

Prothena Corp plc  
Form DEFA14A  
March 31, 2014

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

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SCHEDULE 14A  
(Rule 14a-101)  
INFORMATION REQUIRED IN PROXY STATEMENT  
SCHEDULE 14A INFORMATION  
Proxy Statement Pursuant to Section 14(a) of the  
Securities Exchange Act of 1934  
(Amendment No. )

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Filed by the Registrant

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Check the appropriate box:

- Preliminary Proxy Statement
- Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))
- Definitive Proxy Statement
- Definitive Additional Materials
- Soliciting Material Pursuant to § 240.14a-12

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PROTHENA CORPORATION PUBLIC LIMITED COMPANY  
(Exact name of registrant as specified in its charter)

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(Name of Person(s) Filing Proxy Statement, if other than the Registrant)

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Prothena Corporation plc

Directors' Report and Financial Statements

Year Ended: 31 December 2013

Registered number: 518146

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Prothena Corporation plc

Directors' Report and Financial Statements

	Page
Contents	
Directors and Other Information	<u>1</u>
Directors' Report	<u>2</u>
Statement of Directors' Responsibilities	<u>29</u>
Independent Auditor's Report	<u>30</u>
Group Financial Statements	
Consolidated Balance Sheets	<u>32</u>
Consolidated Statements of Operations	<u>33</u>
Consolidated Statements of Cash Flows	<u>34</u>
Consolidated Statements of Shareholders' Equity	<u>35</u>
Notes Forming Part of the Consolidated Financial Statements	<u>36</u>
Parent Company Financial Statements	
Parent Company Balance Sheet	<u>57</u>
Parent Company Statement of Cash Flows	<u>58</u>
Parent Company Statement of Shareholders' Equity	<u>59</u>
Parent Company Notes Forming Part of the Financial Statements	<u>60</u>

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Prothena Corporation plc

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Ireland

Registered Number 518146

Prothena Corporation plc

## Directors' Report

The directors present their annual report and audited financial statements for Prothena Corporation plc ("Prothena" or "the Company") and its subsidiary undertakings (collectively "the group") for the year ended 31 December 2013.

The directors have elected to prepare the Consolidated Financial Statements in accordance with Section 1 of the Companies (Miscellaneous Provisions) Act 2009 (as amended), which provides that a true and fair view of the state of affairs and profit or loss of the group may be given by preparing the financial statements in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"), as defined in Section 1(1) of the Companies (Miscellaneous Provisions) Act 2009 (as amended), to the extent that the use of those principles in the preparation of the financial statements does not contravene any provision of the Companies Acts, 1963-2013 or of any regulations made thereunder.

The Company was incorporated in Ireland as a private limited company under the name "Neotope Corporation Limited" on September 26, 2012. The Company was subsequently re-registered as a public limited company and changed the name of the company to "Neotope Corporation plc". On November 1, 2012, the Company's shareholders resolved to change the name of the company to "Prothena Corporation plc", and this was approved by the Irish Registrar of Companies on November 7, 2012.

## Principal Activities, Business Review and Future Developments

Prothena 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 initiated a Phase 1 clinical trial for NEOD001, with successful first patient dosing in April 2013. The Phase 1 clinical trial of NEOD001 is evaluating its safety and tolerability in patients with AL amyloidosis. The Company also plans to initiate Phase 1 clinical trials for PRX002 and PRX003 in 2014 and 2015, respectively. The Company's strategy is to identify antibody candidates for clinical development and commercialization 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 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.

## Results and Dividends

The group recorded a loss of \$41.0 million for the year ended December 31, 2013 (2012: loss of \$41.4 million). The consolidated results of the group are set out on page 33 of the financial statements. The directors do not recommend the payment of a dividend.



Prothena Corporation plc

Directors' Report (continued)

### Principal Risks and Uncertainties

You should carefully consider the risks described below, together with all of the other information included in this Directors Report in considering our business and prospects. Set forth below and elsewhere in this report and in other documents we file with the United States Securities Exchange Commission, or SEC, are descriptions of the risks and uncertainties that could cause our actual results to differ materially from the results contemplated by the forward-looking statements contained in this report. If any of the following risks materialize, our business could be materially harmed, and our financial condition, operating results, cash flows or growth prospectus could be adversely impacted and could result in a complete loss on your investment. Additional risks and uncertainties that are not yet identified or that we think are immaterial may also materially harm our business, financial condition or operating results.

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

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

We may not generate the cash that is necessary to finance our operations in the foreseeable future. We have not generated any significant third party external revenues to date. We have incurred losses of \$41.0 million, \$41.4 million and \$29.7 million for the years ended December 31, 2013, 2012, and 2011, respectively. We expect to continue to incur substantial losses for the foreseeable future as we:

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

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

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

As of December 31, 2013, we had cash and cash equivalents of \$176.7 million. In addition, we received a \$30.0 million upfront payment in February 2014 from Roche pursuant to the License Agreement because the applicable Hart-Scott-Rodino waiting period expired in January 2014. Also, we expect to receive a \$15.0 million near-term clinical milestone payment from Roche in 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 trial for NEOD001, 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 that we initiated in April 2013. We have also entered into the License Agreement under which we will collaborate with Roche to develop and commercialize PRX002. Under this License Agreement, 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 Phase 1 clinical trial or any future clinical trials for NEOD001, and to estimate the anticipated completion date with any degree of accuracy, or any potential future drug candidates, or to develop and receive regulatory approval for PRX002 and any future Licensed Products, and raises concerns that attempts to provide estimates of timing may be misleading by implying a greater degree of certainty than actually exists.

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

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

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

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



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

We are subject to the reporting and other obligations under the Securities Exchange Act of 1934, as amended, or the Exchange Act, including the requirements of Section 404 of the Sarbanes-Oxley Act of 2002, which require annual management assessments of the effectiveness of our internal control over financial reporting. However, our auditors will not be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 until we are no longer an “emerging growth company” as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, if we continue to take advantage of the exemptions available to us through the JOBS Act.

The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation to meet the detailed standards under the rules. During the course of its testing, our management may identify material weaknesses or deficiencies which may not be remedied in time to meet the deadline imposed by the Sarbanes-Oxley Act of 2002. These reporting and other obligations place significant demands on our management and administrative and operational resources, including accounting resources.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of Financial Statements for external purposes in accordance with accounting principles generally accepted in the United States. Any failure to maintain effective internal controls could have an adverse effect on our business, financial position and results of operations. Our historical financial information is not necessarily representative of the results we would have achieved as a separate, publicly traded company and may not be a reliable indicator of our future results.

Our financial results previously were included within the consolidated results of Elan; however, we were not directly subject to the reporting and other requirements of the Exchange Act until our separation from Elan on December 20, 2012, which we refer to herein as the “Separation and Distribution.” The historical financial information we have included or incorporated by reference in this report may not reflect what our results of operations, financial position and cash flows would have been had we been an independent, publicly traded company during the periods presented or what our results of operations, financial position and cash flows will be in the future. This is primarily because:

- our historical financial information reflects allocations for services historically provided to us by Elan, which allocations may not reflect the costs we will incur for similar services in the future as an independent company;

- subsequent to the completion of the Separation and Distribution, the cost of capital for our business may be higher than Elan’s cost of capital prior to the Separation and Distribution because Elan’s current cost of debt will likely be lower than ours; and

- our historical financial information does not reflect changes that we have incurred as a result of the separation of the Prothena Business from Elan, including changes in the cost structure, personnel needs, financing and operations of the contributed business as a result of the separation from Elan and from reduced economies of scale.

