

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," "inte "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 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;
- our ability to obtain additional financing
- tax treatment of our separation from Elan and subsequent distribution of our ordinary shares;
- restrictions on our taking certain actions due to tax rules and covenants with Elan;
- the impact of our separation from Elan and risks relating to our ability to operate effectively as a stand-alone, publicly traded company, including, without limitation:
  - our ability to achieve benefits from our separation;
  - changes in our cost structure, management, financing and business operations;
  - growth in costs and expenses;
- our ability to maintain financial flexibility and sufficient cash, cash equivalents, and investments and other assets capable of being monetized to meet our liquidity requirements;
- disruptions in the U.S. and global capital and credit markets;
- fluctuations in foreign currency exchange rates;
- extensive government regulation;
- the volatility of our share price;
- general changes in U.S. Generally Accepted Accounting Principles;
- business disruptions caused by information technology failures; and
- the other risks and uncertainties described in Part II, Item 1, "Risk Factors."

We undertake no obligation to revise or update any forward-looking statements to reflect any event or circumstance that arises after the date of this report, or to conform such statements to actual results or changes in our expectations. Except with respect to our trademarks, the trademarks, trade names and service marks appearing in this report are the property of their respective owners.

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

Overview

We are a clinical stage biotechnology company focused on the discovery, development and commercialization of novel antibodies for the treatment of a broad range of diseases that involve protein misfolding or cell adhesion. We focus on the discovery, development and commercialization of therapeutic monoclonal antibodies directed specifically to disease causing proteins. Our antibody-based product candidates target a broad range of potential indications including AL and AA forms of amyloidosis (NEOD001), Parkinson's disease and other synucleinopathies (PRX002) and inflammatory diseases and 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 is evaluating its 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 formed under the laws of Ireland. Our business consists of a substantial portion of Elan's former drug discovery business platform, including Neotope Biosciences Limited and its wholly owned subsidiaries Onclave Therapeutics Limited and Prothena Biosciences Inc (which for the period prior to separation and distribution we refer to herein as the "Prothena Business"). 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 Condensed Consolidated Financial Statements" included in Item 1 of this report and in Note 2 to the audited Consolidated Financial Statements included in Item 8 of our 2012 Form 10-K.

The Separation and Distribution

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 (the "Separation and Distribution"). On December 7, 2012, the Elan board of directors approved a deemed in specie distribution by Prothena issuing directly to the holders of Elan ordinary shares and Elan American Depository Shares, or ADS, on a pro rata basis, Prothena ordinary shares representing 99.99% of Prothena's outstanding shares (with the remaining 0.01% of Prothena's outstanding shares, which were previously issued to the original incorporators of Prothena and which we refer to as the "incorporator shares," being mandatorily redeemed by Prothena after the related demerger). On December 12, 2012, shareholders of Elan voted to approve the "in specie distribution" as required by Elan's Articles of Association. On December 20, 2012, each holder of Elan ordinary shares or ADSs received 1 Prothena ordinary share for every 41 Elan ordinary shares or Elan ADSs held at the close of business on the record date for the distribution, subject to certain conditions.

Immediately after the Separation and Distribution, a wholly-owned subsidiary of Elan subscribed for 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 subscription, 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 subscription for 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 subsidiaries Onclave Therapeutics Limited and Prothena Biosciences Inc, 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 nine months ended September 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 those periods.

Prior to the Separation and Distribution on December 20, 2012, centralized support costs were allocated to us for the purposes of preparing the condensed consolidated financial statements based on our estimated usage of the resources. Our estimated usage of the centralized support resources was determined by estimating our portion of the most appropriate driver for each category of centralized support costs such as headcount or labor hours, depending on the nature of the costs. We believe that such allocations were made on a reasonable basis, but may not necessarily be indicative of the costs that would have been incurred if we had

operated on a standalone basis. For additional information regarding the basis of preparation, refer to Note 2 of the "Notes to the Condensed Consolidated Financial Statements" included in Item 1 of this report.

Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with Generally Accepted Accounting Principles in the United States ("U.S. 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. We believe the following policies to be critical to the judgments and estimates used in the preparation of our financial statements.

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 nine months ended September 30, 2012, and as if Financial Accounting Standards Board, or FASB, Accounting Standard Codification, or ASC, Topic 810, "Consolidation," or ASC 810, had been applied throughout. The condensed consolidated financial statements have been prepared in conformity with U.S. GAAP, by aggregating financial information from the components of Prothena described in Note 2 to the condensed consolidated financial statements.

The accompanying 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 three and nine months ended September 30, 2012 were $1.8 million and $5.8 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 for 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, we are eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not Emerging Growth Companies. We have 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. Except as noted in the next paragraph,there have been no new accounting pronouncements or changes to accounting pronouncements during the nine months ended September 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.

In July 2013, the FASB issued a new accounting standard update on the financial statement presentation of unrecognized tax benefits. The new guidance provides that a liability related to an unrecognized tax benefit would be presented as a reduction of a deferred tax asset for a net operating loss carryforward, a similar tax loss or a tax credit carryforward if such settlement is required or expected in the event the uncertain tax position is disallowed. The new guidance becomes effective on January 1, 2015 and will be applied prospectively to unrecognized tax benefits that exist at the effective date with retrospective applications permitted. We are currently assessing the impact of this new guidance.

