Prothena Corp plc Form 10-Q May 05, 2014

#### 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 March 31, 2014 Or

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

Commission file number: 001-35676

## PROTHENA CORPORATION PUBLIC LIMITED COMPANY

(Exact name of registrant as specified in its charter)

Ireland	98-1111119
(State or other jurisdiction of	(I.R.S. Employer
incorporation or organization)	Identification Number)
650 Gateway Boulevard	94080
South San Francisco, California	94000
(Address of principal executive offices)	(Zip Code)
Registrant's telephone number, including area code: (650)	837-8550

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  $\circ$  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  $\circ$  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 o Accelerated filer  $\circ$ 

Non-accelerated filer o(Do not check if a smaller reporting company) Smaller reporting company o 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 April 25, 2014 was 21,904,780.

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## PART I. FINANCIAL INFORMATION

#### ITEM 1. FINANCIAL STATEMENTS

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

(unautited)	March 31, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	\$195,052	\$176,677
Receivable from Roche	2,161	—
Receivable from related party	46	58
Deferred tax assets	77	81
Prepaid expenses and other current assets	2,262	1,406
Total current assets	199,598	178,222
Non-current assets:		
Property and equipment, net	3,233	3,372
Deferred tax assets	979	816
Total non-current assets	4,212	4,188
Total assets	\$203,810	\$182,410
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	\$2,128	\$1,790
Accrued research and development	4,359	1,542
Income taxes payable		184
Other current liabilities	2,477	3,890
Total current liabilities	8,964	7,406
Non-current liabilities:		
Deferred rent	1,835	1,734
Total liabilities	10,799	9,140
Commitments and contingencies (Note 6)		
Shareholders' equity:		
Euro deferred shares, €22 nominal value:		—
Authorized shares — 10,000 at March 31, 2014 and December 31, 2013		
Issued and outstanding shares — none at March 31, 2014 and December 31, 2013		
Ordinary shares, \$0.01 par value:	219	219
Authorized shares — 100,000,000 at March 31, 2014 and December 31, 2013		
Issued and outstanding shares — 21,904,780 and 21,856,261 at March 31, 2014 and		
December 31, 2013, respectively		
Additional paid-in capital	216,281	214,392
Accumulated deficit	(23,489)	(41,341)
Total shareholders' equity	193,011	173,270
Total liabilities and shareholders' equity	\$203,810	\$182,410
See accompanying Notes to Condensed Consolidated Financial Statements.		

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

	Three Month	ns Ended March	n 31,
	2014	2013	
Collaboration revenue	\$32,096	\$—	
Revenue—related party	138	171	
Total revenue	32,234	171	
Operating expenses:			
Research and development	9,342	5,957	
General and administrative	4,873	3,181	
Total operating expenses	14,215	9,138	
Income (loss) from operations	18,019	(8,967	)
Other income (expense):			
Interest income	19	22	
Other income (expense), net	(35	) —	
Total other income (expense)	(16	) 22	
Income (loss) before income taxes	18,003	(8,945	)
Provision for income taxes	151	6	
Net income (loss)	\$17,852	\$(8,951	)
Net income (loss) per share attributable to holders of ordinary shares			
Basic	\$0.82	\$(0.51	)
Diluted	\$0.78	\$(0.51	)
Shares used to compute net income (loss) per share attributable to holders of ordinary shares			
Basic	21,884	17,679	
Diluted	22,942	17,679	
See accompanying Notes to Condensed Consolidated Financial Statements.			

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

	Three Months 2014	s Ended March 2013	31,
Operating activities			
Net income (loss)	\$17,852	\$(8,951	)
Adjustments to reconcile net income (loss) to cash provided by (used in) operating activities:			
Depreciation and amortization	175	137	
Share-based compensation	1,343	340	
Excess tax benefit from share-based award exercises	(207	) —	
Deferred income taxes	(159	) —	
Changes in operating assets and liabilities:	(	,	
Receivable from Roche	(2,161	) —	
Receivable from related party	12	(38	)
Other assets	(707	) (271	)
Accounts payable, accruals and other liabilities	1,746	3,680	,
Net cash provided by (used in) operating activities	17,894	(5,103	)
Investing activities			/
Purchases of property and equipment	(26	) (110	)
Net cash used in investing activities	(26	) (110	ý
Financing activities		, ( -	/
Post separation adjustments to the funding provided by Elan		(84	)
Proceeds from issuance of ordinary shares upon exercise of stock options	310	<u> </u>	/
Excess tax benefit from share-based award exercises	207		
Public offering costs	(10	) —	
Net cash provided by (used in) financing activities	507	(84	)
Net increase (decrease) in cash and cash equivalents	18,375	(5,297	ý
Cash and cash equivalents, beginning of the year	176,677	124,860	,
Cash and cash equivalents, end of the period	\$195,052	\$119,563	
	1 )		
Supplemental disclosures of cash flow information			
Cash paid for income taxes, net of refunds	\$436	\$23	
1 '			
Supplemental disclosures of non-cash investing and financing activities			
Acquisition of property and equipment under accounts payable and accrued liabilitie	s \$10	\$—	
Accrued deferred offering costs	\$43	\$—	
See accompanying Notes to Condensed Consolidated Financial Statements.			

1.Organization

Description of Business

Prothena Corporation plc and subsidiaries ("Prothena" or the "Company") is a clinical stage biotechnology company focused on the discovery, development and commercialization of novel antibodies for the potential treatment of diseases that involve protein misfolding or cell adhesion. The Company is focused on therapeutic monoclonal antibodies directed specifically to disease causing proteins. The Company's antibody-based product candidates target a number of potential indications including AL and AA forms of amyloidosis (NEOD001), Parkinson's disease and other related synucleinopathies (PRX002) and novel cell adhesion targets involved in inflammatory diseases and cancers (PRX003). 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.

The Company is a public limited company formed under the laws of Ireland. The Company separated from Elan Corporation Limited, formerly Elan Corporation, plc ("Elan"), which was subsequently acquired by Perrigo Company plc ("Perrigo"), on December 20, 2012. Prothena's 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 are referred to herein as the "Prothena Business"). Prior to December 21, 2012, the Prothena Business operated as part of Elan and not as a separate stand-alone entity. After the separation from Elan, and the related distribution of the Company's ordinary shares to Elan's shareholders (the "Separation and Distribution"), the Company's ordinary shares to Elan's shareholders (the "Separation and Distribution"), the Company's ordinary shares to Elan's shareholders (the "Separation and Distribution"), the Company's ordinary shares to Elan's shareholders (the symbol "PRTA" on December 21, 2012 and currently trade on The NASDAQ Global Select Market.

#### Liquidity and Business Risks

As of March 31, 2014, the Company had an accumulated deficit of \$23.5 million and cash and cash equivalents of \$195.1 million, respectively. Based on the Company's business plans, management believes that the Company's cash and cash equivalents at March 31, 2014 are sufficient to meet its obligations for at least the next twelve months. To operate beyond such period, or if the Company elects to increase its spending on development programs significantly above current long-term plans or enters into potential licenses and or other acquisitions of complementary technologies, products or companies, the Company 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 \$84.5 million, after deducting the underwriting discount and estimated offering expenses, in an underwritten public offering.

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 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on March 7, 2014 (the "2013 Form 10-K"). The Condensed Consolidated Financial Statements of Prothena Corporation plc are presented in U.S. dollars, which is the functional currency of the Company. 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.

#### 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 presentation 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 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. Although we achieved net income in the first quarter of 2014, primarily as a result of the \$30.0 million upfront milestone payment under the License Agreement, we expect to incur substantial losses for the foreseeable future.

#### 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 March 31, 2014, 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, 2013 on Form 10-K, other than those listed below. Revenue Recognition

Revenue is recognized when earned and non-refundable, when payment is reasonably assured, and when there is no future obligation with respect to the revenue, in accordance with the terms prescribed in the applicable contract.

#### Multiple Element Arrangements

The Company's revenues are generated primarily through its license, development and commercialization agreement. These types of agreements generally contain multiple elements, or deliverables, which may include (i) licenses to the Company's technology, (ii) R&D activities to be performed on behalf of the collaborative partner, and (iii) in certain cases, services or obligations in connection with the manufacturing or supply of pre-clinical and clinical material. Payments to the Company under these arrangements typically include one or more of the following: non-refundable, upfront license fees; funding of research and/or development efforts; milestone payments; and royalties on future product sales.