We are also responsible for the additional costs associated with being an independent, public company, including costs related to corporate governance and compliance with the rules of The NASDAQ Stock Market, or NASDAQ, and the SEC. In addition, we incur costs and expenses, including professional fees, to comply with Irish corporate and tax laws and financial reporting requirements and costs and expenses incurred in connection with holding the meetings of our board of directors, or our Board, in Ireland. Prior to the Separation and Distribution, the Prothena Business was operated by Elan as part of its broader corporate organization, rather than as an independent company. Elan or one of its affiliates performed various corporate functions for us, including, but not limited to, legal, treasury, accounting, auditing, risk management, information technology, human resources, corporate affairs, tax administration,

certain governance functions and external reporting. Our historical financial results include allocations of corporate expenses from Elan for these and similar functions. These allocations of cash and non-cash expenses are less than the comparable expenses we have incurred thus far as a separate publicly traded company. Therefore, our Consolidated Financial Statements may not be indicative of our future performance as an independent company. Our future success depends on our ability to retain key personnel and to attract, retain and motivate qualified personnel.

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

Our collaborators, prospective collaborators and suppliers may need assurances that our financial resources and stability on a stand-alone basis are sufficient to satisfy their requirements for doing or continuing to do business with us.

Some of our collaborators, prospective collaborators and suppliers may need assurances that our financial resources and stability on a stand-alone basis are sufficient to satisfy their requirements for doing or continuing to do business with us. If our collaborators, prospective collaborators or suppliers are not satisfied with our financial resources and stability, it could have a material adverse effect on our ability to develop our drug candidates, enter into licenses or other agreements and on our business, financial condition or results of operations.

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

We have entered into certain agreements with Elan in connection with the Separation and Distribution, which set forth the main terms of the separation and provide a framework for our initial relationship with Elan. These agreements may have terms that are materially disadvantageous to us or are otherwise not as favorable as those that might be negotiated between unaffiliated third parties. In December 2013, Elan was acquired by Perrigo and in February 2014, Perrigo caused Elan to sell all of its shares of Prothena in an underwritten offering. As a result of the acquisition of Elan by Perrigo and the subsequent sale of all of its shares of Prothena, Perrigo/Elan may be less willing to collaborate with us in connection with the agreements to which we and Elan are a party and other matters.

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

Our success is largely dependent on the success of our research and development programs, which are at an early stage. Our drug candidates are still in early stages of development and we have only one drug candidate in its first Phase 1 clinical trials. We may not be able to successfully discover, develop, obtain regulatory approval for or commercialize any drug candidates.

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

Before obtaining regulatory approvals for the commercial sale of any drug candidate for a target indication, we must demonstrate with substantial evidence gathered in well-controlled clinical trials, and, with respect to approval in the United States, to the satisfaction of the United States Food and Drug Administration, or FDA, or, with respect to approval in other countries, similar regulatory authorities in those countries, that the drug candidate is safe and effective for use for that target indication. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain, and subject to unanticipated delays. Despite our efforts, our drug candidates may not:

- offer improvement over existing, comparable products;
- be proven safe and effective in clinical trials; or
- meet applicable regulatory standards.

Positive results in preclinical studies of a drug candidate may not be predictive of similar results in humans during clinical trials, and promising results from early clinical trials of a drug candidate may not be replicated in later clinical trials. Interim results of a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries



have suffered significant setbacks in late-stage clinical trials even after achieving promising results in early-stage development. Accordingly, the results from completed preclinical studies and clinical trials for our drug candidates may not be predictive of the results we may obtain in later stage trials or studies. Our preclinical studies or clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials, or to discontinue clinical trials altogether.

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

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

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

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

We cannot predict whether we will encounter problems with our Phase 1 clinical trial for NEOD001 or any future clinical trials that will cause us or any regulatory authority to delay or suspend those clinical trials or delay the analysis of data derived from them. For example, our current Phase 1 NEOD001 clinical trial targets patients with amyloidosis, an orphan population with a relatively small pool of patients who may be eligible, accessible and interested in participating in clinical trials. A number of events, including any of the following, could delay the completion of our planned clinical trials and negatively impact our ability to obtain regulatory approval for, and to market and sell, a particular drug candidate:

- conditions imposed on us by the FDA or any foreign regulatory authority regarding the scope or design of our clinical trials;

- delays in obtaining, or our inability to obtain, required approvals from institutional review boards, or IRBs, or other reviewing entities at clinical sites selected for participation in our clinical trials;

- insufficient supply or deficient quality of our drug candidates or other materials necessary to conduct our clinical trials;

- delays in obtaining regulatory agency agreement for the conduct of our clinical trials;

- lower than anticipated enrollment and retention rate of subjects in clinical trials for a variety of reasons, including size of patient population, nature of trial protocol, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications;

- serious and unexpected drug-related side effects experienced by patients in clinical trials; or

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

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

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

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

- varying interpretation of data by the FDA or similar foreign regulatory authorities;
- failure to achieve primary or secondary endpoints or other failure to demonstrate efficacy;
- unforeseen safety issues; or

• lack of adequate funding to continue the clinical trial.

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

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

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

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

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

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

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



limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a drug candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that drug candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our drug candidates.

We rely on obtaining and maintaining orphan drug exclusivity for NEOD001, if approved, but may not ensure that we will enjoy market exclusivity in a particular market.

NEOD001 has been granted orphan drug designation by the FDA for the treatment of AL and AA amyloidosis and by the European Medicines Agency, or EMA, for the treatment of AL amyloidosis. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the European Union, the EMA's Committee for Orphan Medicinal Products, or COMP, grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union. Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biological product or where there is no satisfactory method of diagnosis, prevention, or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity. In the European Union, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Even though we have obtained orphan drug designation for NEOD001 in the United States and Europe, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. Further, even if we obtain orphan drug designation for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

Even if our drug candidates receive regulatory approval in the United States, we may never receive approval or commercialize our products outside of the United States.

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval would

impair our ability to develop foreign markets for our drug candidates.

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

Both before and after regulatory approval to market a particular drug candidate, the manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, distribution and record keeping related to the product are subject to

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

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

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

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

Undesirable side effects caused by our drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly. Even if any of our drug candidates receives marketing approval, as greater numbers of patients use a drug following its approval, an increase in the incidence of side effects or the incidence of other post-approval problems that were not seen or anticipated during pre-approval clinical trials could result in a number of potentially significant negative consequences, including:

- regulatory authorities may withdraw their approval of the product;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

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



We deal with hazardous materials and must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Some of our research and development activities involve the controlled storage, use, and disposal of hazardous materials. We are subject to federal, state, and local laws and regulations governing the use, manufacture, storage, handling, and disposal of these hazardous materials. Although we believe that our safety procedures for the handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident, state or federal authorities may curtail our use of these materials, and we could be liable for any civil damages that result, which may exceed our financial resources and may seriously harm our business. Because we believe that our laboratory and materials handling policies and practices sufficiently mitigate the likelihood of materials liability or third-party claims, we currently carry no insurance covering such claims. An accident could damage, or force us to shut down, our operations.

#### Risks Related to the Commercialization of Our Drug Candidates

Even if any of our drug candidates receives regulatory approval, if such approved product does not achieve broad market acceptance, the revenues that we generate from sales of the product will be limited.

Even if any drug candidates we may develop or acquire in the future obtain regulatory approval, they may not gain broad market acceptance among physicians, healthcare payors, patients and the medical community. The degree of market acceptance for any approved drug candidate will depend on a number of factors, including:

- the indication and label for the product and the timing of introduction of competitive products;
- demonstration of clinical safety and efficacy compared to other products;
- prevalence and severity of adverse side effects;
- availability of coverage and adequate reimbursement from managed care plans and other third-party payors;
- convenience and ease of administration;
- cost-effectiveness;
- other potential advantages of alternative treatment methods; and
- the effectiveness of marketing and distribution support of the product.