Results of Operations

Comparison of Three and Nine Months Ended September 30, 2013 and 2012

Revenue

	Three Months Ended September 30,		Year-to-Year Change	Percentage Change
	2013	2012		
	(Dollars in thousands)			
Revenues—related party	$171	$944	$(773)	(82)%

	Nine Months Ended September 30,		Year-to-Year Change	Percentage Change
	2013	2012		
	(Dollars in thousands)			
Revenues—related party	$509	$2,083	$(1,574)	(76)%

Revenue for the three and nine months ended September 30, 2013 and 2012 was comprised of fees earned from the provision of research and development services to Elan.

Total revenues decreased $0.8 million, or 82%, during the three months ended September 30, 2013 as compared to the prior year, and decreased $1.6 million, or 76%, during the nine months ended September 30, 2013 compared to the same period in the prior year. The decrease in revenue was primarily due to a reduction in the scope of the R&D services provided to Elan.

Operating Expenses

	Three Months Ended September 30,		Year-to-Year Change	Percentage Change
	2013	2012		
	(Dollars in thousands)			
Research and development	$6,348	$7,530	$(1,182)	(16)%
General and administrative	3,389	2,082	1,307	63 %
Total operating expenses	$9,737	$9,612	$125	1 %

	Nine Months Ended September 30,		Year-to-Year Change	Percentage Change
	2013	2012		
	(Dollars in thousands)			
Research and development	$20,452	$24,306	$(3,854)	(16)%
General and administrative	9,782	6,967	2,815	40 %
Total operating expenses	$30,234	$31,273	$(1,039)	(3)%

Total operating expenses consist of R&D expenses and general and administrative, or G&A, expenses. Our operating expenses for the three and nine months ended September 30, 2013 were $9.7 million and $30.2 million, respectively, compared to $9.6 million and $31.3 million, respectively, for the same periods in the prior year. Our R&D expenses primarily consist of personnel costs and related expenses including share-based compensation, external costs associated with preclinical activities and regulatory operations related to our drug programs, including NEOD001, PRX002, PRX003 and our discovery programs and cost in providing research services to Elan's ELND005 program. Our G&A expenses primarily consist of professional services expenses and personnel costs and related expenses, including share-based compensation and, for the nine months ended September 30, 2012, certain centralized support costs that had been allocated to us by Elan based on our estimated usage of the resources. Share-based

compensation expense during the nine months ended September 30, 2012 was allocated to us by Elan. Additional information regarding the allocation of centralized G&A expenses is discussed above under the caption "Carve-out of the Results of Operations, Financial Condition and Cash Flows of the Prothena Business".

Research and Development Expenses

Our research and development expenses decreased by $1.2 million, or 16%, for the three months ended September 30, 2013, and decreased by $3.9 million, or 16%, for the nine months ended September 30, 2013 compared to the same periods in the prior year. The decrease for the three months ended September 30, 2013 was primarily due to overall lower spending on NEOD001 partially offset by an increase in expenses associated with our PRX002 program. The decrease for the nine months ended September 30, 2013 was primarily due to a decrease in share-based compensation expense and lower NEOD001 program costs, partially offset by increases in personnel costs and external expenses attributable 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 nine months ended September 30, 2013 and 2012, and the cumulative amounts to date (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,		Cumulative to Date
	2013	2012	2013	2012	
NEOD001 [1]	$945	$2,073	$2,436	$5,914	$25,875
Other R&D [2]	5,403	5,457	18,016	18,392	
	$6,348	$7,530	$20,452	$24,306	

(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

Our general and administrative expenses increased by $1.3 million, or 63% ,for the three months ended September 30, 2013, and increased $2.8 million, or 40%, for the nine months ended September 30, 2013 compared to the same periods of the prior year. 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 $1.4 million for the nine months ended September 30, 2013. For the nine months ended September 30, 2012, G&A expenses were presented on a “carve-out” basis as the Prothena Business consisted of a substantial portion of Elan’s former drug discovery business platform. Accordingly, G&A expenses during the nine months ended September 30, 2012 consisted of $1.2 million of direct expense incurred by the Prothena Business and $5.8 million of indirect expenses which was based on an allocation to the Prothena Business by Elan.

Interest Income

	Three Months Ended September 30,		Year-to-Year Change	Percentage Change
	2013	2012		
	(Dollars in thousands)			
Interest income	$14	$—	$ 14	nm

	Nine Months Ended September 30,		Year-to-Year Change	Percentage Change
	2013	2012		
	(Dollars in thousands)			
Interest income	$50	$—	$ 50	nm

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nm = not meaningful

Interest income increased by $14,000 and $50,000 for the three and nine months ended September 30, 2013 compared to the same periods of the prior year and primarily due to interest earned on our money market accounts. For the three and nine months ended September 30, 2012, no interest income was allocated to the Prothena Business by Elan.

Provision for Income Taxes

	Three Months Ended September 30,		Year-to-Year Change	Percentage Change
	2013	2012		
	(Dollars in thousands)			
Provision for income taxes	$137	$—	$ 137	nm

	Nine Months Ended September 30,		Year-to-Year Change	Percentage Change
	2013	2012		
	(Dollars in thousands)			
Provision for income taxes	$267	$—	$ 267	nm

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nm = not meaningful

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 nine months ended September 30, 2012 and are consistent with the asset and liability method prescribed by ASC 740. 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 nine months ended September 30, 2013 was $0.1 million and $0.3 million, respectively, compared to $Nil for both the three and nine months ended September 30, 2012. The tax provision reflects U.S. federal taxes. No tax benefit has been recorded related to tax losses recognized in Ireland and any deferred tax assets for those losses are offset by a valuation allowance.