Revenue under license, development and commercialization agreements is recognized based on the performance requirements of the contract. Determinations of whether persuasive evidence of an arrangement exists and whether delivery has occurred or services have been rendered are based on management's judgments regarding the fixed nature

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of the fees charged for deliverables and the collectability of those fees.

The Company recognizes revenue related to license, development and commercialization agreements in accordance with the provisions of Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 605-25, "Revenue Recognition - Multiple-Element Arrangements." The Company evaluates all deliverables within an arrangement to determine whether or not they provide value on a stand-alone basis. Based on this evaluation, the deliverables are separated into units of

accounting. The arrangement consideration that is fixed or determinable at the inception of the arrangement is allocated to the separate units of accounting based on their relative selling prices.

To determine the selling price of a separate deliverable, the Company uses the hierarchy as prescribed in ASC Topic 605-25 based on vendor-specific objective evidence (VSOE), third-party evidence (TPE) or best estimate of selling price (BESP). VSOE is based on the price charged when the element is sold separately and is the price actually charged for that deliverable. TPE is determined based on third party evidence for a similar deliverable when sold separately and BESP is the estimated selling price at which we would transact a sale if the elements of collaboration and license arrangements were sold on a stand-alone basis to the buyer.

Payments or full reimbursements resulting from our R&D efforts for those arrangements where such efforts are considered as deliverables are recognized as the services are performed and are presented on a gross basis so long as there is persuasive evidence of an arrangement, the fee is fixed or determinable, and collection of the related receivable is reasonably assured. However, such funding is recognized as a reduction of R&D expense when the Company engages in a R&D project jointly with another entity, with both entities participating in project activities and sharing costs and potential benefits of the project.

Milestone Revenue

The Company accounts for milestones under ASU No. 2010-17, Milestone Method of Revenue Recognition. Under the milestone method, contingent consideration received from the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity's performance or on the occurrence of a specific outcome resulting from the entity's performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, and (iii) that would result in additional payments being due to the entity. At the inception of an agreement that includes milestone payments, the Company evaluates whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether (a) the consideration is commensurate with either (1) the entity's performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, (b) the consideration relates solely to past performance, and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. The Company evaluates factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve a particular milestone, the level of effort and investment required to achieve such milestone and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment.

The Company generally classifies each of its milestones into one of three categories: (i) clinical milestones, (ii) regulatory and development milestones, and (iii) commercial milestones. Clinical milestones are typically achieved when a product candidate advances into or completes a defined phase of clinical research. For example, a milestone payment may be due to the Company upon the initiation of a clinical trial for a new indication. Regulatory and development milestones are typically achieved upon acceptance of the submission for marketing approval of a product candidate or upon approval to market the product candidate by the FDA or other regulatory authorities. For example, a milestone payment may be due to the Company upon filing of a Biologics License Application (BLA) with the FDA. Commercial milestones are typically achieved when an approved pharmaceutical product reaches certain defined levels of net royalty sales by the licensee of a specified amount within a specified period.

Commercial milestone payments and milestone payments that are not deemed to be substantive will be accounted for as a contingent revenue payment with revenue recognized when all contingencies are lifted, which is expected to be upon achievement of the milestone, assuming all revenue recognition criteria are met.

Profit Share Revenue

For agreements, with profit sharing arrangements, the Company will record its share of the pre-tax commercial profit as collaboration revenue when the profit sharing can be reasonably estimated and collectability is reasonably assured.

Royalty Revenue

The Company will recognize revenue from royalties based on licensees' sales of the Company's products or products using the Company's technologies. Royalties are recognized as earned in accordance with the contract terms when royalties from licensees can be reasonably estimated and collectability is reasonably assured. Net Income per Ordinary Share

Basic net income per ordinary share is computed by dividing net income attributable to ordinary shareholders by the weighted average number of ordinary shares outstanding during the period less the weighted average number of unvested restricted ordinary shares subject to the right of repurchase. Diluted net income per ordinary share is computed by giving effect to all dilutive potential ordinary shares including options.

Comprehensive Income (Loss)

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

Segment and Concentration of Risks

The Company operates in one segment. The Company's chief operating decision maker (the "CODM"), its Chief Executive Officer, manages the Company's operations on a consolidated basis for purposes of allocating resources. When evaluating the Company's financial performance, the CODM reviews all financial information on a consolidated basis.

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash and cash equivalents and accounts receivable. The Company places its cash equivalents with high credit quality financial institutions and by policy, limits the amount of credit exposure with any one financial institution. Deposits held with banks may exceed the amount of insurance provided on such deposits. The Company has not experienced any losses on its deposits of cash and cash equivalents and its credit risk exposure is up to the extent recorded on the Company's consolidated balance sheet.

The Company's accounts receivable are derived from Elan located in Ireland for all periods presented. For the quarter ended March 31, 2014 it also included amounts due from Roche entities located in the U.S. and Switzerland under the License Agreement that became effective January 22, 2014. All of the Company's long-lived assets were held in the United States. Revenue recorded in the Statements of Operations consists of collaboration revenue related to the upfront payment from Roche under the License Agreement and reimbursement for research and development services and 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.

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

Emerging Growth Company Status

As an Emerging Growth Company under the Jumpstart Our Business Startups Act ("JOBS Act"), the Company is eligible to take advantage of certain exemptions from various reporting requirements that apply 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.

**Recent Accounting Pronouncements** 

In July 2013, the FASB issued ASU 2013-11, Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit when a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists, on the financial statement presentation of unrecognized tax benefits. The new guidance provides that a liability related to an unrecognized tax benefit 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 can be applied prospectively to unrecognized tax benefits that exist at the effective date with retrospective applications permitted. The Company has presented its unrecognized tax benefits as a reduction in its deferred tax assets in its Condensed

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Consolidated balance sheet as of December 31, 2013 and March 31, 2014.

3. Fair Value Measurements

The Company measures certain financial assets and liabilities at fair value on a recurring basis, including cash equivalents. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on

assumptions that market participants would use in pricing an asset or a liability. A three-tier fair value hierarchy is established as a basis for considering such assumptions and for inputs used in the valuation methodologies in measuring fair value:

- Level 1 Observable inputs such as quoted prices (unadjusted) for identical assets or liabilities in active markets. 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
- Level 2 which all significant inputs are observable in the market or can be derived from observable market data. Where applicable, these models project future cash flows and discount the future amounts to a present value using market-based observable inputs including interest rate curves, foreign exchange rates, and credit ratings. Level 3  $\frac{\text{Unobservable inputs that are supported by little or no market activities, which would require the Company to$

## 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. The carrying amounts of certain financial instruments, such as cash equivalents, accounts receivable, accounts payable and accrued liabilities, approximate fair value due to their relatively short maturities, and low market interest rates, if applicable.

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 \$173.9 million and \$153.3 million in money market funds included in cash and cash equivalents at March 31, 2014 and December 31, 2013, respectively.

4. Composition of Certain Balance Sheet Items

Property and Equipment, net

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

	March 31, 2014	December 31, 2013
Machinery and equipment	\$5,660	\$5,649
Leasehold improvements	1,927	1,927
Purchased computer software	110	85
	7,697	7,661
Less: accumulated depreciation and amortization	(4,464	) (4,289 )
Property and equipment, net	\$3,233	\$3,372

Depreciation and amortization expense was \$0.2 million and \$0.1 million for the three months ended March 31, 2014 and 2013, respectively.

Other Current Liabilities

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

	March 31,	December 31,
	2014	2013
Payroll and related expenses	\$1,266	\$2,800
Professional services	688	616
Accrued offering costs	43	82
Deferred rent	138	138
Other	342	254
Other current liabilities	\$2,477	\$3,890
5. Net income (loss) Per Share		

Basic net income (loss) per share is calculated by dividing net income (loss) by the weighted-average number of ordinary shares outstanding during the period. Shares used in diluted net income (loss) 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 three months ended March 31, 2013, and therefore diluted net loss per share is equal to basic net loss per share. During the three months ended March 31, 2014, diluted net income per ordinary share is computed by giving effect to all dilutive potential ordinary shares including options.