Consequently, even if we discover, develop and commercialize a product, the product may fail to achieve broad market acceptance and we may not be able to generate significant revenue from the product

The success of PRX002 in the United States is dependent upon the strength and performance of our collaboration with Roche. If we fail to maintain our existing collaboration with Roche, such termination would likely have a material adverse effect on our ability to commercialize PRX002 and our business. Furthermore, if we opt out of profit and loss sharing with Roche, our revenues from PRX002 will be reduced.

The success of sales of PRX002 in the United States will be dependent on the ability of Roche to successfully develop in collaboration with us, and launch and commercialize PRX002, if approved by the FDA, pursuant to the License Agreement we entered into in December 2013. Our collaboration with Roche is complex, particularly in the context of our U.S. commercialization of PRX002, with respect to financial provisions, allocations of responsibilities, and the respective rights of the parties in decision making. Accordingly, significant aspects of the commercialization of PRX002 require Roche to execute its responsibilities under the arrangement, or require Roche's agreement or approval, prior to implementation, which could cause significant delays that may materially impact the potential success of PRX002 in the U.S. In addition, Roche may under some circumstances independently develop products that compete with PRX002, or Roche may decide to not commit sufficient resources to the marketing and distribution of PRX002. If we are not able to collaborate effectively with Roche on plans and efforts to develop and commercialize PRX002, our business could be severely and adversely affected.

Furthermore, the terms of the License Agreement provide that Roche has the ability to terminate such arrangement for any reason after the first anniversary of the License Agreement at any time upon 90 days' notice (if prior to first commercial sale) or 180 days' notice (if after first commercial sale). For example, Roche may determine that the outcomes of clinical trials have made PRX002 a less attractive commercial product and terminate our collaboration. If the License Agreement is terminated, our business



and our ability to generate revenue from sales of PRX002 will be substantially harmed and we will be required to develop our own sales and marketing organization or enter into another strategic collaboration in order to commercialize PRX002 in the United States. Such efforts may not be successful and, even if successful, would require substantial time and resources to carry out.

The manner in which Roche launches PRX002, including the timing of launch and potential pricing, will have a significant impact on the ultimate success of PRX002 in the United States, and the success of the overall commercial arrangement with Roche. If launch of commercial sales of PRX002 in the United States by Roche is delayed or prevented, our revenue will suffer and our stock price will decline. Further, if launch and resulting sales by Roche are not deemed successful, our stock price will decline. Any lesser effort by Roche in its PRX002 sales and marketing efforts may result in lower revenue and thus lower profits with respect to the United States. The outcome of Roche's commercialization efforts in the United States could also have an effect on investors' perception of potential sales of PRX002 outside of the United States, which could also cause a decline in our stock price.

Furthermore, pursuant to the License Agreement, 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 each case unless we elect to opt out of profit and loss sharing. If we elect to opt out of profit and loss sharing, we will instead receive sales milestones and royalties, and our revenue, if any, from PRX002 will be reduced.

Our ability to receive any significant revenue from PRX002 will be dependent on Roche's efforts and our participation in profit and loss sharing, and may result in lower levels of income than if we marketed or developed our product candidates entirely on our own. Roche may not fulfill its obligations or carry out marketing activities for PRX002 as diligently as we would like. We could also become involved in disputes with Roche, which could lead to delays in or termination of commercialization programs and time-consuming and expensive litigation or arbitration. If Roche terminates or breaches the License Agreement, or otherwise decides not to complete its obligations in a timely manner, the chances of successfully developing or marketing PRX002 would be materially and adversely affected. Outside of the United States, we are solely dependent on the efforts and commitments of Roche, either directly or through third parties, to further commercialize PRX002. If Roche's efforts are unsuccessful, our ability to generate future product sales from PRX002 outside the United States would be significantly reduced.

Under our License Agreement, outside of the United States, Roche has responsibility for developing and commercializing PRX002 and any future Licensed Products targeting alpha-synuclein. As a consequence, any progress and commercial success outside of the United States is dependent solely on Roche's efforts and commitment to the program. For example, Roche may delay, reduce or terminate development efforts relating to PRX002 outside of the United States, or under some circumstances independently develop products that compete with PRX002, or decide not to commit sufficient resources to the marketing and distribution of PRX002.

In the event that Roche does not diligently commercialize PRX002, the License Agreement provides us the right to terminate the License Agreement in connection with a material breach uncured for 90 days after notice thereof. However, our ability to enforce the provisions of the License Agreement so as to obtain meaningful recourse within a reasonable timeframe is uncertain. Further, any decision to pursue available remedies including termination would impact the potential success of PRX002, including inside the United States, and we may choose not to terminate as we may not be able to find another partner and any new collaboration likely will not provide comparable financial terms to those in our arrangement with Roche. In the event of our termination, this may require us to commercialize PRX002 on our own, which is likely to result in significant additional expense and delay. Significant changes in Roche's business strategy, resource commitment and the willingness or ability of Roche to complete its obligations under our arrangement could materially affect the potential success of the product. Furthermore, if Roche does not successfully develop and commercialize PRX002 outside of the United States, our potential to generate future revenue outside of the United States would be significantly reduced.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell approved products, we may be unable to generate product revenue.

We do not currently have an organization for the sales, marketing and distribution of pharmaceutical products. In order to market any products that may be approved by the FDA, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. We have entered

into a strategic collaboration for PRX002 with Roche and may develop our own sales force and marketing infrastructure to co-promote PRX002 in the United States for the treatment of Parkinson's disease and any future Licensed Products approved for Parkinson's disease in the United



States. If we exercise our co-promotion option and are unable to develop our own sales force and marketing infrastructure to effectively commercialize PRX002 or other Licensed Products, our ability to generate additional revenue from potential sales of PRX002 or such products in the United States may be harmed. In addition, our right to copromote PRX002 and other Licensed Products will terminate if we commence a Phase 3 study for a competitive product that treats Parkinson's disease. For our other approved products, if we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable.

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

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

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

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

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers and enhanced penalties for non-compliance;

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

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

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

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

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

The markets for our drug candidates are subject to intense competition. If we are unable to compete effectively, our drug candidates may be rendered noncompetitive or obsolete.

The research, development and commercialization of new drugs is highly competitive. We will face competition with respect to all drug candidates we may develop or commercialize in the future from pharmaceutical and biotechnology companies worldwide. The key factors affecting the success of any approved product will be its indication, label, efficacy, safety profile, drug interactions, method of administration, pricing, coverage, reimbursement and level of promotional activity relative to those of competing drugs.

Furthermore, many large pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations are pursuing the development of novel drugs that target the same indications we are targeting with our research and development program. We face, and expect to continue to face, intense and increasing competition as new products enter the market and advanced technologies become available.

Many of our competitors have:

- significantly greater financial, technical and human resources than we have and may be better equipped to discover, develop, manufacture and commercialize drug candidates;
- more extensive experience in preclinical testing and clinical trials, obtaining regulatory approvals and manufacturing and marketing pharmaceutical products;



- drug candidates that have been approved or are in late-stage clinical development; and/or collaborative arrangements in our target markets with leading companies and research institutions

Competitive products may render our research and development program obsolete or noncompetitive before we can recover the expenses of developing and commercializing our drug candidates. Furthermore, the development of new treatment methods and/or the widespread adoption or increased utilization of any vaccine or development of other products or treatments for the diseases we are targeting could render any of our drug candidates noncompetitive, obsolete or uneconomical. If we successfully develop and obtain approval for a drug candidate, we will face competition based on the safety and effectiveness of the approved product, the timing of its entry into the market in relation to competitive products in development, the availability and cost of supply, marketing and sales capabilities, coverage, reimbursement, price, patent position and other factors. Even if we successfully develop drug candidates but those drug candidates do not achieve and maintain market acceptance, our business will not be successful.