Liquidity and Capital Resources

Overview

	September 30, 2013	December 31, 2012
Working capital	$95,223	$124,097
Cash and cash equivalents	101,859	124,860
Total assets	107,936	129,283
Other non-current liabilities	1,440	1,055
Total liabilities	9,155	2,799
Total shareholders' equity	98,781	126,484

Prior to the separation of the Prothena Business from Elan, 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 use 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 subscribe for 18% of our outstanding ordinary shares (as calculated immediately following the subscription).

Working capital was $95.2 million at September 30, 2013, a decrease of $28.9 million from working capital as of December 31, 2012. This decrease was principally attributable to a reduction in net cash and cash equivalents balances of $23.0 million due primarily to fund our operating expenses, a $3.1 million increase in accrued research and development and a $2.9 million increase in accounts payable and other current liabilities.

As of September 30, 2013, we had $101.9 million in cash and cash equivalents. Based on our current business plan, we believe that our 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 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.

October 2013 Equity Financing

In October 2013 we completed an underwritten public offering of an aggregate of 6,796,500 of our ordinary shares at a public offering price of $22.00 per share, which consisted of 4,177,079 newly issued ordinary shares sold by us and 2,619,421 shares sold by Janssen Pharmaceutical, a wholly-owned subsidiary of Johnson & Johnson, as selling shareholder. We received aggregate net proceeds of approximately $84.7 million, after deducting the underwriting discount and estimated offering costs. We did not receive any proceeds from the sale of 2,619,421 ordinary shares sold, which represented Janssen Pharmaceutical's remaining shareholding in Prothena.

Cash Flows for the Nine Months Ended September 30, 2013 and 2012

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

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	Nine Months Ended September 30,	
	2013	2012
Net cash used in operating activities	$(22,262)	$(26,437)
Net cash used in investing activities	(538)	(274)
Net cash (used in) provided by financing activities	(201)	26,711
Net decrease in cash and cash equivalents	$(23,001)	$—

Cash Used in Operating Activities

Net cash used in operating activities was $22.3 million and $26.4 million during the nine months ended September 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 partially offset by higher net loss adjusted for non cash charges.

Cash Used in Investing Activities

Net cash used in investing activities was $0.5 million and $0.3 million during the nine months ended September 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 during the nine months ended September 30, 2013 was $0.2 million consisting of the cash paid for deferred offering costs associated with our October 2013 equity financing and final settlement of liabilities as a result of our separation from Elan. Net cash provided by financing activities was $26.7 million during the nine months ended September 30, 2012, reflecting funding provided by Elan.

Off-Balance Sheet Arrangements

At September 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.

Contractual Obligations

Our main contractual obligations as of September 30, 2013 consist of operating leases of $10.4 million and purchase obligations of $0.2 million. As of the reporting date, our purchase obligations increased to $1.5 million due to additional firm purchase commitments relating to our PRX003 program, due within the next twelve months. Operating leases represent our future minimum rental commitments under our operating leases. Purchase obligations represent our non-cancelable purchase commitments to suppliers.

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 which is denominated in Euros. 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. Accordingly, our interest income fluctuates with short-term market conditions.

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

Changes in Internal Control over Financial Reporting

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

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

Investing in our ordinary shares involves a high degree of risk. Our 2012 Form 10-K includes a detailed discussion of our risk factors under the heading ""Part I. Item 1A-Risk Factors." Set forth below are certain changes from the risk factors previously disclosed in our 2012 Form 10-K and subsequent 10-Qs. You should consider carefully the risk factors discussed in our 2012 Form 10-K, and subsequent 10-Qs 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, and subsequent 10-Qs 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 $29.9 million for the nine months ended September 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; and
- 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;

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 September 30, 2013, we had cash and cash equivalents of $101.9 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;
- our ability to establish research collaborations, strategic collaborations, licensing or other arrangements;
- the costs to satisfy our obligations under potential future collaborations; and

- the timing, receipt, and amount of revenues or royalties, if any, from any approved drug candidates.

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

We are not able to provide specific estimates of the timelines or total costs to complete the ongoing Phase 1 clinical trial for NEOD001 that we initiated in April 2013. 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 product candidates in our research and development pipeline will experience difficulties, delays or failures. This makes it difficult to estimate the total costs to complete this ongoing 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 product candidates 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;
- 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.

Our future success depends on our ability to retain our chief executive officer and to attract, retain and motivate qualified personnel.

We are highly dependent on Dr. Dale Schenk, our President and Chief Executive Officer. We expect that we will continue to pay our key executives less cash compensation than what they were paid by Elan. There can be no assurance that we will be able to retain Dr. Schenk or any of our key executives. The loss of the services of Dr. Schenk or any other person on which we become highly dependent might impede the achievement of our research and development objectives. Recruiting and retaining qualified scientific personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific personnel from universities and research institutions.

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 its first Phase 1 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 products;
- be proven safe and effective in clinical trials; or
- meet applicable regulatory standards.