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

	Three Months Ended March 31,		
	2014	2013	
Numerator (basic and dilutive):			
Net income (loss)	\$17,852	\$(8,951	)
Denominator (basic):			
Weighted-average ordinary shares outstanding	21,884	17,679	
Denominator (diluted):			
Weighted-average ordinary shares outstanding	21,884	17,679	
Dilutive stock options outstanding	1,058		
Net weighted average ordinary shares outstanding	22,942	17,679	
Net income (loss) per share attributable to holders of ordinary shares:			
Basic net income (loss) per share	\$0.82	\$(0.51	)
Diluted net income (loss) per share	\$0.78	\$(0.51	)
The equivalent ordinary shares not included in diluted net income (loss) per s	hare because their of	fact would be	

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

	Three Months Ended March 31,	
	2014	2013
Period end stock options to purchase ordinary shares	390	914
Restricted stock units	—	_
Total	390	914
6. Commitments and Contingencies		

Operating Lease

The Company has a noncancelable operating lease agreement for office and research and development space in the U.S. that expires in November 2020 with an estimated annual rent payment of approximately \$1.9 million. The lease provides for approximately 50,400 of rentable square feet at a base rent that increases annually.

Future minimum payments under operating leases as of March 31, 2014, are as follows (in thousands):

Year Ended December 31,	Operating Lease
2014 (Remaining 9 months)	\$980
2015	1,756
2016	1,930
2017	2,009
2018	2,089
Thereafter	4,230
Total future minimum lease payments	\$12,994

The Company recognizes rent expense on a straight-line basis over the noncancelable lease term and records the difference between cash rent payments and the recognition of rent expense as a deferred rent liability. Where leases contain escalation clauses, rent abatements, and/or concessions, such as rent holidays and landlord or tenant incentives or allowances, the Company applies them in the determination of straight-line rent expense over the lease term. The Company records the tenant improvement allowance as deferred rent and associated expenditures as leasehold improvements that are being amortized over the shorter of their estimated useful life or the term of the lease. Rent expense was \$0.4 million and \$0.3 million for the three months ended March 31, 2014 and 2013, respectively. Indemnity Obligations

The Company has entered into indemnification agreements with its current, and former, directors and officers and certain key employees. These agreements contain provisions that may require the Company, among other things, to indemnify such persons against certain liabilities that may arise because of their status or service and advance their expenses incurred as a result of any indemnifiable proceedings brought against them. The obligations of the Company pursuant to the indemnification agreements continue during such time as the indemnified person serves the Company and continues thereafter until such time as a claim can be brought. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited; however, the Company has a director and officer insurance policy that limits its exposure and enables the Company to recover a portion of any future amounts paid. As a result of its insurance policy coverage, the Company believes the estimated fair value of these indemnification agreements is minimal. Accordingly, the Company had no liabilities recorded for these agreements as of March 31, 2014 and 2013.

#### Commitments

As of March 31, 2014, the Company had non-cancelable purchase commitments to suppliers for \$4.7 million of which \$3.2 million is included in accrued current liabilities, and contractual obligations under license agreements of \$1.0 million. The following is a summary of the Company's non-cancelable purchase commitments and contractual obligations as of March 31, 2014 (in thousands):

	Total	2014 (Remainin 9 months)	e	2016	2017	2018	Thereafter
Purchase Obligations	\$4,741	\$ 4,741	\$—	\$—	\$—	\$—	\$—
Contractual obligations under license agreements <sup>(1)</sup>	1,049	64	85	85	85	85	645
Total	\$5,790	\$ 4,805	\$85	\$85	\$85	\$85	\$645

<sup>(1)</sup> Excludes future obligations pursuant to the cost-sharing arrangement under the Company's License Agreement with Roche. Amounts of such obligations, if any, cannot be determined at this time.

#### 7. Roche License Agreement

Overview

In December 2013, the Company entered into a License, Development, and Commercialization Agreement, or the License Agreement, with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc., or collectively, Roche, to develop and commercialize certain antibodies that target alpha-synuclein, including PRX002, which are referred to collectively as "Licensed Products." On January 22, 2014 the License Agreement with Roche became effective following the expiration of the Hart-Scott-Rodino (HSR) waiting period. Upon the effectiveness of the License Agreement, the Company granted to Roche an exclusive, worldwide license to develop, make, have made, use, sell, offer to sell, import, and export the Licensed Products. The Company will retain certain rights to conduct development of the License Agreement, the Company and Roche will work exclusively with each other to research and develop antibody products targeting

alpha-synuclein potentially including incorporation of Roche's proprietary Brain Shuttle<sup>™</sup> technology to potentially increase delivery of therapeutic antibodies to the brain. The License Agreement provides that Roche would make an upfront payment to the Company of \$30.0 million, which was received in February 2014, and the clinical milestone payment of \$15.0 million triggered by the initiation of the Phase 1 study for PRX002 in the clinic, which occurred in April 2014.

For PRX002, Roche is also obligated to pay:

• up to \$380.0 million upon the achievement of development, regulatory and various first commercial sales milestones;

• up to an additional \$175.0 million in ex-U.S. commercial sales milestones; and

• tiered, high single-digit to high double-digit royalties in the teens on ex-U.S. annual net sales, subject to certain adjustments.

Roche bears 100% of the cost of conducting the research activities under the License Agreement. In the United States, the parties will share all development and commercialization costs, as well as profits, all of which will be allocated 70% to Roche and 30% to the Company, for PRX002 in the Parkinson's disease indication, as well as any other Licensed Products and/or indications for which the Company opts in to participate in co-development and co-funding. After the completion of specific clinical trial activities, the Company may opt out of the co-development and cost and profit sharing on any co-developed Licensed Products and instead receive U.S. commercial sales milestones totaling up to \$155.0 million and tiered, single-digit to high double-digit royalties in the teens based on U.S. annual net sales, subject to certain adjustments, with respect to the applicable Licensed Product.

The Company filed an investigational new drug application with the U.S. Food and Drug Administration for PRX002 and subsequently initiated a Phase 1 study in 2014. Following the Phase 1 study, Roche will be primarily responsible for developing, obtaining and maintaining regulatory approval for, and commercializing Licensed Products. Roche will also become responsible for the clinical and commercial manufacture and supply of Licensed Products within a defined time period following the effective date of the License Agreement.

In addition, the Company has an option under the License Agreement to co-promote PRX002 in the U.S. in the Parkinson's disease indication. If the Company exercises such option, it may also elect to co-promote additional Licensed Products in the U.S. approved for Parkinson's disease. Outside the U.S., Roche will have responsibility for developing and commercializing the Licensed Products. Roche bears all costs for product clinical development in support of regulatory approval for all territories outside the U.S. and will pay the Company a variable royalty based on annual net sales of the Licensed Products outside the U.S.

While Roche will record product revenue from sales of the Licensed Products, the Company and Roche will share in the net profits and losses of sales of the PRX002 for the Parkinson's disease indication in the U.S. on a 70/30% basis with the Company receiving 30% of the profit and losses provided that the Company has not exercised its opt-out right.

The License Agreement continues on a country-by-country basis until the expiration of all payment obligations under the License Agreement. The License Agreement may also be terminated (i) by Roche at will after the first anniversary of the effective date of the License Agreement, either in its entirety or on a Licensed Product-by-Licensed Product basis, upon 90 days' prior written notice to the Company prior to first commercial sale and 180 days' prior written notice to Prothena after first commercial sale, (ii) by either party, either in its entirety or on a Licensed Product-by-Licensed Product or region-by-region basis, upon written notice in connection with a material breach uncured 90 days after initial written notice, and (iii) by either party, in its entirety, upon insolvency of the other party. The License Agreement may be terminated by either party on a patent-by-patent and country-by-country basis if the other party challenges a given patent in a given country. The Company's rights to co-develop Licensed Products under the License Agreement will terminate if the Company commences certain studies for certain types of competitive products. The Company's rights to co-promote Licensed Products under the License Agreement will terminate if the Company commences a Phase 3 study for such competitive products.

The License Agreement cannot be assigned by either party without the prior written consent of the other party, except to an affiliate of such party or in the event of a merger or acquisition of such party, subject to certain conditions. The License Agreement also includes customary provisions regarding, among other things, confidentiality, intellectual property ownership, patent prosecution, enforcement and defense, representations and warranties, indemnification, insurance, and arbitration and dispute resolution.

Collaboration accounting

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The License Agreement was evaluated under ASC 808, Collaborative Agreements. At the outset of the contract, the Company concluded that this agreement does not qualify as a collaboration under ASC 808 because Prothena is not an active participant as a result of the opt-out provision. The Company believes that Roche is the principal in the sales transactions with third parties as it is the primary obligor, bearing inventory and credit risk. The Company will record its share of pre-tax commercial profit generated from the collaboration with Roche, as collaboration revenue when the profit share can be reasonably estimated and collectability is reasonably assured. Prior to commercialization of a Licensed Product, the Company's portion of the expenses related to the License Agreement reflected on its income statement will be limited to R&D expenses. After commercialization, if the Company opts-in to co-detail commercialization expenses related to commercialization efforts, will be recorded as SG&A expense and will be

factored into the computation of the profit and loss share. The Company will record the portion of the net receivable related to commercialization activities as collaboration revenue.