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

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

We believe that any of our drug candidates approved as a biologic product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our drug candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biologic products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

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

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

the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;

federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other

third-party payors that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

15

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the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that impose criminal and civil liability for executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;

the federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to "payments or other transfers of value" made to physicians, which is defined to include doctors, dentists, optometrists, podiatrists and chiropractors, and teaching hospitals and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by the physicians and their immediate family members. Manufacturers were required to begin data collection on August 1, 2013, and to submit reports to CMS by March 31, 2014 and by the 90th day of each subsequent calendar year. CMS will commence disclosure of such information on a publicly available website by September 2014;

HIPAA, as amended by the Health Information Technology and Clinical Health Act, and its implementing regulations, which impose obligations on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; and

analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to significant civil, criminal, and administrative penalties, including, without limitation, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, damages, fines and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our collaborators, is found not to be in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also adversely affect our business.

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

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

- decreased demand for any approved drug candidates;
- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;

distractio**n** of management's attention;

16

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substantial monetary awards to patients or other claimants;  
loss of revenues; and the inability to successfully commercialize any approved drug candidates.

We currently have clinical trial liability insurance coverage in the aggregate amount of \$15.0 million annual coverage limit for our clinical trials, of which at least \$5.0 million annual coverage limit can be applied for our ongoing Phase 1 clinical trial of NEOD001. However, our insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for any of our drug candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain this product liability insurance on commercially reasonable terms. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

#### Risks Related to Our Dependence on Third Parties

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

We do not have the ability to independently conduct clinical trials for our drug candidates, and we rely on third parties, such as consultants, contract research organizations, medical institutions, and clinical investigators, to perform this function. Our reliance on these third parties for clinical development activities results in reduced control over these activities. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. Although we have and will enter into agreements with these third parties, we will be responsible for confirming that our clinical trials are conducted in accordance with their general investigational plans and protocols. Moreover, the FDA requires us to comply with regulations and standards, commonly referred to as cGCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities and requirements. If we or any of our third party contractors fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with cGCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

To date, we believe our consultants, contract research organizations and other similar entities with which we are working have performed well; however, if these third parties do not successfully carry out their contractual duties, meet expected deadlines, or comply with applicable regulations, we may be required to replace them. Although we believe that there are a number of other third-party contractors we could engage to continue these activities, we may not be able to enter into arrangements with alternative third-party contractors or to do so on commercially reasonable terms, which may result in a delay of our planned clinical trials. Accordingly, we may be delayed in obtaining regulatory approvals for our drug candidates and may be delayed in our efforts to successfully develop our drug candidates.

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

If we do not establish additional strategic collaborations, we may have to alter our research and development plans.

Our drug research and development programs and potential commercialization of our drug candidates will require substantial additional cash to fund expenses. Our strategy includes potentially collaborating with additional leading pharmaceutical and

17

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biotechnology companies to assist us in furthering development and potential commercialization of some of our drug candidates, in some or all geographies. It may be difficult to enter into one or more of such collaborations in the future. We face significant competition in seeking appropriate collaborators and these collaborations are complex and time-consuming to negotiate and document. We may not be able to negotiate collaborations on acceptable terms, or at all, in which case we may have to curtail the development of a particular drug candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring our drug candidates to market and generate product revenue.

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

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

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

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

We anticipate continued reliance on third-party manufacturers if we are successful in obtaining marketing approval from the FDA and other regulatory agencies for any of our drug candidates, and our commercialization of any of our drug candidates may be halted, delayed or made less profitable if those third parties fail to obtain such approvals, fail to provide us with sufficient quantities of drug product or fail to do so at acceptable quality levels or prices.

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

In addition, the facilities used by our contract manufacturers to manufacture our drug candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit a BLA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with

cGMPs, for manufacture of both active drug substances and finished drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. If the FDA or a comparable foreign

regulatory authority does not approve these facilities for the manufacture of our drug candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our drug candidates, if approved.

We depend on third-party suppliers for key raw materials used in our manufacturing processes, and the loss of these third-party suppliers or their inability to supply us with adequate raw materials could harm our business.

We rely on third-party suppliers for the raw materials required for the production of our drug candidates. Our dependence on these third-party suppliers and the challenges we may face in obtaining adequate supplies of raw materials involve several risks, including limited control over pricing, availability, quality and delivery schedules. We cannot be certain that our suppliers will continue to provide us with the quantities of these raw materials that we require or satisfy our anticipated specifications and quality requirements. Any supply interruption in limited or sole sourced raw materials could materially harm our ability to manufacture our products until a new source of supply, if any, could be identified and qualified. Although we believe there are currently several other suppliers of these raw materials, we may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could delay the development and potential commercialization of our drug candidates, including limiting supplies necessary for clinical trials and regulatory approvals, which would have a material adverse effect on our business.

#### Risks Related to Our Intellectual Property

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

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

In addition, we cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us or our affiliates. Even if patents have issued or will issue, we cannot guarantee that the claims of these patents are or will be valid or enforceable or will provide us with any significant protection against competitive products or otherwise be commercially valuable to us. Patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the U.S. Patent and Trademark Office, or the USPTO, for the entire time prior to issuance as a U.S. patent. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Consequently, we cannot be certain that we or our licensors or co-owners were the first to invent, or the first to file patent applications on, our drug candidates or their use as drugs. In the event that a third party has also filed a U.S. patent application relating to our drug candidates or a similar invention, we may have to participate in interference or derivation proceedings declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial and it is possible that our efforts would be unsuccessful, resulting in a loss of our U.S. patent position. Furthermore, we may not have identified all U.S. and foreign patents or published applications that affect our business either by blocking our ability to commercialize our drugs or by covering similar technologies. Composition-of-matter patents on the biological or chemical active pharmaceutical ingredient are generally considered to be the strongest form of intellectual property protection for pharmaceutical products, as such patents provide protection without regard to any method of use. We cannot be certain that the claims in our patent applications covering composition-of-matter of our product candidates will be considered patentable by the USPTO and courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our issued composition-of-matter patents will not be found invalid or unenforceable if challenged.

Method-of-use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted

indications, physicians may prescribe these products “off-label.” Although off-label prescriptions may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to prevent or prosecute.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation, and switch the U.S. patent system from a “first-to-invent” system to a “first-to-file” system. Under a “first-to-file” system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The U.S. Patent and Trademark Office recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first-to-file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

We may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office, or become involved in opposition, derivation, reexamination, inter partes review, post-grant review, or other patent office proceedings or litigation, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third party patent rights.

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

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

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

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

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

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

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. Although we are not currently aware of any litigation or other proceedings or third-party claims of intellectual property infringement related to our drug candidates, the pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may hold or obtain patents in the future and allege that the use of our technologies infringes these patent claims or that we are employing their proprietary technology without authorization.

In addition, third parties may challenge or infringe upon our existing or future patents. Proceedings involving our patents or patent applications or those of others could result in adverse decisions regarding:  
the patentability of our inventions relating to our drug candidates; and/or



the enforceability, validity or scope of protection offered by our patents relating to our drug candidates.

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

If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may:

- incur substantial monetary damages;

- encounter significant delays in bringing our drug candidates to market; and/or

- be precluded from participating in the manufacture, use or sale of our drug candidates or methods of treatment requiring licenses.