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 products. Our success will, in addition to the factors discussed above, depend on the successful commercialization of our 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 several years and some or all may never become commercially available. Accordingly, we may never generate revenues through the sale of products.

If clinical trials of 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. For example, our current Phase 1 NEOD001 clinical trial targets patients with amyoloidosis, an orphan population with a relatively small pool of patients who may be eligible, accessible and interested in participating in clinical trials. 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.

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.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our drug candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is inherently unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a drug candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any drug candidate and it is possible that none of our existing drug candidates or any drug candidates we may seek to develop in the future will ever obtain regulatory approval.

Our drug candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a drug candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a drug candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our drug candidates may not be sufficient to support the submission of a Biologics License Application, or BLA, or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; or
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our drug candidates, which would significantly harm our business, results of operations and prospects. In addition, even if we were to obtain approval, regulatory authorities may approve any of

our drug candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent

on the performance of costly post-marketing clinical trials, or may approve a drug candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that drug candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our drug candidates.

Both before and after marketing approval, our drug candidates are subject to ongoing regulatory requirements and continued regulatory review, and if we fail to comply with these continuing requirements, we could be subject to a variety of sanctions and the sale of any approved products could be suspended.

Both before and after regulatory approval to market a particular drug candidate, the manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, distribution and record keeping related to the product are subject to extensive, ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practice, or cGMP, requirements and current good clinical practice, or cGCP, requirements for any clinical trials that we conduct post-approval. Any regulatory approvals that we receive for our drug candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the drug candidate. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with the regulatory requirements of the FDA and other applicable U.S. and foreign regulatory authorities could subject us to administrative or judicially imposed sanctions, including:

- restrictions on the marketing of our products or their manufacturing processes;
- warning letters;
- civil or criminal penalties;
- fines;
- injunctions;
- product seizures or detentions;
- import or export bans;
- voluntary or mandatory product recalls and related publicity requirements;
- suspension or withdrawal of regulatory approvals;
- total or partial suspension of production; and
- refusal to approve pending applications for marketing approval of new products or supplements to approved applications.

The FDA’s policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

If side effects are identified during the time our drug candidates are in development or after they are approved and on the market, we may choose to or be required to perform lengthy additional clinical trials, discontinue development of the affected drug candidate, change the labeling of any such products, or withdraw any such products from the market, any of which would hinder or preclude our ability to generate revenues.

Undesirable side effects caused by our drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly. Even if any of our drug candidates receives marketing approval, as greater numbers of patients use a drug

following its approval, an increase in the incidence of side effects or the incidence of other post-approval problems that were not seen or anticipated during pre-approval clinical trials could result in a number of potentially significant negative consequences, including:

- regulatory authorities may withdraw their approval of the product;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;

- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could substantially increase the costs and expenses of developing, commercializing and marketing any such drug candidates or could harm or prevent sales of any approved products.

Risks Related to the Commercialization of Our Drug Candidates

If government and third-party payors fail to provide coverage and adequate reimbursement rates for any of our drug candidates that receive regulatory approval, our revenue and prospects for profitability will be harmed.

In both domestic and foreign markets, our sales of any future products will depend in part upon the availability of reimbursement from third-party payors. Such third-party payors include government health programs such as Medicare, managed care providers, private health insurers, and other organizations. There is significant uncertainty related to the third-party coverage and reimbursement of newly approved drugs. Coverage and reimbursement may not be available for any drug that we or our collaborators commercialize and, even if these are available, the level of reimbursement may not be satisfactory. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Third-party payors are also increasingly attempting to contain healthcare costs by demanding price discounts or rebates and limiting both coverage and the amounts that they will pay for new drugs, and, as a result, they may not cover or provide adequate payment for our drug candidates. We might need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any future products to such payors' satisfaction. Such studies might require us to commit a significant amount of management time and financial and other resources. Our future products might not ultimately be considered cost-effective. Adequate third-party reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we or our collaborators may not be able to successfully commercialize any product candidates for which marketing approval is obtained.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drugs vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we or our collaborators might obtain marketing approval for a drug in a particular country, but then be subject to price regulations that delay commercial launch of the drug, possibly for lengthy time periods, and negatively impact our ability to generate revenue from the sale of the drug in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates, even if our drug candidates obtain marketing approval.

U.S. and foreign governments continue to propose and pass legislation designed to reduce the cost of healthcare. In the United States, we expect that there will continue to be federal and state proposals to implement similar governmental controls. In addition, recent changes in the Medicare program and increasing emphasis on managed care in the United States will continue to put pressure on pharmaceutical product pricing. For example, in 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the Healthcare Reform Law, was enacted. The Healthcare Reform Law substantially changes the way healthcare is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Among the provisions of the Healthcare Reform Law of importance to the pharmaceutical industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
-

expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers and enhanced penalties for non-compliance;

- a new Medicare Part D coverage gap discount program, under which manufacturers must agree to offer 50 percent point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;

- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the federal poverty level beginning in 2014, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- a licensure framework for follow-on biologic products;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements under the federal Open Payments program and its implementing regulations;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since the Healthcare Reform Law was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. On March 1, 2013, the President signed an executive order implementing the 2% Medicare payment reductions, and on April 1, 2013, these reductions went into effect. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and, accordingly, our financial operations.