Multiple Element Consideration

The License Agreement was evaluated under ASC 605-25, Multiple Element Arrangements. The License Agreement includes the following deliverables: (1) an exclusive royalty bearing license, with the right to sublicense to develop and commercialize certain antibodies that target alpha-synuclein, including PRX002 delivered at the effective date; (2) the Company's obligation to supply clinical material as requested by Roche for a period up to twelve months; (3) the Company's obligation to provide manufacturing related services to Roche for a period up to twelve months; (4) the Company's obligation to provide development activities under the development plan including the preparation and filing of the IND and initiation of the Phase I clinical trial estimated to be carried out over the next two years and (5) the Company's obligation to provide indeterminate research services for up to three years at rates that are not significantly discounted and fully reimbursable by Roche.

All of the deliverables were deemed to have stand-alone value and to meet the criteria to be accounted for as separate units of accounting under ASC Topic 605-25. Factors considered in the determination included, among other things, for the license, the research and development capabilities of Roche and Roche's sublicense rights, and for the remaining deliverables the fact that they are not proprietary and can be and have been provided by other vendors. The amount of allocable arrangement consideration is limited to amounts that are fixed or determinable excluding refund rights, concessions or performance bonuses. As such, the Company will exclude from such allocable consideration the milestone payments and royalties regardless of the probability of receipt because such payments are not considered fixed or determinable. Such milestone payments and royalties will be evaluated separately as the related contingencies are resolved. Consideration for research services were not allocated as the amount is not fixed and determinable and is not at a significant incremental discount. There are no refund rights, concessions or performance bonuses to consider.

The Company allocated the fixed and determinable consideration to the license and other deliverables using the relative selling price method based on the best estimate of selling price for the license and third party evidence for the remaining deliverables. The best estimate of selling price for the license was based on a discounted cash flow model. The key assumptions used in the discounted cash flow model used to determine the best estimate of selling price for the license granted to Roche under the License Agreement included the market opportunity for commercialization of PRX002 in the U.S. and the Royalty Territory (for jointly funded products the Royalty Territory is worldwide except for the U.S. for all Licensed Products that are not jointly funded the Royalty Territory is worldwide), the probability of successfully developing and commercializing PRX002, the remaining development costs for PRX002, and the estimated time to commercialization of PRX002.

The Company's discounted cash flow model included several market conditions and entity-specific inputs, including the likelihood that clinical trials will be successful, the likelihood that regulatory approval will be obtained and the product commercialized, the appropriate discount rate, the market locations, size and potential market share of the product, the expected life of the product, and the competitive environment for the product. The market assumptions were generated using a patient-based forecasting approach, with key epidemiological, market penetration, dosing, compliance, length of treatment, and pricing assumptions derived from primary and secondary market research, referenced from third-party sources.

The Company concluded that a change in the assumptions used to determine the BESP of the license deliverable would not have a significant effect on the allocation of arrangement consideration. Based on the relative selling price method, the amount that the Company recognized on the effective date of the agreement concurrent with the delivery of the license and know-how was limited to the lesser of the amount otherwise allocable using the relative selling price method, which based on the discounted cash flow model was determined to be \$34.7 million, or the non-contingent amount which was the \$30.0 million upfront fee. As the remaining deliverables are delivered, any consideration received will be allocated to license revenue and the other deliverables based on their relative

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percentages until such time as the full allocated consideration of \$34.7 million has been recognized as license revenue, and the balance of the monetary consideration will be recorded as an offset against R&D expenses. The Company recognized the \$30.0 million upfront payment as collaboration license revenue in the three months ended March 31, 2014.

The Company will recognize the research reimbursement as collaboration revenue as earned. The Company recognized \$0.3 million as collaboration service revenue in the three months ended March 31, 2014 for research reimbursement from Roche. Cost sharing payments to Roche will be recorded as R&D expenses. The Company recognized \$0.2 million in R&D expense for payments made to Roche during the three months ended March 31, 2014. Reimbursement for development costs from Roche under the cost-sharing arrangement will be allocated between license revenue and an offset to R&D expenses based on the relative selling price method until the full allocated consideration of \$34.7 million has been recognized as license revenue, after which the full

reimbursement would be recorded as an offset to R&D expenses. Reimbursement for development costs from Roche during the three months ended March 31, 2014 were \$2.0 million, of which \$1.8 million was recognized as collaboration license revenue and \$0.2 million was recognized as an offset to R&D expenses. Milestone accounting

The Company concluded that the \$15.0 million clinical milestone triggered upon the initiation of the Phase 1 study from PRX002 in the clinic, which occurred in April 2014 is consistent with the definition of a substantive milestone included in ASU No. 2010-17, Milestone Method of Revenue Recognition. Accordingly, the Company will recognize payments related to the achievement of this milestone when the milestone is achieved. The milestone payment will be allocated to the units of accounting based on the relative selling price method for income statement classification purposes. Factors considered in this determination included scientific and regulatory risk that must be overcome to achieve each milestone, the level of effort and investment required to achieve the milestone, and the monetary value attributed to the milestone.

The clinical and regulatory milestones under the License Agreement after the point at which the Company could opt-out are not considered to be substantive due to the fact that active participation in the development actives that generate the milestones is not required by the License Agreement, and the Company can opt-out of these activities. There are no refund or claw-back provisions and the milestones are uncertain of occurrence even after the Company has opted out. Based on this determination, these milestones will be recognized similar to the commercial milestone, which will be accounted for as contingent revenue payments with revenue recognized upon achievement of the milestone assuming all revenue recognition criteria are met.

The Company did not recognize any milestone payments under the License Agreement during the three months ended March 31, 2014.

8. Shareholders' Equity

Ordinary Shares

As of March 31, 2014, the Company had 100,000,000 ordinary shares authorized for issuance with a par value of \$0.01 per share and 21,904,780 ordinary shares issued and outstanding. Each ordinary share is entitled to one vote and, on a pro rata basis, to dividends when declared and the remaining assets of the Company in the event of a winding up.

Euro Deferred Shares

As of March 31, 2014, the Company had 10,000 Euro Deferred Shares authorized for issuance with a nominal value of €22 per share. No Euro Deferred Shares are outstanding at March 31, 2014. The rights and restrictions attaching to the Euro Deferred Shares rank pari passu with the ordinary shares and are treated as a single class in all respects. February 2014 Offering

In February 2014 Elan Science One Limited, or ESOL, an indirect wholly owned subsidiary of Perrigo Company plc, or Perrigo, sold 3,182,253 ordinary shares of Prothena at a price to the public of \$26.00 per ordinary share, before the underwriting discount. As a result, ESOL and Perrigo no longer own any ordinary shares of Prothena.

The Company did not receive any of the proceeds from the offering, and the total number of the Company's ordinary shares outstanding did not change as a result of this offering. The Company paid the costs associated with the sale of these ordinary shares (other than the underwriting discount, fees and disbursements of counsel for the selling shareholder) pursuant to a Subscription and Registration Rights Agreement dated November 8, 2012 by and between the Company, Elan and ESOL.

9. Share-Based Compensation

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. Options under the LTIP may be granted for periods up to ten years. All options issued to date have had a ten year life. Under the LTIP, the Company is authorized

to issue a total of 2,650,000 ordinary shares. During the three months ended March 31, 2014 and 2013, the Company granted 509,000 and 1,366,000 share options, respectively, under its LTIP. The Company's options awards generally vest over four years. As of March 31, 2014, 167,500 ordinary shares

remain available for grant and options to purchase 2,433,981 ordinary shares granted from the LTIP were outstanding with a weighted-average exercise price of approximately \$12.19 per share. In March 2014, our Board approved an increase of 2.9 million additional ordinary shares authorized for issuance under our 2012 Long Term Incentive Plan, subject to shareholder approval.