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

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

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

We rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable; however, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of our employees were previously employed at universities, Elan or Elan subsidiaries, or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

#### Risks Related to Our Ordinary Shares

The market price of our shares may fluctuate widely.

Our ordinary shares commenced trading on The NASDAQ Global Market on December 21, 2012 and currently trade on The NASDAQ Global Select Market. We cannot predict the prices at which our ordinary shares may trade at. The market price of our ordinary shares may fluctuate widely, depending upon many factors, some of which may be beyond our control, including:

- our ability to obtain financing as needed;

- progress in and results from our clinical trials, including our Phase 1 and any future clinical trials of NEOD001;

- our collaboration with Roche pursuant to the License Agreement to develop and commercialize PRX002, as well as any future Licensed Products targeting alpha-synuclein;
- failure or delays in advancing our preclinical drug candidates or other drug candidates we may develop in the future, into clinical trials;
- results of clinical trials conducted by others on drugs that would compete with our drug candidates;
  - issues in manufacturing our drug candidates;
- regulatory developments or enforcement in the United States and foreign countries;
- developments or disputes concerning patents or other proprietary rights;
- introduction of technological innovations or new commercial products by our competitors;
- changes in estimates or recommendations by securities analysts, if any, who cover our company;
- public concern over our drug candidates;
- litigation;
- future sales of our ordinary shares;
- general market conditions;
- changes in the structure of healthcare payment systems;
- failure of any of our drug candidates, if approved, to achieve commercial success;
- economic and other external factors or other disasters or crises;
- period-to-period fluctuations in our financial results;
- overall fluctuations in U.S. equity markets;
- our quarterly or annual results, or those of other companies in our industry;
- announcements by us or our competitors of significant acquisitions or dispositions;
- the operating and share price performance of other comparable companies;
- investor perception of our company and the drug development industry;
- natural or environmental disasters that investors believe may affect us; or
  - fluctuations in the budget of federal, state and local governmental entities around the world.

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

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

As with any publicly traded company, your percentage ownership in us may be diluted in the future because of equity issuances for acquisitions, capital raising transactions or otherwise. We may need to raise additional capital in the future. If we are able to raise additional capital, we may issue equity or convertible debt instruments, which may severely dilute your ownership interest in us. In addition, we intend to continue to grant option awards to our directors, officers and employees, which would

dilute your ownership stake in us. As of December 31, 2013, the number of ordinary shares authorized under our equity plan is 2,650,000.

For as long as we are an emerging growth company, we will be exempt from certain reporting requirements, including those relating to accounting standards and disclosure about our executive compensation, that apply to other public companies.

In April 2012, President Obama signed into law the JOBS Act. The JOBS Act contains provisions that, among other things, relax certain reporting requirements for emerging growth companies, including certain requirements relating to accounting standards and compensation disclosure. We are classified as an emerging growth company, which is defined as a company with annual gross revenues of less than \$1 billion, that has been a public reporting company for a period of less than five years, and that does not have a public float of \$700 million or more in securities held by non-affiliated holders. We will remain an emerging growth company until the earliest of (i) the end of the fiscal year in which the market value of our ordinary shares that are held by non-affiliates exceeds \$700 million as of the end of the second fiscal quarter, (ii) the end of the fiscal year in which we have total annual gross revenues of \$1 billion or more during such fiscal year, (iii) the date on which we issue more than \$1 billion in non-convertible debt in a three-year period or (iv) the end of the fiscal year following the fifth anniversary of the date of the first sale of our ordinary shares pursuant to an effective registration statement filed under the Securities Act of 1933, as amended, or the Securities Act.

For as long as we are an emerging growth company, 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.” These include, but are not limited to, (i) reduced obligations with respect to the disclosure of selected financial data in registration statements filed with the Securities and Exchange Commission, (ii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, (iii) an exception from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, and (iv) exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and the requirement to obtain shareholder approval of any golden parachute payments not previously approved. As noted above, under the JOBS Act, emerging growth companies can delay 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. We intend to take advantage of such extended transition period. Since we would then not be required to comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies, our Consolidated Financial Statements may not be comparable to the financial statements of companies that comply with public company effective dates. If we were to elect to comply with these public company effective dates, such election would be irrevocable pursuant to Section 107 of the JOBS Act.

If we were treated as a passive foreign investment company for U.S. federal income tax purposes, it could result in adverse U.S. federal income tax consequences to U.S. holders of our ordinary shares.

Although not free from doubt, based on the current market price of our ordinary shares and the value and composition of our assets, we do not believe we will be a PFIC for U.S. federal income tax purposes for our current taxable year. However, the application of the PFIC rules is subject to uncertainty in several respects, and we cannot assure you the U.S. Internal Revenue Service, or IRS, will not take a contrary position. A non-U.S. corporation will be considered a PFIC for any taxable year if either (1) at least 75% of its gross income for such year is passive income or (2) at least 50% of the value of its assets (based on an average of the quarterly values of the assets during such year) is attributable to assets that produce or are held for the production of passive income (the “asset test”). In general, the total value of our assets for purposes of the asset test will be determined based on the market price of our ordinary shares. As a result, fluctuations in the market price of our ordinary shares may cause us to become a PFIC. In addition, changes in the composition of our income or assets may cause us to become a PFIC. A separate determination must be made each taxable year as to whether we are a PFIC (after the close of each taxable year). If we are a PFIC for our current taxable year, certain adverse U.S. federal income tax consequences could apply to U.S. persons who acquire our ordinary shares with respect to any “excess distribution” received from us and any gain from a sale or other disposition of our ordinary shares.

Irish law differs from the laws in effect in the United States and may afford less protection to holders of our ordinary shares.

It may not be possible to enforce court judgments obtained in the United States against us in Ireland based on the civil liability provisions of the U.S. federal or state securities laws. In addition, there is uncertainty as to whether the courts of Ireland would

23

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recognize or enforce judgments of U.S. courts obtained against us or our directors or officers based on the civil liabilities provisions of the U.S. federal or state securities laws or hear actions against us or those persons based on those laws. We have been advised that the United States currently does not have a treaty with Ireland providing for the reciprocal recognition and enforcement of judgments in civil and commercial matters. Therefore, a final judgment for the payment of money rendered by any U.S. federal or state court based on civil liability, whether or not based solely on federal or state securities laws, would not automatically be enforceable in Ireland.

As an Irish incorporated company, we are governed by the Irish Companies Acts 1963-2013, which differ in some material respects from laws generally applicable to U.S. corporations and shareholders, including, among others, differences relating to interested director and officer transactions and shareholder lawsuits. Likewise, the duties of directors and officers of an Irish company generally are owed to the company only. Shareholders of Irish companies generally do not have a personal right of action against directors or officers of the company and may exercise such rights of action on behalf of the company only in limited circumstances. Accordingly, holders of our ordinary shares may have more difficulty protecting their interests than would holders of securities of a corporation incorporated in a jurisdiction of the United States.

Irish law differs from the laws in effect in the United States with respect to defending unwanted takeover proposals and may give our board of directors less ability to control negotiations with hostile offerors.

We are subject to the Irish Takeover Panel Act, 1997, Takeover Rules, 2013, or the Irish Takeover Rules. Under the Irish Takeover Rules, our Board is not permitted to take any action that might frustrate an offer for our shares once our Board has received an approach that may lead to an offer or has reason to believe that such an offer is or may be imminent, subject to certain exceptions. Potentially frustrating actions such as (i) the issue of shares, options or convertible securities, (ii) material acquisitions or disposals, (iii) entering into contracts other than in the ordinary course of business or (iv) any action, other than seeking alternative offers, which may result in frustration of an offer, are prohibited during the course of an offer or at any earlier time during which our Board has reason to believe an offer is or may be imminent. These provisions may give our Board less ability to control negotiations with hostile offerors and protect the interests of holders of ordinary shares than would be the case for a corporation incorporated in a jurisdiction of the United States.