We expect that the Healthcare Reform Law, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Legislation and regulations affecting the pricing of pharmaceuticals might change before our drug candidates are approved for marketing. Any reduction in reimbursement from Medicare or other government healthcare programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs.

There can be no assurance that our drug candidates, if they are approved for sale in the United States or in other countries, will be considered medically reasonable and necessary for a specific indication, that they will be considered cost-effective by third-party payors, that coverage or an adequate level of reimbursement will be available, or that third-party payors' reimbursement policies will not adversely affect our ability to sell our drug candidates profitably if they are approved for sale.

Our drug candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

Our drug candidates are regulated by the FDA as biologic products and we intend to seek approval for these products pursuant to the BLA pathway. The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated pathway for the approval of biosimilar and interchangeable biologic products. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biologic products.

We believe that any of our drug candidates approved as a biologic product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our drug candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a

biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biologic products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

We may be subject, directly or indirectly, to federal and state anti-kickback, fraud and abuse, false claims, physician payment transparency, health information privacy and security, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

If we obtain FDA approval for any of our drug candidates and begin commercializing those products in the United States, our operations may be directly, or indirectly through our customers, subject to various federal and state fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, which may constrain the business or financial arrangements and relationships through which we sell, market and distribute any drugs for which we obtain marketing approval. In addition, we may be subject to physician payment transparency laws and patient privacy regulation by both the federal government and the states and foreign jurisdictions in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that impose criminal and civil liability for executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- the federal Open Payments program, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to "payments or other transfers of value" made to physicians, which is defined to include doctors, dentists, optometrists, podiatrists and chiropractors, and teaching hospitals and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by the physicians and their immediate family members, with data collection beginning on August 1, 2013, requirements for manufacturers to submit reports to CMS by March 31, 2014 and the 90th day of each subsequent calendar year, and disclosure of such information to be made by CMS on a publicly available website beginning in September 2014;
- HIPAA, as amended by the Health Information Technology and Clinical Health Act, and its implementing regulations, which impose obligations on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business

practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to significant civil, criminal, and administrative penalties, including, without limitation, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, damages, fines and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including

our collaborators, is found not to be in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also adversely affect our business.

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; and
- the inability to successfully commercialize any approved drug candidates.

We currently have clinical trial liability insurance coverage for our ongoing Phase 1 clinical trial of NEOD001 with a $5.0 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 cGCPs, 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. If we or any of our third party contractors fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with cGCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

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, meet expected deadlines, or comply with applicable regulations, 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, we may not be able to enter into arrangements with alternative third-party contractors or to do so on commercially reasonable terms, which 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.

In addition, our third-party contractors are not our employees, and except for remedies available to us under our agreements with such third-party contractors, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, nonclinical and preclinical programs. If third-party contractors do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates. As a result, our results of operations and the commercial prospects for our drug candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

We have no manufacturing capacity and depend on a third-party manufacturer to produce our preclinical and clinical trial drug supplies.

We do not currently operate manufacturing facilities for preclinical or clinical production of any of our drug candidates. We have limited experience in drug manufacturing, and we lack the resources and the capabilities to manufacture any of our drug candidates on a clinical or commercial scale. As a result, we rely on a single third-party manufacturer to supply, store, and distribute preclinical and clinical supply of our drug candidates, and plan to continue to do so until we increase the number of manufacturers with whom we contract. Any performance failure on the part of our existing or future manufacturers could delay clinical development or regulatory approval of our drug candidates or commercialization of any approved products, producing additional losses and depriving us of potential product revenue.

Our drug candidates require precise, high quality manufacturing. Failure by our contract manufacturer to achieve and maintain high manufacturing standards could result in patient injury or death, product recalls or withdrawals, delays or failures in testing or delivery, cost overruns, or other problems that could seriously hurt our business. Contract manufacturers may encounter difficulties involving production yields, quality control, and quality assurance. These manufacturers are subject to ongoing periodic and unannounced inspections by the FDA and corresponding state and foreign agencies to ensure strict compliance with cGMPs and other applicable government regulations and corresponding foreign standards; however, we do not have control over third-party manufacturers' compliance with these regulations and standards.

If a contract manufacturer cannot perform as agreed, we may be required to replace it. Although we believe there are a number of potential replacements as our manufacturing processes are not manufacturer specific, we may incur added costs and delays in identifying and qualifying any such replacements because the FDA must approve any replacement manufacturer prior to manufacturing our drug candidates. Such approval would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our drug candidates after receipt of FDA approval.

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, and our commercialization of any of our drug candidates may be halted, delayed or made less profitable if those third parties fail to obtain such approvals, fail to provide us with sufficient quantities of drug product or fail to do so at acceptable quality levels or prices.

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.

In addition, the facilities used by our contract manufacturers to manufacture our drug candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit a BLA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs, for manufacture of both active drug substances and finished drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, they will not

be able to secure and/or maintain regulatory approval for their manufacturing facilities. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our drug candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our drug candidates, if approved.

Risks Related to Our Intellectual Property

If we are unable to adequately protect or enforce the intellectual property relating to our drug candidates our ability to successfully commercialize our drug candidates will be harmed.

Our success depends in part on our ability to obtain patent protection both in the United States and in other countries for our drug candidates. Our ability to protect our drug candidates from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the scope of claims made under these patents, our ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions. Accordingly, rights under any issued patents may not provide us with sufficient protection for our drug candidates or provide sufficient protection to afford us a commercial advantage against competitive products or processes.