Prothena 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 values 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. Since the Company has no historic employee share option exercise data, the simplified method has been used to estimate the expected life of all options. Although the fair value of share 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 results of operations, although it will have no impact on its overall financial position. The amount of unearned share-based compensation currently estimated to be expensed from now through the year 2017 related to unvested share-based payment awards at March 31, 2014 is \$16.9 million. The weighted-average period over which the unearned share-based compensation is expected to be recognized is 3.1 years. If there are any modifications or cancellations of the underlying unvested securities, the Company may be required to accelerate, increase or cancel any remaining unearned share-based compensation 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 months ended March 31, 2014 and 2013 was based on awards from the LTIP granted to Prothena employees. The following table summarizes share-based compensation expense for the periods presented (in thousands):

	Three Mon	Three Months Ended		
	March 31,			
	2014	2013		
Research and development <sup>(1)</sup>	\$483	\$79		
General and administrative	860	261		
Total	\$1,343	\$340		

<sup>(1)</sup> Includes \$46,000 and zero of share-based compensation expense for the three months ended March 31, 2014 and 2013, respectively, related to an option granted to a consultant.

The fair value of the options granted to employees during the three months ended March 31, 2014 and 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 March 31,	
	2014	2013
Expected volatility	83.9%	84.0%
Risk-free interest rate	1.8%	1.0%
Expected dividend yield	%	%
Expected life (in years)	6.0	6.0
Weighted average grant date fair value	\$21.20	\$4.32

The following table summarizes the Company's share option activity during the three months ended March 31, 2014:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2013	1,973,500	\$7.50	9.17	\$37,528
Granted	509,000	29.80		
Canceled				
Outstanding at March 31, 2014	2,433,981	\$12.19	9.12	\$63,581
Vested and expected to vest at March 31, 2014	2,322,548	\$12.02	9.11	\$61,065
Vested at March 31, 2014	640,161	\$6.40	8.87	\$20,426

The following table summarizes information about the Company's share options outstanding as of March 31, 2014: Options Outstanding Weighted

			Weighted -			
			Average	Weighted		Weighted
Range of Ex	xercise Prices	Number of Optio	Remaining	Average	Number of Option	nsAverage
			Contractual Life	Exercise Price		<b>Exercise</b> Price
			(Years)			
\$6.03	\$6.03	453,375	8.83	\$6.03	131,437	\$6.03
6.41	6.41	809,606	8.83	6.41	354,058	6.41
6.65	6.65	50,000	8.96	6.65	50,000	6.65
6.73	6.73	366,000	9.00	6.73	104,666	6.73
8.21	17.63	162,500	9.22	12.15		_
20.04	20.04	13,500	9.50	20.04		_
20.17	20.17	40,000	9.43	20.17	—	
24.26	24.26	30,000	9.59	24.26	—	
29.52	29.52	25,000	9.84	29.52		_
29.81	29.81	484,000	9.85	29.81	—	
\$6.03	\$29.81	2,433,981	9.12	\$12.19	640,161	\$6.40

10. Income Taxes

The major taxing jurisdictions for the Company are Ireland and the U.S.. The Company's income tax provision was \$151,000 and \$6,000 for the three months ended March 31, 2014 and 2013, respectively. The provision for income taxes differs from the statutory tax rate of 12.5% applicable to Ireland primarily due to Irish net operating losses for which a tax provision benefit is not recognized and due to U.S. income taxed at different rates. Our income tax provision reflects our estimate of the effective tax rate expected to be applicable for the full year and we re-evaluate this estimate each quarter based on our forecasted tax expense for the full year. Jurisdictions with a projected loss for the year where no tax benefit can be recognized are excluded from the estimated annual effective tax rate. The Company's deferred tax assets are composed primarily of its Irish subsidiaries' net operating loss carryovers, state net operating loss carryforwards available to reduce future taxable income of the Company's U.S. subsidiary, federal and state tax credit carryforwards and other temporary differences. We maintain a valuation allowance against certain U.S. federal and state and Irish deferred tax assets. Each reporting period, we evaluate the need for a valuation allowance on our deferred tax assets by jurisdiction.

No provision for income tax in Ireland has been recognized on undistributed earnings of our foreign subsidiaries because we consider such earnings to be indefinitely reinvested.

11. Related Parties

Prior to December 21, 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 separation). Elan was subsequently acquired by Perrigo Company plc, or Perrigo, in December 2013 and such 3,182,253 ordinary shares were held by Elan Science One Limited, or ESOL, an indirect wholly owned subsidiary of Perrigo as of December 31, 2013.

February 2014 Offering

In February 2014, ESOL sold 3,182,253 ordinary shares of Prothena at a price to the public of \$26.00 per ordinary share, before the underwriting discount. As a result, ESOL and Perrigo no longer owned any ordinary shares of Prothena as of such sale.

The Company did not receive any of the proceeds from the offering, and the total number of the Company's ordinary shares outstanding did not change as a result of this offering. The Company paid the expenses associated with the sale of these ordinary shares (other than the underwriting discount, fees and disbursements of counsel for the selling shareholder) pursuant to a Subscription and Registration Rights Agreement dated November 8, 2012 by and between the Company, Elan and ESOL.

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. The related party revenue recognized by the Company for the three months ended March 31, 2014 and 2013 consisted of fees arising from R&D services provided to Elan. Additionally, the results of operations for the time period prior to the separation 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 would provide to the Company, and the Company would 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 included 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 payment terms of the agreement generally provided that the Company would 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%. Similarly, Elan would pay the Company for the time spent by each of the Company's employee providing services to Elan, which would 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 TSA expired on December 31, 2013.

**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 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. Revenue recognized by the Company for the three months ended March 31, 2014 and 2013 included fees arising from R&D services provided to Elan of \$138,000 and \$171,000, respectively.

#### 12. Subsequent Events

In April 2014, the Company together with Roche initiated a Phase 1 clinical trial of PRX002. The study is a randomized, double-blind, placebo-controlled, single ascending dose study in healthy subjects. It is designed to assess PRX002 for safety, tolerability, pharmacokinetics and immunogenicity. As a result of this initiation, the Company earned a \$15.0 million milestone payment from Roche under the License Agreement.

# 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 "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "due," "estimate," "expect," "goal," "intend," " "plan," "predict," "potential," "positioned," "seek," "should," "target," "will," "would," and other similar expressions that are p of or indicate future events and future trends, or the negative of these terms or other comparable terminology. Forward-looking statements are subject to risks and uncertainties, and actual events or results may differ materially. Factors that could cause our actual results to differ materially include, but are not limited to, those discussed under "Risk Factors" in this report. We also face risks and uncertainties relating to our business including: our ability to obtain additional financing in future offerings;

our operating losses;

our collaboration with Roche pursuant to the License Agreement to develop and commercialize PRX002, as well as any future licensed products targeting alpha-synuclein;

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;

expected activities and responsibilities of us and Roche under the License Agreement;

our potential receipt of revenue under the License Agreement, including milestone and royalty revenue;

the satisfaction of conditions under the License Agreement required for continued commercialization, and the payment of potential milestone payments, royalties and fulfillment of other Roche obligations under the License Agreement;

expectations with respect to our intent and ability to carry out plans to promote PRX002 for the treatment of Parkinson's disease in the U.S. through our co-promotion option under the License Agreement;

our ability to protect our patents and other intellectual property;

loss of key employees;

tax treatment of our separation from Elan, now owned by Perrigo, and subsequent distribution of our ordinary shares; restrictions on our taking certain actions due to tax rules and covenants with Elan;

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;

business disruptions caused by information technology failures; and

• the other risks and uncertainties described in Part II, Item 1, "Risk Factors" of this quarterly report and the risk factors in our Annual Report on Form 10-K.

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 2013 Form 10-K.

#### Overview

We are a clinical stage biotechnology company focused on the discovery, development and commercialization of novel antibodies for the potential treatment of diseases that involve protein misfolding or cell adhesion. We focus on therapeutic monoclonal antibodies directed specifically to disease causing proteins. Our antibody-based product candidates target a number of potential indications including AL and AA forms of amyloidosis (NEOD001), Parkinson's disease and other related synucleinopathies (PRX002) and novel cell adhesion targets involved in inflammatory diseases and cancers (PRX003). Our strategy is to identify antibody candidates for clinical development and commercialization 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. We separated from Elan Corporation Limited (formerly Elan Corporation, plc), or Elan, which subsequently became a wholly owned subsidiary of Perrigo Company plc, or Perrigo, on December 20, 2012. Our ordinary shares began trading on The NASDAQ Global Market under the symbol "PRTA" on December 21, 2012 and currently trade on The NASDAQ Global Select Market. 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"). Prior to December 21, 2012, the Prothena Business operated as part of Elan and not as a separate stand-alone entity. 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 Note 2 of the "Notes to the Consolidated Financial Statements" included in Item 8 of the 2013 Form 10-K.