Transfers of our ordinary shares may be subject to Irish stamp duty.

Transfers of our shares effected by means of the transfer of book entry interests in DTC should not be subject to Irish stamp duty. However, if a shareholder holds our ordinary shares directly rather than beneficially through DTC any transfer of those shares could be subject to Irish stamp duty (currently at the rate of 1% of the higher of the price paid or the market value of the shares acquired). Payment of Irish stamp duty is generally a legal obligation of the transferee. The potential for stamp duty could adversely affect the price of your shares.

We do not anticipate paying cash dividends, and accordingly, shareholders must rely on share appreciation for any return on their investment.

We anticipate losing money for the foreseeable future and, even if we do ever turn a profit, we intend to retain future earnings, if any, for the development, operation and expansion of our business. Thus, we do not anticipate declaring or paying any cash dividends for the foreseeable future. Therefore, the success of an investment in our ordinary shares will depend upon appreciation in their value and in order to receive any income or realize a return on your investment, you will need to sell your Prothena ordinary shares. There can be no assurance that our ordinary shares will maintain their price or appreciate in value.

Dividends paid by us may be subject to Irish dividend withholding tax.

Although we do not currently anticipate paying cash dividends, if we were to do so in the future, a dividend withholding tax (currently at a rate of 20%) may arise. A number of exemptions from dividend withholding tax exist such that shareholders resident in the U.S. and shareholders resident in other countries that have entered into a double taxation treaty with Ireland may be entitled to exemptions from dividend withholding tax subject to the completion of certain dividend withholding tax declaration forms.

Shareholders entitled to an exemption from Irish dividend withholding tax on any dividends received from us will not be subject to Irish income tax in respect of those dividends, unless they have some connection with Ireland other than their shareholding (for example, they are resident in Ireland). Shareholders who receive dividends subject to Irish dividend withholding tax will generally have no further liability to Irish income tax on those dividends.



Prothena shares, received by means of a gift or inheritance could be subject to Irish capital acquisitions tax. Irish capital acquisitions tax (CAT) could apply to a gift or inheritance of our shares irrespective of the place of residence, ordinary residence or domicile of the parties. This is because our shares will be regarded as property situated in Ireland. The person who receives the gift or inheritance has primary liability for CAT. Gifts and inheritances passing between spouses are exempt from CAT. At the date hereof, children have a tax-free threshold of €225,000 in respect of taxable gifts or inheritances received from their parents. It is recommended that each shareholder consult his or her own tax advisor as to the tax consequences of holding our shares or receiving dividends from us.

#### Going Concern

These Consolidated Financial Statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“U.S. GAAP”). The Consolidated Financial Statements of Prothena are presented in U.S. dollars, which is the functional currency of Prothena, and have been prepared on a going concern basis. The financial information for all periods prior to the separation and distribution were prepared by aggregating financial information from the components of Prothena as described above. All financial information presented after December 20, 2012 was consolidated and includes the accounts of the Company and its wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

On the basis of its current cash resources and its business plan for 2014 and 2015 the directors consider it is appropriate to prepare the financial statements on a going concern basis. These financial statements do not include any adjustments that would result from the going concern basis of preparation being inappropriate.

Prothena Corporation plc

Directors' Report (continued)

Directors, Secretary and Their Interests

The directors and secretary who held office at 31 December 2013 had no interests other than those shown below in the shares of the Company.

The following table sets forth information regarding interest in shares held by directors and secretary who held office at 31 December 2013.

Name	December 31,	
	2013	2012
Lars Ekman	243	243
Dale Schenk	211	211
Richard Collier	1,219	1,219
Shane Cooke	—	—
Christopher S Henney <sup>(1)</sup>	—	—
Dennis Selkoe <sup>(2)</sup>	4,208	4,208
Secretary		
Tara Nickerson	344	344

<sup>(1)</sup> Dr. Henney was appointed to the board on March 16, 2013.

<sup>(2)</sup> Dr. Selkoe was appointed to the board on July 22, 2013.

The following table sets forth information regarding interest in share options made during 2013 to directors and secretary who held office at 31 December 2013.

Director	Date of grant	Exercise price	As of January 1, 2013	Granted during 2013	At 31 December 2013	Earliest exercisable date	Expiry date
Lars Ekman	January 29, 2013	\$6.41	—	125,000	125,000	January 29, 2014	January 29, 2023
Dale Schenk	January 29, 2013	\$6.03	—	450,000	450,000	January 29, 2014	January 29, 2023
Richard Collier	January 29, 2013	\$6.41	—	50,000	50,000	January 29, 2014	January 29, 2023
Shane Cooke	January 29, 2013	\$6.41	—	50,000	50,000	January 29, 2014	January 29, 2023
Christopher Henney	March 18, 2013	\$6.65	—	50,000	50,000	March 18, 2014	March 18, 2023
Dennis Selkoe	July 22, 2013	\$16.42	—	50,000	50,000	July 22, 2014	July 22, 2023
Secretary							
Tara Nickerson	January 29, 2013	\$6.41	—	54,000	54,000	January 29, 2014	January 29, 2023
	April 1, 2013	\$6.73	—	46,000	46,000	January 29, 2014	April 1, 2023

According to the register of director's interests, options to purchase ordinary shares in the Company were granted during the financial year 2013 to each of the directors and to the secretary; however, there were no options exercised



by them during the financial year 2013.

Prothena Corporation plc

Directors' Report (continued)  
Political Donations

During the year, the group and the Company did not make any donations disclosable in accordance with The Electoral Act, 1997.

#### Significant Shareholdings

The following table presents information as to the beneficial ownership of our ordinary shares as of March 1, 2014 for each person, or group of affiliated persons, known by us to beneficially own more than 5% of our ordinary shares; Percentage ownership of our ordinary shares in the table is based on 21,902,937 ordinary shares issued and outstanding on March 1, 2014.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percent
5% Shareholders:		
FMR LLC 245 Summer Street Boston, MA 02109	2,753,292	12.6 %
T. Rowe Price Associates, Inc. 100 E. Pratt Street Baltimore, MD 21202	2,259,906	10.3
Entities affiliated with RA Capital Management 20 Park Plaza, Suite 1200 Boston, MA 02116	1,641,167	7.5
Wellington Management Company, LLP 280 Congress Street Boston, MA 02210	1,419,643	6.5
Entities affiliated with OrbiMed Advisors 601 Lexington Avenue, 54th Floor New York, NY 10022	1,202,000	5.5

#### Research and Development

During the years ended 31 December 2013 and 2012, the Company's expenditure on research and development ("R&D") activities amounted to \$26.1 million and \$34.1 million, respectively.

#### Subsidiary Undertakings

The Company's subsidiaries are Neotope Biosciences Limited, Onclave Therapeutics Limited and Prothena Biosciences Inc.



Prothena Corporation plc

Directors' Report (continued)  
Financial Risk Management

#### Foreign Currency Risk

Prothena's business is primarily conducted in U.S. dollars except for its agreement with the its contract manufacturer for clinical supplies which is denominated in Euros. The Company recorded a loss on foreign currency exchange rate differences of approximately \$226,000 during the year ended December 31, 2013. At this time, we do not believe that our foreign exchange risk is material. However, if the Company continues or increases its business activities that require the use of foreign currencies, the Company may incur further losses if the Euro and other such currencies strengthen against the U.S. dollar.