In addition, we cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us or our affiliates. Even if patents have issued or will issue, we cannot guarantee that the claims of these patents are or will be valid or enforceable or will provide us with any significant protection against competitive products or otherwise be commercially valuable to us. Patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the U.S. Patent and Trademark Office, or the USPTO, for the entire time prior to issuance as a U.S. patent. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Consequently, we cannot be certain that we or our licensors or co-owners were the first to invent, or the first to file patent applications on, our drug candidates or their use as drugs. In the event that a third party has also filed a U.S. patent application relating to our drug candidates or a similar invention, we may have to participate in interference or derivation proceedings declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial and it is possible that our efforts would be unsuccessful, resulting in a loss of our U.S. patent position. Furthermore, we may not have identified all U.S. and foreign patents or published applications that affect our business either by blocking our ability to commercialize our drugs or by covering similar technologies.

Composition-of-matter patents on the biological or chemical active pharmaceutical ingredient are generally considered to be the strongest form of intellectual property protection for pharmaceutical products, as such patents provide protection without regard to any method of use. We cannot be certain that the claims in our patent applications covering composition-of-matter of our product candidates will be considered patentable by the USPTO and courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our issued composition-of-matter patents will not be found invalid or unenforceable if challenged.

Method-of-use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products “off-label.” Although off-label prescriptions may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to prevent or prosecute.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation, and switch the U.S. patent system from a “first-to-invent” system to a “first-to-file” system. Under a “first-to-file” system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The U.S. Patent and Trademark Office recently developed new regulations and procedures

to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first-to-file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

We may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office, or become involved in opposition, derivation, reexamination, inter partes review, post-grant review, or other patent office proceedings or litigation, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to

commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third party patent rights.

We may not be able to protect our intellectual property rights throughout the world.

The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties in protecting or are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed.

We license patent rights from third-party owners. Such licenses may be subject to early termination if we fail to comply with our obligations in our licenses with third parties, which could result in the loss of rights or technology that are material to our business.

We are a party to licenses that give us rights to third-party intellectual property that is necessary or useful for our business, and we may enter into additional licenses in the future. Under these license agreements we are obligated to pay the licensor fees, which may include annual license fees, milestone payments, royalties, a percentage of revenues associated with the licensed technology and a percentage of sublicensing revenue. In addition, under certain of such agreements, we are required to diligently pursue the development of products using the licensed technology. If we fail to comply with these obligations and fail to cure our breach within a specified period of time, the licensor may have the right to terminate the applicable license, in which event we could lose valuable rights and technology that are material to our business.

If the licensor retains control of prosecution of the patents and patent applications licensed to us, we may have limited or no control over the manner in which the licensor chooses to prosecute or maintain its patents and patent applications and have limited or no right to continue to prosecute any patents or patent applications that the licensor elects to abandon.

We jointly own certain patent rights with third parties. Our ability to out-license these patent rights, or to prevent the third party from out-licensing these patent rights, may be limited in certain countries.

We jointly own certain patents and patent applications with third parties, and may jointly own patents and patent applications with third parties in the future. Unless we enter into an agreement with the joint owner, we will be subject to certain default rules pertaining to joint ownership. Certain countries require the consent of all joint owners to license jointly owned patents, and if we are unable to obtain such consent from the joint owner, we may not be able to license our rights under these patents and patent applications. In certain other countries, including the United States, the joint owner could license its rights under these patents and patent applications to another party without our consent and without any duty of accounting to us.

Litigation regarding patents, patent applications and other proprietary rights may be expensive and time consuming. If we are involved in such litigation, it could cause delays in bringing drug candidates to market and harm our ability to operate.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. Although we are not currently aware of any litigation or other proceedings or third-party claims of intellectual property infringement related to our drug candidates, the pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may hold or obtain patents in the future and allege that the use of our technologies infringes these patent claims or that we are employing their proprietary technology without authorization. Elan is involved in litigation with the Alzheimer's Institute of America, or AIA. While the lawsuit was dismissed with prejudice, AIA appealed the result and if the appeal is successful, AIA may institute suit against us related to our research activities. If we become involved in this matter it may distract our management and result in substantial costs, although Elan is contractually obligated pursuant to the terms of the Demerger Agreement to reimburse us for our expenses and indemnify us for any damages.

In addition, third parties may challenge or infringe upon our existing or future patents. Proceedings involving our patents or patent applications or those of others could result in adverse decisions regarding:

- the patentability of our inventions relating to our drug candidates; and/or
- the enforceability, validity or scope of protection offered by our patents relating to our drug candidates.

Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us.

If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient

resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may:

- incur substantial monetary damages;
- encounter significant delays in bringing our drug candidates to market; and/or
- be precluded from participating in the manufacture, use or sale of our drug candidates or methods of treatment requiring licenses.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition by potential partners or customers in our markets of interest. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

Risks Relating to the Separation and Distribution

We may not realize some or all of the potential benefits we expect from our separation from Elan.

We may not realize the benefits we anticipate from our separation from Elan. These benefits include the following:

- greater strategic focus of financial resources and management's efforts;
- direct and differentiated access to capital resources;
- enhanced investor ability to evaluate our financial performance and strategy against our peer group; and
- improved ability to align management incentive compensation with our performance by issuing options exercisable for Prothena ordinary shares.