Recent Developments

#### NEOD001

On April 23, 2014, we announced interim findings from the ongoing Phase 1 clinical trial of NEOD001. On April 29, 2014, we presented interim data demonstrating cardiac biomarker responses from the ongoing Phase 1 study in patients with AL amyloidosis and persistent organ dysfunction at the XIV International Symposium on Amyloidosis, conference in Indianapolis, Indiana. The interim findings support the planned advancement of the NEOD001 clinical program into a Phase 2/3 study later this year.

#### **PRX002**

In April 2014, we together with Roche initiated a Phase 1 clinical trial of PRX002. The study is a randomized, double-blind, placebo-controlled, single ascending dose study in healthy subjects. It is designed to assess PRX002 for safety, tolerability, pharmacokinetics and immunogenicity. As a result of this initiation, we earned a \$15.0 million milestone payment from Roche under the License Agreement, as described below. Collaboration with Roche

In December 2013, we entered into a License, Development, and Commercialization Agreement, or the License Agreement, with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc., or collectively, Roche, to develop and commercialize certain antibodies that target alpha-synuclein, including PRX002, which are referred to collectively as "Licensed Products." The License Agreement became effective following the expiration of the applicable Hart-Scott-Rodino waiting period on January 17, 2014, which triggered an upfront payment to us of \$30.0 million from Roche, which we received in February 2014.

Pursuant to the License Agreement, we and Roche will collaborate to research and develop antibody products targeting alpha-synuclein. Roche will provide funding for a research collaboration between us and Roche focused on optimizing early stage antibodies targeting alpha-synuclein, potentially including incorporation of Roche's proprietary Brain Shuttle<sup>TM</sup> technology to increase delivery of therapeutic antibodies to the brain.

We filed an investigational new drug application with the U.S. Food and Drug Administration, or FDA for PRX002 and subsequently initiated a Phase 1 study in 2014. Following the Phase 1 study, Roche will be primarily responsible for

developing, obtaining and maintaining regulatory approval for, and commercializing Licensed Products. Roche will also become responsible for the clinical and commercial manufacture and supply of Licensed Products within a defined time period following the effective date of the License Agreement.

In addition to the \$30.0 million upfront payment and the clinical milestone payment of \$15.0 million triggered by the initiation of the Phase 1 study for PRX002 in the clinic, which occurred in April 2014, for PRX002, Roche is also obligated to pay the following:

• up to \$380.0 million upon the achievement of development, regulatory and various first commercial sales milestones;

 $\bullet$  up to an additional \$175.0 million in ex-U.S. commercial sales milestones; and

• tiered, high single-digit to high double-digit royalties in the teens on ex-U.S. annual net sales, subject to certain adjustments.

In the U.S., the parties will share all development and commercialization costs, as well as profits, all of which will be allocated 70% to Roche and 30% to us, for PRX002 in the Parkinson's disease indication, as well as any other Licensed Products and/or indications for which we opt in to co-develop and co-fund. We may opt out of the co-development and cost and profit sharing on any co-developed Licensed Products and instead receive U.S. commercial sales milestones totaling up to \$155.0 million and tiered, single-digit to high double-digit royalties in the teens based on U.S. annual net sales, subject to certain adjustments, with respect to the applicable Licensed Product. In addition, we have an option under the License Agreement to co-promote PRX002 in the U.S. in the Parkinson's disease indication. If we exercise such option, we may also elect to co-promote additional Licensed Products in the U.S. approved for Parkinson's disease. Outside the U.S., Roche will have responsibility for developing and commercializing the Licensed Products.

February 2014 Offering

In February 2014 Elan Science One Limited, or ESOL, an indirect wholly owned subsidiary of Perrigo Company plc, or Perrigo, sold 3,182,253 ordinary shares of Prothena. The ordinary shares were sold at a price to the public of \$26.00 per ordinary share, before the underwriting discount. As a result, ESOL and Perrigo no longer owned any ordinary shares of Prothena as of such sale.

We did not receive any of the proceeds from the offering. We paid the costs associated with the sale of these ordinary shares (other than the underwriting discount, fees and disbursements of counsel for the selling shareholder) pursuant to a Subscription and Registration Rights Agreement dated November 8, 2012 by and between us, Elan and ESOL. 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 consolidated financial statements for the periods prior to December 21, 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. For additional information regarding the basis of preparation, refer to Note 2 of the "Notes to the Consolidated Financial Statements" included in Item 8 of the 2013 Form 10-K. Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our 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 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.

#### **Revenue Recognition**

Revenue is recognized when earned and non-refundable, when payment is reasonably assured, and when there is no future obligation with respect to the revenue, in accordance with the terms prescribed in the applicable contract. Multiple Element Arrangements

Our revenues are generated primarily through our license, development and commercialization agreement. These types of agreements generally contain multiple elements, or deliverables, which may include (i) licenses to our technology, (ii) R&D activities to be performed on behalf of the collaborative partner, and (iii) in certain cases, services or obligations in connection with the manufacturing or supply of pre-clinical and clinical material. Payments to us under these arrangements typically include one or more of the following: non-refundable, upfront license fees; funding of research and/or development efforts; milestone payments; and royalties on future product sales. Revenue under license, development and commercialization agreements is recognized based on the performance requirements of the contract. Determinations of whether persuasive evidence of an arrangement exists and whether delivery has occurred or services have been rendered are based on management's judgments regarding the fixed nature of the fees charged for deliverables and the collectability of those fees. Should changes in conditions cause management to determine that these criteria are not met for any new or modified transactions, revenue recognized could be adversely affected.

We recognize revenue related to license, development and commercialization agreements in accordance with the provisions of Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 605-25, "Revenue Recognition - Multiple-Element Arrangements." We evaluate all deliverables within an arrangement to determine whether or not they provide value on a stand-alone basis. Based on this evaluation, the deliverables are separated into units of accounting. The arrangement consideration that is fixed or determinable at the inception of the arrangement is allocated to the separate units of accounting based on their relative selling prices. We may exercise significant judgment in determining whether a deliverable is a separate unit of accounting, as well as in estimating the selling prices of such unit of accounting. A change in such judgment could result in a significant change in the period in which revenue is recognized.

To determine the selling price of a separate deliverable, we use the hierarchy as prescribed in ASC Topic 605-25 based on vendor-specific objective evidence (VSOE), third-party evidence (TPE) or best estimate of selling price (BESP). VSOE is based on the price charged when the element is sold separately and is the price actually charged for that deliverable. TPE is determined based on third party evidence for a similar deliverable when sold separately and BESP is the estimated selling price at which we would transact a sale if the elements of collaboration and license arrangements were sold on a stand-alone basis to the buyer. We may not be able to establish VSOE or TPE for the deliverables within collaboration and license arrangements, as we may not have a history of entering into such arrangements or selling the individual deliverables within such arrangements separately. In addition, there may be significant differentiation in these arrangements, which indicates that comparable third party pricing may not be available. We may determine that the selling price for the deliverables within collaboration and license arrangements should be determined using BESP. The process for determining BESP involves significant judgment on our part and includes consideration of multiple factors such as estimated direct expenses and other costs, and available data. Payments or full reimbursements resulting from our R&D efforts for those arrangements where such efforts are considered as deliverables are recognized as the services are performed and are presented on a gross basis so long as there is persuasive evidence of an arrangement, the fee is fixed or determinable, and collection of the related receivable is reasonably assured. However, such funding is recognized as a reduction of R&D expense when we engage in a R&D project jointly with another entity, with both entities participating in project activities and sharing costs and potential benefits of the project. Accordingly, reimbursement of R&D expenses pursuant to the cost-sharing provisions of our agreements with Roche is recognized as a reduction to R&D expense. Milestone Revenue

We account for milestones under ASU No. 2010-17, Milestone Method of Revenue Recognition. Under the milestone method, contingent consideration received from the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity's performance or on the occurrence of a specific outcome resulting from the entity's performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, and (iii) that would result in additional payments being due to the entity. At the inception of an agreement that includes milestone payments, we evaluate whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an

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assessment of whether (a) the consideration is commensurate with either (1) the entity's performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, (b) the consideration relates solely to past performance, and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. We evaluate factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this

assessment. The conclusion as to whether milestone payments are substantive involves management judgment regarding the factors noted above.