#### Interest Rate Sensitivity

The Company's exposure to interest rate risk is limited to its cash equivalents, which consist of accounts maintained in money market funds. The Company have assessed that there is no material exposure to interest rate risk given the nature of money market funds. In general, money market funds are not subject to market risk because the interest paid on such funds fluctuates with the prevailing interest rate. Accordingly, the Company's interest income fluctuates with short-term market conditions.

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

#### Credit Risk

All of the Company's accounts receivables are due from a single customer to whom it provides R&D services. the Company does not believe that its credit risk is significant. As of December 31, 2013, its receivables from this customer totaled less than \$0.1 million.

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 pursuant to its investment policy, it 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 have not experienced any losses on its deposits of cash and cash equivalents.

#### Accounting Records

The directors believe that they have complied with the requirement of Section 202 of the Companies Act, 1990 with regard to books of account by employing personnel with appropriate expertise and by providing adequate resources to the financial function. The books of account of the Company are maintained in accordance with Section 202(1)(6) of the Companies Act.

#### Auditor

KPMG Chartered Accountants has been appointed as auditors and in accordance with Section 160(2) of the Companies Act, 1963, and will continue in office.

On behalf of the board:

/s/ Dale B. Schenk	/s/Shane Cooke	
Dale B. Schenk	Shane Cooke	March 31, 2014
Director	Director	



Prothena Corporation plc

### Statement of Directors' Responsibilities

The directors are responsible for preparing the directors' report and Consolidated Financial Statements in accordance with applicable law and regulations.

Company law requires the directors to prepare Consolidated Financial Statements for each financial period which give a true and fair view of the state of affairs of the parent company and group and of the profit or loss of the group for the period then ended. Under that law, the directors have elected to prepare the Consolidated Financial Statements in accordance with Section 1 of the Companies (Miscellaneous Provisions) Act 2009 (as amended), which provides that a true and fair view of the state of affairs and profit or loss may be given by preparing the Consolidated Financial Statements and parent company financial statements in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"), as defined in Section 1(1) of the Companies (Miscellaneous Provisions) Act 2009 (as amended), to the extent that the use of those principles in the preparation of the financial statements does not contravene any provision of the Companies Acts or of any regulations made thereunder.

In preparing each the Consolidated Financial Statements and the financial statements of the parent company (collectively the 'financial statements'), the directors are required to:

- select suitable accounting policies and then apply them consistently;
- make judgments and estimates that are reasonable and prudent;
- prepare the financial statements on the going concern basis unless it is inappropriate to presume that the group and the Company will continue in business.

The directors are responsible for keeping proper books of account that disclose with reasonable accuracy at any time the financial position of the group and the Company and to enable them to ensure that its financial statements comply with the Companies Acts, 1963 to 2013. They are also responsible for taking such steps as are reasonably open to them to safeguard the assets of the Company and to prevent and detect fraud and other irregularities.

The directors are responsible for the maintenance and integrity of the corporate and financial information included on the group's website. Legislation in the Republic of Ireland governing the preparation and dissemination of financial statements may differ from legislation in other jurisdictions.

The directors are also responsible for preparing a directors' report that complies with the requirements of the Companies Acts, 1963 to 2013.

On behalf of the board:

/s/ Dale B. Schenk      /s/Shane Cooke

Dale B. Schenk      Shane Cooke      March 31, 2014  
Director      Director



Independent Auditor's Report to the Members of Prothena Corporation plc

We have audited the group and the company financial statements (the "financial statements") of Prothena Corporation plc for the year ended 31 December 2013 which comprise the Consolidated Balance Sheet, the Consolidated Statement of Operations, the Consolidated Statement of Cash Flows, the Consolidated Statement of Shareholders' equity and the parent company Balance Sheet, Statement of Cash Flows, Statement of Shareholders' Equity and related notes. These financial statements have been prepared under the accounting policies set out therein.

This report is made solely to the company's members, as a body, in accordance with Section 193 of the Companies Act, 1990. Our audit work has been undertaken so that we might state to the company's members those matters we are required to state to them in an auditor's report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the company and the company's members as a body, for our audit work, for this report, or for the opinions we have formed.

Respective responsibilities of directors and auditor

As explained more fully in the Directors' Responsibilities Statement set out on page 29 the directors are responsible for the preparation of the financial statements giving a true and fair view. Our responsibility is to audit and express an opinion on the financial statements in accordance with Irish law and International Standards on Auditing (UK and Ireland). Those standards require us to comply with the Auditing Practices Board's Ethical Standards for Auditors.

Scope of the audit of the financial statements

An audit involves obtaining evidence about the amounts and disclosures in the financial statements sufficient to give reasonable assurance that the financial statements are free from material misstatement, whether caused by fraud or error. This includes an assessment of: whether the accounting policies are appropriate to the company circumstances and have been consistently applied and adequately disclosed; the reasonableness of significant accounting estimates made by the directors; and the overall presentation of the financial statements. In addition, we read all the financial and non-financial information in the annual report to identify material inconsistencies with the audited financial statements. If we become aware of any apparent material misstatements or inconsistencies we consider the implications for our report.

Opinion on financial statements

In our opinion the financial statements:

give a true and fair view, in accordance with US GAAP, to the extent that the use of these principles in the financial statements does not contravene the provisions of the Companies Acts, 1963 to 2013 or any regulation made there under, of the state of the group's and parent company's affairs as at 31 December 2013 and of the group's loss for the year then ended; and

have been properly prepared in accordance with the Companies Acts, 1963 to 2013.

Matters on which we are required to report by the Companies Acts, 1963 to 2013

We have obtained all the information and explanations which we consider necessary for the purposes of our audit.

In our opinion, proper books of account have been kept by the company.

The financial statements are in agreement with the books of account.

In our opinion the information given in the directors' report is consistent with the financial statements.

The net assets of the company, as stated in the balance sheet are more than half of the amount of its called-up share capital and, in our opinion, on that basis there did not exist at 31 December 2013 a financial situation which under Section 40(1) of the Companies (Amendment) Act, 1983 would require the convening of an extraordinary general meeting of the company.



Independent Auditor's Report to the members of Prothena Corporation plc (continued)

Matters on which we are required to report by exception

We have nothing to report in respect of the provisions in the Companies Acts, 1963 to 2013 which require us to report to you if, in our opinion the disclosures of directors' remuneration and transactions specified by law are not made.

/s/ Sean O'Keefe  
Sean O'Keefe  
for and on behalf of  
KPMG  
Chartered Accountants, Statutory Audit firm  
1 Stokes Place  
St. Stephens Green  
Dublin 2 Ireland

March 31, 2014

Prothena Corporation plc  
 Consolidated Balance Sheets  
 As of 31 December 2013 and 2012  
 (in thousands, except par value)

	2013	2012
	\$	\$
Assets		
Current assets:		
Cash and cash equivalents	176,677	124,860
Receivable from related party	58	223
Deferred tax assets	81	73
Prepaid expenses and other current assets	1,406	685
Total current assets	178,222	125,841
Non-current assets:		
Property and equipment, net	3,372	3,442
Deferred tax assets	816	—
Total non-current assets	4,188	3,442
Total assets	182,410	129,283
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	1,790	—
Accrued research and development	1,542	47
Income taxes payable	184	27
Other current liabilities	3,890	1,670
Total current liabilities	7,406	1,744
Non-current liabilities:		
Deferred rent	1,734	1,055
Total liabilities	9,140	2,799
Shareholders' equity:		
Euro deferred shares, €22 nominal value; 10 shares authorised; none issued and outstanding	—	—
Ordinary shares, \$0.01 par value; 100,000 shares authorised; 21,856 and 17,679 shares issued and outstanding at 31 December 2013 and 2012, respectively	219	177
Additional paid-in capital	214,392	126,652
Accumulated deficit	(41,341)	(345)
Total shareholders' equity	173,270	126,484
Total liabilities and shareholders' equity	182,410	129,283
See accompanying Notes to Consolidated Financial Statements.		