We may not achieve the anticipated benefits from our separation for a variety of reasons, including the following:

- the regulatory and other managerial challenges of operating as an independent public company may distract our management team from focusing on our business and strategic priorities;
- we will require substantial ongoing cash investment for the foreseeable future, we will no longer be supported by the revenue and cash flows of Elan's business and we may not be able to issue debt or equity on terms acceptable to us or at all;
- our ability to differentiate our company against our peer group and attract early stage biotechnology investors is largely dependent on the success of our research and development programs, which are at an early stage; and
- we expect to continue to pay our key executives less cash compensation than what they were paid at Elan, so even if we are able to provide potential equity compensation tied specifically to our business, we may not be able to attract and retain key employees as desired.

We also may not fully realize the anticipated benefits from our separation if any of the matters identified as risks in this "Risks Factors" section were to occur. If we do not realize the anticipated benefits from our separation for any reason, our business may be materially adversely affected.

If we are unable to maintain effective internal controls, our business, financial position and results of operations could be adversely affected.

We are subject to the reporting and other obligations under the Securities Exchange Act of 1934, as amended, or the Exchange Act, including the requirements of Section 404 of the Sarbanes-Oxley Act of 2002, which require annual management assessments of the effectiveness of our internal control over financial reporting. However, our auditors will not be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 until we are no longer an "emerging growth company" as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, if we continue to take advantage of the exemptions available to us through the JOBS Act. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation to meet the detailed standards under the rules.

During the course of its testing, our management may identify material weaknesses or deficiencies which may not be remedied in time to meet the deadline imposed by the Sarbanes-Oxley Act of 2002. These reporting and other obligations place significant demands on our management and administrative and operational resources, including accounting resources.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of Financial Statements for external purposes in accordance with accounting principles generally accepted in the United States. Any failure to maintain effective internal controls could have an adverse effect on our business, financial position and results of operations.

Our historical financial information is not necessarily representative of the results we would have achieved as a separate, publicly traded company and may not be a reliable indicator of our future results.

Our financial results previously were included within the consolidated results of Elan; however, we were not directly subject to the reporting and other requirements of the Exchange Act until our separation from Elan in December 2012. The historical financial information we have included in this report may not reflect what our results of operations, financial position and cash flows would have been had we been an independent, publicly traded company during the periods presented or what our results of operations, financial position and cash flows will be in the future. This is primarily because:

- our historical financial information reflects allocations for services historically provided to us by Elan, which allocations may not reflect the costs we will incur for similar services in the future as an independent company;
- subsequent to the completion of the Separation and Distribution, the cost of capital for our business may be higher than Elan's cost of capital prior to the Separation and Distribution because Elan's current cost of debt will likely be lower than ours; and
- our historical financial information does not reflect changes that we have incurred as a result of the separation of the Prothena Business from Elan, including changes in the cost structure, personnel needs, financing and operations of the contributed business as a result of the separation from Elan and from reduced economies of scale.

We are also responsible for the additional costs associated with being an independent, public company, including costs related to corporate governance and compliance with the rules of The NASDAQ Global Market, or NASDAQ, and the SEC. Prior to the Separation and Distribution, the Prothena Business was operated by Elan as part of its broader corporate organization, rather than as an independent company. Elan or one of its affiliates performed various corporate functions for us, including, but not limited to, legal, treasury, accounting, auditing, risk management, information technology, human resources, corporate affairs, tax administration, certain governance functions and external reporting. Our historical financial results include allocations of corporate expenses from Elan for these and similar functions. These allocations of cash and non-cash expenses are less than the comparable expenses we have incurred thus far as a separate publicly traded company. Therefore, our Financial Statements may not be indicative of our future performance as an independent company.

In addition, we incur costs and expenses, including professional fees, to comply with Irish corporate and tax laws and financial reporting requirements and costs and expenses incurred in connection with holding the meetings of our board of directors, or our Board, in Ireland. There can be no assurance that these costs will not exceed the costs historically borne by Elan and those allocated to us in connection with the separation.

The agreements we have entered into with Elan involve conflicts of interest and therefore may have materially disadvantageous terms to us.

We have entered into certain agreements with Elan, including the Demerger Agreement, Tax Matters Agreement, Transitional Services Agreement, Research and Development Services Agreement and Subscription and Registration Rights Agreement, which set forth the main terms of the separation and provide a framework for our initial relationship with Elan. These agreements may have terms that are materially disadvantageous to us or are otherwise not as favorable as those that might be negotiated between unaffiliated third parties. In addition, in July 2013, Elan announced that it had entered into a definitive agreement to be acquired by Perrigo. If this transaction is consummated, Elan may be less willing to collaborate with us in connection with these and other matters.

We believe that we will be a passive foreign investment company for U.S. federal income tax purposes, which could result in adverse U.S. federal income tax consequences to U.S. holders of our ordinary shares.