We generally classify each of our milestones into one of three categories: (i) clinical milestones, (ii) regulatory and development milestones, and (iii) commercial milestones. Clinical milestones are typically achieved when a product candidate advances or completes a defined phase of clinical research. For example, a milestone payment may be due to us upon the initiation of a clinical trial for a new indication. Regulatory and development milestones are typically achieved upon acceptance of the submission for marketing approval of a product candidate or upon approval to market the product candidate by the FDA or other regulatory authorities. For example, a milestone payment may be due to us upon filing of a Biologics License Application (BLA) with the FDA. Commercial milestones are typically achieved when an approved pharmaceutical product reaches certain defined levels of net royalty sales by the licensee of a specified amount within a specified period.

Commercial milestone payments and milestone payments that are not deemed to be substantive will be accounted for as a contingent revenue payment with revenue recognized when all contingencies are lifted, which is expected to be upon achievement of the milestone, assuming all revenue recognition criteria are met.

### Profit Share Revenue

For agreements, with profit sharing arrangements, we will record our share of the pre-tax commercial profit as collaboration revenue when the profit sharing can be reasonably estimated and collectability is reasonably assured. If profit sharing estimates are materially different from actual results it could impact the amount of revenue recognized in future periods. If the profit share cannot be reasonably estimated or collectability of the profit share amount is not reasonably assured, our portion of the profit share it could impact the amount of revenue recognized in future periods. Royalty Revenue

We will recognize revenue from royalties based on licensees' sales of our products or products using its technologies. Royalties are recognized as earned in accordance with the contract terms when royalties from licensees can be reasonably estimated and collectability is reasonably assured. If we can no longer estimate royalty revenue or our estimates are materially different from actual results it could impact the amount of revenue recognized in future periods.

## Share-based Compensation

We account for our share-based compensation in accordance with the fair value recognition provisions of current authoritative guidance. Share-based awards, including stock options, are measured at fair value as of the grant date and recognized to expense over the requisite service period (generally the vesting period), which we have elected to amortize on a straight-line basis. Since share-based compensation expense is based on awards ultimately expected to vest, it has been reduced by an estimate for future forfeitures. We estimate forfeitures at the time of grant and revise our estimate, if necessary, in subsequent periods. We estimate the fair value of options granted using the Black-Scholes option valuation model. Significant judgment is required in determining the proper assumptions used in these models. The assumptions used include the risk free interest rate, expected term, expected volatility and expected dividend yield. We base our assumptions on historical data when available or when not available, on a peer group of companies. However, these assumptions consist of estimates of future market conditions, which are inherently uncertain, and therefore subject to our judgment and therefore any changes in assumptions could significantly impact the future grant date fair value of share-based awards.

Total share-based compensation expense for the three months ended March 31, 2014 and 2013 was \$1.3 million, and \$0.3 million, respectively.

## **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 described in Note 2 to the Condensed Consolidated Financial Statements under the heading "Recent Accounting Pronouncements", there have been no new accounting pronouncements or changes to accounting

pronouncements during the three months ended March 31, 2014, as compared to the recent accounting pronouncements described in our 2013 Form 10-K, that are of significance or potential significance to us.

## Results of Operations Comparison of Three Months Ended March 31, 2014 and 2013 Revenue

	Three Months Ended March 31,20142013		Percentage Change 2014/2013	
	(Dollars in thou			
Collaboration revenue	\$32,096	\$—	nm	
Revenue—related party	138	171	(19	)%
Total revenue	\$32,234	\$171	nm	

nm = not meaningful

Total revenue for the three months ended March 31, 2014 and 2013 was \$32.2 million compared to \$0.2 million, respectively. Collaboration revenue includes reimbursements under our License Agreement with Roche, which became effective January 22, 2014. Collaboration revenue for the three months ended March 31, 2014 consisted of a one-time, non-refundable, non-creditable upfront payment of \$30.0 million, reimbursement for development costs of \$2.0 million, of which, \$1.8 million was recognized as collaboration license revenue and reimbursement of \$0.3 million for research services.

We are eligible to receive a \$15.0 million payment from Roche upon achievement of a clinical milestone related to the initiation of the Phase 1 study for PRX002 in the clinic, which occurred in April 2014.

Related-party revenue for the three months ended March 31, 2014 and 2013 was comprised of fees earned from the provision of research and development services to Elan (acquired by Perrigo). Total related-party revenue decreased by \$33,000, or 19%, during the three months ended March 31, 2014 compared to the prior year due to a reduction in the scope of the R&D services provided to Elan.

**Operating Expenses** 

	Three Months Ended March 31,			Percentage Change	
	2014 2013		2014/2013		
	(Dollars in thousands)				
Research and development	\$9,342	5,957	57	%	
General and administrative	4,873	3,181	53	%	
Total operating expenses	\$14,215	\$9,138	56	%	

Total operating expenses consist of research and development, or R&D expense and general and administrative, or G&A, expenses. Our operating expenses for the three months ended March 31, 2014 and 2013 were \$14.2 million and \$9.1 million, respectively. Our R&D expenses primarily consisted 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 costs of providing research services to Elan's ELND005 program. Pursuant to our License Agreement with Roche, in 2014 we began making payments to Roche for our share of the development expenses incurred by Roche related to PRX002 programs, which is included in our R&D expense. We recorded reimbursements from Roche for development and supply services based on the relative percentages as an offset to R&D expense. Our G&A expenses primarily consist of professional services expenses and personnel costs and related expenses, including share-based compensation. Research and Development Expenses

Our R&D expenses increased by \$3.4 million, or 57%, for the three months ended March 31, 2014 compared to the same period in the prior year. The increase for the three months ended March 31, 2014 compared with the same period in the prior year

was primarily due to increased external expenses, related to drug development and drug manufacturing primarily associated with our PRX002 and PRX003 programs and higher personnel costs including share-based compensation expenses.

We expect our R&D expenses to increase in 2014 primarily due to increased spending for the with the manufacturing costs and IND enabling toxicology studies for PRX003, the initiation of a Phase 2/3 clinical trial for NEOD001 and higher costs associated with development and manufacturing costs incurred under our cost-sharing arrangement with Roche including the initiation of a Phase 1 clinical trial for PRX002.

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;

elinical 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 with successful first patient dosing in a Phase 1 clinical trial) NEOD001, PRX002 and other R&D expenses for the three months ended March 31, 2014 and 2013, and the cumulative amounts to date (in thousands):

	Three Months Ended March 31,		Cumulative	
	2014	2013	to Date	
NEOD001 <sup>(1)</sup>	\$1,474	\$866	\$28,710	
PRX002 <sup>(2)</sup>	2,571	1,979	23.508	
Other R&D <sup>(3)</sup>	5,297	3,112		
	\$9,342	\$5,957		

Cumulative R&D costs to date for NEOD001 include the costs incurred from the date when the program has been

- <sup>(1)</sup> separately tracked in preclinical development. Expenditures in the early discovery stage are not tracked by program and accordingly have been excluded from this cumulative amount.
- Cumulative R&D costs to date for PRX002 include the costs incurred from the date when the program has been
   (2) separately tracked in preclinical development. Expenditures in the early discovery stage are not tracked by program and accordingly have been excluded from this cumulative amount.

Other R&D is comprised of preclinical development and discovery programs that have not had successful first

(3) patient dosing in a Phase 1 clinical trial, including PRX003, and research costs we incurred in providing research services to Elan's ELND005 program.

General and Administrative Expenses

Our G&A expenses increased by \$1.7 million, or 53%, for the three months ended March 31, 2014 compared to the same period in prior year. The increase in expenses over the prior year related primarily to higher personnel costs including share-based compensation expenses and increased legal costs associated with being a public company.

The Company expects G&A expenses to increase in 2014 over the prior year primarily due to increases in personnel, legal and other administrative expenses associated with a growing public company.

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## Other Income (Expense)

	Three Months Ended March 31		Change	
	2014	2014 2013		)13
	(Dollars in thousands)			
Interest income	\$19	\$22	(14	)%
Other income (expense), net	(35	) —	nm	
Total Other Income (Expense)	\$(16	) 22	(173	)%

#### nm = not meaningful

Interest income decreased by \$3,000 for the three months ended March 31, 2014 compared to the same period in prior year primarily due to lower interest earned on our cash and money market accounts. Other income (expense), net was primarily due to foreign exchange losses from transactions with vendors denominated in Euros. Provision for Income Taxes

	Three Months H	Percentage Change	
	2014	2013	2014/2013
	(Dollars in thousands)		
Provision for income taxes	\$151	6	nm

The tax provision for the three months ended March 31, 2014 and 2013, was \$151,000 and \$6,000, respectively. The tax provision reflects U.S. federal taxes associated with nominal, recurring profits attributable to intercompany services that the Company's U.S. subsidiary performs for the Company. 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

	March 31,	December 31,
	2014	2013
Working capital	\$190,634	\$170,816
Cash and cash equivalents	195,052	176,677
Total assets	203,810	182,410
Other non-current liabilities	1,835	1,734
Total liabilities	10,799	9,140
Total shareholders' equity	193,011	173,270

Working capital was \$190.6 million at March 31, 2014, an increase of \$19.8 million from working capital as of December 31, 2013. This increase was principally attributable to a higher net cash and cash equivalents balance of \$18.4 million primarily due to the \$30.0 million upfront payment from Roche.