While the determination of passive foreign investment company, or "PFIC," status is fact specific, and generally cannot be made until the close of the taxable year in question, based on the market price of our ordinary shares and the value and composition of our assets, we believe we will be a PFIC for U.S. federal income tax purposes for our current taxable year. A non-U.S. corporation

will be considered a PFIC for any taxable year if either (1) at least 75% of its gross income for such year is passive income or (2) at least 50% of the value of its assets (based on an average of the quarterly values of the assets during such year) is attributable to assets that produce or are held for the production of passive income (the "asset test"). In general, the total value of our assets for purposes of the asset test will be determined based on the market price of our ordinary shares. A separate determination must be made each taxable year as to whether we are a PFIC (after the close of each taxable year). We believe we will be a PFIC for our current taxable year unless our share value increases and/or we invest a substantial amount of the cash and other passive assets we hold in assets that produce active income. Because we expect to be a PFIC for our current taxable year, certain adverse U.S. federal income tax consequences could apply to U.S. persons who have acquired our ordinary shares with respect to any "excess distribution" received from us and any gain from a sale or other disposition of our ordinary shares.

Relationships between certain of our executive officers and directors with our principal shareholder could adversely affect our other shareholders and/or present actual, potential or perceived conflicts of interest.

Certain of our executive officers and directors are former officers and employees of Elan and thus have professional relationships with Elan's executive officers and directors. Our Chairman of the Board, Dr. Lars G. Ekman, is Elan's former President of Research and Development and a former member of Elan's board of directors. Our Chief Executive Officer and director, Dr. Dale B. Schenk, has held the position of Executive Vice President and Chief Scientific Officer for Elan. Our director, Shane Cooke, is a former director of Elan and Elan's former Chief Financial Officer, Executive Vice President and Head of Elan Drug Technologies. Our director, Richard T. Collier, is Elan's former Executive Vice President and General Counsel. Our Head of Corporate and Business Development and Secretary, Dr. Tara Nickerson, has held the position of Vice President and Head of Business Development for Elan Pharmaceuticals, Inc., a subsidiary of Elan. Our Chief Scientific Officer and Head of Research and Development, Dr. Gene Kinney, has held the position of Senior Vice President, Pharmacological Sciences for Elan. In addition, certain of our other employees and directors have a meaningful financial interest in Elan as a result of their ownership of Elan ordinary shares, options and other equity awards. These relationships may create, or may create the appearance of, conflicts of interest when these directors and officers face decisions that could have different implications for Elan than for us.

Risks Related to Our Ordinary Shares

A sustained 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 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:

- 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;
- our ability to obtain financing as needed;
- 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.

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.

Your percentage ownership in Prothena may be diluted in the future.

Your percentage ownership in us may be diluted in the future because of equity issuances for acquisitions, capital market transactions or otherwise. We may need to raise additional capital in the future. If we are able to raise additional capital, we may issue equity or convertible debt instruments, which may severely dilute your ownership interest in us. In addition, we intend to continue to grant option awards to our directors, officers and employees, which would dilute your ownership stake in us. As of September 30, 2013, the number of ordinary shares authorized under our equity plan is 2,650,000.

Future sales of our ordinary shares could adversely affect the trading price of our ordinary shares.

All of our ordinary shares will be freely tradable without restriction or further registration under the Securities Act unless the shares are “restricted securities” under the Securities Act or are owned by our “affiliates” as those terms are defined in the rules under the Securities Act. “Restricted securities” and shares held by “affiliates” may be sold in the public market if registered or if they qualify for an exemption from registration under Rule 144. Further, we have filed a registration statement to cover the shares issuable under our equity-based benefit plans.

In addition, subsequent to our October 2013 equity offering, a wholly-owned subsidiary of Elan held approximately 15% of our outstanding ordinary shares. The ordinary shares held by a wholly-owned subsidiary of Elan are restricted securities, and Elan has agreed to cause the disposition of our ordinary shares as soon as a disposition is warranted consistent with the business purposes for Elan’s retention of our ordinary shares. We have agreed that, upon the request of Elan, we will use our reasonable best efforts to effect a registration under applicable federal and state securities laws of any of our ordinary shares issued to Elan. The sales of significant amounts of our ordinary shares or the perception in the market that this will occur may result in the lowering of the market price of our ordinary shares.

In connection with our October 2013 equity offering, Elan agreed not to dispose of or hedge any shares or any securities convertible into or exchangeable for our ordinary shares for a period of 90 days from October 2, 2013.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

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

SIGNATURES

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

Dated: November 12, 2013

Prothena Corporation plc
(Registrant)

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

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

EXHIBIT INDEX

The following exhibits have been filed with this report:

Exhibit No.	Description	Previously Filed				Filed Herewith
		Form	File No.	Filing Date	Exhibit	
2.2	Amendment Number One to the Amended and Restated Intellectual Property License and Contribution Agreement, retroactively effective December 20, 2012, by and among Neotope Biosciences Limited, Elan Pharma International Limited, Elan Pharmaceuticals, LLC, Elan Corporation, plc, and Crimagua Limited	S-1/A	333-191218	9/30/2013	2.2(b)	
3.1	Amended and Restated Memorandum and Articles of Association of Prothena Corporation plc	10-K	001-35676	3/29/2013	3.1	
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					X
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					X
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					X
101.INS+	XBRL Instance Document					X
101.SCH+	XBRL Taxonomy Extension Schema Document					X
101.CAL+	XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF+	XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB+	XBRL Taxonomy Extension Label Linkbase Document					X

101.PRE+	XBRL Taxonomy Extension Presentation Linkbase Document	X

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* 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.