As of March 31, 2014, we had \$195.1 million in cash and cash equivalents which includes the \$30.0 million upfront payment we received in February 2014 from Roche pursuant to the License Agreement. In addition, we are eligible to receive a \$15.0 million payment from Roche upon achievement of a clinical milestone related to the initiation of the Phase 1 study for PRX002 in the clinic, which occurred in April 2014. 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

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capital in the future in order to continue the research and development of our drug candidates. As of March 31, 2014, \$7.1 million of our outstanding cash and cash equivalents related to U.S. operations that management asserted was permanently reinvested. If these funds were repatriated back to Ireland we would incur a withholding tax from the dividend distribution.

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 current and potential future collaborations; and the timing, receipt, and amount of revenues or royalties, if any, from any approved drug candidates. Pursuant to the License Agreement with Roche, in the U.S., we and Roche will share all development and commercialization costs, as well as profits, all of which will be allocated 70% to Roche and 30% to us, for PRX002 in the Parkinson's disease indication, as well as any other Licensed Products and/or indications for which we opt in to co-develop and co-fund. In order to develop and obtain regulatory approval for our potential products we may need to raise substantial additional funds. We expect to raise any such additional funds through public or private equity or debt financings, collaborative agreements with corporate partners or other arrangements. We cannot assume that such additional financings will be available on acceptable terms, if at all, and such financings may only be available on terms dilutive to our shareholders.

Cash Flows for the Three Months Ended March 31, 2014 and 2013

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

	Three Months Ended March 31,			
	2014	2013		
Net cash provided by (used in) operating activities	\$17,894	\$(5,103	)	
Net cash used in investing activities	(26	) (110	)	
Net cash provided by (used in) financing activities	507	(84	)	
Net increase (decrease) in cash and cash equivalents	\$18,375	\$(5,297	)	
Cash Drawidad hay (Used in) One mating Astivities				

Cash Provided by (Used in) Operating Activities

Net cash provided by operating activities was \$17.9 million for three months ended March 31, 2014 primarily due to receipt of the upfront payment of \$30.0 million from Roche partially offset by \$14.2 million in expenses and adjusted to exclude non-cash charges and increases in accrued liabilities. Net cash used in operating activities was \$5.1 million for the three months ended March 31, 2013 consisting primarily of net losses (adjusted to exclude non-cash charges) offset by increases to accounts payable and other liabilities.

Cash Used in Investing Activities

Net cash used in investing activities was \$26,000 and \$110,000 for the three months ended March 31, 2014 and 2013, respectively, consisting of purchases of property and equipment.

Cash Provided by (Used in) Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2014 was \$0.5 million primarily consisting of proceeds from issuance of common stock upon exercise of stock options. Net cash used in financing activities was \$0.1 million for the three months ended March 31, 2013, consisted of the final settlement of liabilities as a result of our separation from Elan.

**Off-Balance Sheet Arrangements** 

At March 31, 2014, 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 March 31, 2014 consist of operating leases of \$13.0 million, contractual obligations under license agreements of \$1.0 million and purchase obligations of \$4.7 million of which \$3.2 million is included in the accrued current liabilities. Operating leases represent our future minimum rental commitments under our operating leases. Purchase obligations represent our non-cancelable purchase commitments to suppliers. The following is a summary of our contractual obligations as of March 31, 2014 (in thousands):

	-	2014					
	Total	(remaining	g 2015	2016	2017	2018	Thereafter
		9 months)					
Operating leases	\$12,994	\$ 980	\$1,756	\$1,930	\$2,009	\$2,089	\$4,230
Purchase Obligations	4,741	4,741		—	—	—	—
Contractual obligations under license agreements <sup>(1)</sup>	1,049	64	85	85	85	85	645
Total	\$18,784	\$ 5,785	\$1,841	\$2,015	\$2,094	\$2,174	\$4,875

<sup>(1)</sup> Excludes future obligations pursuant to the cost-sharing arrangement under our License Agreement with Roche. Amounts of such obligations, if any, cannot be determined at this time.

# 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. We recorded a loss on foreign currency exchange rate differences of approximately \$36,000 during the three months ended March 31, 2014. At this time, we do not believe that our foreign exchange risk is material. However, if we continue or increase our business activities that require the use of foreign currencies, we may incur further losses if the Euro and other such currencies strengthen against the U.S. dollar.

## Interest Rate Risk

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 interest rate 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 are to preserve principal and maintain proper liquidity to meet our operating requirements. Our investment policy also specifies credit quality standards for our investments and limits the amount of credit exposure to any single issue, issuer or type of investment.

### Credit Risk

Our accounts receivables are due from two customers, Roche our collaboration partner and Elan (acquired by Perrigo) to whom we provide R&D services. We do not believe that our credit risk is significant. As of March 31, 2014, our receivables from these customers totaled \$2.2 million.

Financial instruments that potentially subject us to concentration of credit risk consist of cash and cash equivalents and accounts receivable. We place our cash and cash equivalents with high credit quality financial institutions and pursuant to our investment policy, we limit the amount of credit exposure with any one financial institution. Deposits held with banks may exceed the amount of insurance provided on such deposits. We have not experienced any losses on our deposits of cash and cash equivalents.

## ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer, or CEO, and chief financial officer, or CFO, evaluated the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15 under the Securities Exchange Act of 1934, as amended (Exchange Act), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our CEO and CFO concluded that, as of March 31, 2014, our disclosure controls and procedures are designed and are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our CEO and CFO, as appropriate, to allow timely decisions regarding required disclosure.

Our 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.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during our first fiscal quarter ended March 31, 2014 that 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 Annual Report on Form 10-K for 2013 includes a detailed discussion of our business and the risks to our business. You should carefully read that Form 10-K. You should also read and carefully consider the risks described below and the other information in this Quarterly Report on Form 10-Q. If any of such risks actually occur, our business, operating results, financial condition, cash flows or growth prospects would be adversely affected. 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 have not yet identified or that we currently think are immaterial could also have a material adverse affect our business, operating results, financial condition, cash flows or growth prospects, and could result in a loss of all or part of your investment.

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

We anticipate that we will incur losses for the foreseeable future and we may never sustain profitability. We may not generate the cash that is necessary to finance our operations in the foreseeable future. We earned net income of \$17.9 million for the three months ended March 31, 2014 and incurred losses of \$41.0 million and \$41.4 million for the years ended December 31, 2013 and 2012, respectively. Although we achieved net income in the first quarter of 2014, primarily as a result of the \$30.0 million upfront milestone payment under the License Agreement, we expect to incur substantial losses for the foreseeable future as we:

conduct our Phase 1 clinical trials for NEOD001 and PRX002 and initiate additional clinical trials, if supported by the results of these Phase 1 trials;

develop and commercialize our product candidates, including NEOD001, PRX002 and PRX003 and any other antibodies targeting alpha-synuclein pursuant to our License Agreement with Roche;

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 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 sustain profitability.

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

As of March 31, 2014, we had cash and cash equivalents of \$195.1 million. In addition, we earned a \$15.0 million clinical milestone payment from Roche in April 2014. 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 trials for NEOD001 and PRX002, and our development and commercialization activities, including our portion of similar costs relating to PRX002 in the United States pursuant to our License Agreement with Roche;

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 or PRX002. Under the License Agreement with Roche, we are responsible for 30% of all development and commercialization costs for PRX002 for the treatment of Parkinson's disease in the United States, and for any future Licensed Products and/or indications that we opt to co-develop in the United States, in each case unless we elect to opt out of profit and loss sharing. Our right to co-develop PRX002 and other Licensed Products under the License Agreement will terminate if we commence certain studies for a competitive product that treats Parkinson's disease or other indications that we opted to co-develop. In addition, our right to co-promote PRX002 and other Licensed Products will terminate if we commence a Phase 3 study for a competitive product that treats Parkinson's disease.

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 our ongoing clinical trials and to estimate anticipated completion dates with any degree of accuracy, which raises concerns that attempts to quantify costs and 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.