/s/ Dale B. Schenk      /s/ Shane Cooke  
 Dale B. Schenk      Shane Cooke      March 31, 2014  
 Director      Director

Prothena Corporation plc

Consolidated Statements of Operations  
 For the Years Ended 31 December 2013 and 2012  
 (in thousands, except per share data)

	2013	2012
	\$	\$
Revenues—related party	676	2,658
Operating expenses:		
Research and development	26,052	34,139
General and administrative	15,051	9,929
Total operating expenses	41,103	44,068
Loss from operations	(40,427	) (41,410
Other income (expense):		
Interest income	71	5
Other income (expense), net	(225	) —
Total other income (expense)	(154	) 5
Loss before income taxes	(40,581	) (41,405
Provision for income taxes	415	6
Net loss	(40,996	) (41,411
Basic and diluted net loss per share	(2.20	) (2.84
Shares used to compute basic and diluted net loss per share	18,615	14,593
See accompanying Notes to Consolidated Financial Statements.		

/s/ Dale B. Schenk      /s/Shane Cooke

Dale B. Schenk      Shane Cooke      March 31, 2014  
 Director      Director



## Prothena Corporation plc

Consolidated Statements of Cash Flows  
 For the Years Ended 31 December 2013 and 2012  
 (in thousands)

	2013	2012
	\$	\$
Operating activities		
Net loss	(40,996	) (41,411
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	660	468
Share-based compensation	3,128	6,098
Deferred income taxes	(538	) —
Gain on disposal of fixed asset	(29	) —
Changes in operating assets and liabilities:		
Receivable from related party	165	(223
Other assets	(721	) (467
Accounts payable, accruals and other liabilities	6,233	(6,537
Net cash used in operating activities	(32,098	) (42,072
Investing activities		
Purchases of property and equipment	(564	) (1,301
Proceeds from disposal of fixed asset	29	—
Net cash used in investing activities	(535	) (1,301
Financing activities		
Proceeds from funding provided by Elan	—	145,233
Repayment of funding provided by Elan	—	(3,000
Post separation adjustments to the funding provided by Elan	(84	) —
Proceeds from issuance of ordinary shares to Elan	—	26,000
Proceeds from issuance of ordinary shares in public offering, net	84,534	—
Net cash provided by financing activities	84,450	168,233
Net increase in cash and cash equivalents	51,817	124,860
Cash and cash equivalents, beginning of the year	124,860	—
Cash and cash equivalents, end of the period	176,677	124,860
Supplemental disclosures of cash flow information		
Cash paid for income taxes, net of refunds	796	—
Supplemental disclosures of non cash investing and financing activities		
Acquisition of property and equipment under accounts payable and accrued liabilities	26	—
Accrued deferred offering costs	82	—
See accompanying Notes to Consolidated Financial Statements.		

Prothena Corporation plc  
 Consolidated Statements of Shareholders' Equity  
 For the Years Ended 31 December 2013 and 2012  
 (in thousands, except share data)

	Ordinary Shares		Additional Paid-in Capital	Accumulated Deficit	Parent Company Equity	Total Shareholders' Equity (Deficit)
	Number	Amount				
		\$	\$	\$	\$	\$
Balances at 31 December 2011	—	—	—	—	(6,436 )	(6,436 )
Contribution of net assets to Prothena and issuance of ordinary shares	14,496,929	145	100,684	—	(100,829 )	—
Issuance of ordinary shares to Elan	3,182,253	32	25,968	—	—	26,000
Share-based compensation	—	—	—	—	6,098	6,098
Net funding provided by Elan	—	—	—	—	142,233	142,233
Net loss	—	—	—	(345 )	(41,066 )	(41,411 )
Balances at 31 December 2012	17,679,182	177	126,652	(345 )	—	126,484
Issuance of ordinary shares in public offering, net of issuance costs of \$7.4 million	4,177,079	42	84,411	—	—	84,453
Share-based compensation	—	—	3,128	—	—	3,128
Post separation adjustment to the funding provided by Elan	—	—	201	—	—	201
Net loss	—	—	—	(40,996 )	—	(40,996 )
Balances at 31 December 2013	21,856,261	219	214,392	(41,341 )	—	173,270

See accompanying Notes to Consolidated Financial Statements.

Prothena Corporation plc

Notes

forming part of the 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 initiated a Phase 1 clinical trial for NEOD001, with successful first patient dosing in April 2013. The Phase 1 clinical trial of NEOD001 is evaluating its safety and tolerability in patients with AL amyloidosis. The Company also plans to initiate Phase 1 clinical trials for PRX002 and PRX003 in 2014 and 2015, respectively. The Company's strategy is to identify antibody candidates for clinical development by applying our 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 commenced trading on The NASDAQ Global Market under the symbol “PRTA” on December 21, 2012 and currently trade on The NASDAQ Global Select Market.

In connection with the Separation and Distribution, Elan invested total cash in the Company of \$125.0 million in return for 18% of the Company's outstanding ordinary shares (as calculated immediately following the consummation of such subscription) that a wholly-owned subsidiary of Elan subscribed for immediately following the Separation and Distribution.

Liquidity and Business Risks

As of December 31, 2013, the Company had an accumulated deficit of \$41.3 million and cash and cash equivalents of \$176.7 million, respectively. Based on the Company's business plans, management believes that the Company's cash and cash equivalents at December 31, 2013 are sufficient to meet its obligations for at least the next respective twelve months. To operate beyond such period, or if the Company elects to increase its spending on development programs significantly above current long-term plans or enters into potential licenses and or other acquisitions of complementary technologies, products or companies, the Company may need additional capital. The Company expects to continue to finance future cash needs that exceed its operating activities primarily through its current cash and cash equivalents, and to the extent necessary, through proceeds from public or private equity or debt financings, loans and collaborative agreements with corporate partners or other arrangements. In October 2013, the Company sold an aggregate of 4,177,079 ordinary shares for net proceeds of approximately \$84.5 million, after deducting the underwriting discount and estimated offering expenses, in an underwritten public offering. In addition, the Company received a \$30.0 million upfront payment in February 2014 from Roche pursuant to the License Agreement, and the Company expects to receive a \$15.0 million near-term clinical milestone payment from Roche in 2014. Although the Company believes, based on our current business plans, that its existing cash and cash equivalents will be sufficient to meet its obligations for at least the next twelve months, the Company anticipates that it will require additional capital

in the future in order to continue the research and development of its drug candidates.  
The Company have based this estimate on assumptions that may prove to be wrong, and the Company could use its available



Prothena Corporation plc  
Notes (continued)

capital resources sooner than it currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of its product candidates, the Company is unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development of its product candidates. The Company's future capital requirements will depend on numerous factors, including, without limitation, the timing of initiation, progress, results and costs of its clinical trials; the results of its 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; its ability to establish research collaborations, strategic collaborations, licensing or other arrangements; the costs to satisfy its obligations under 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 United States, the Company 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 the Company opts in to co-develop and co-fund. In order to develop and obtain regulatory approval for its potential products the Company may need to raise substantial additional funds. The Company expects to raise any such additional funds through public or private equity or debt financings, collaborative agreements with corporate partners or other arrangements. The Company 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 its shareholders.

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 Prothena Business historically operated as part of Elan and not as a separate stand-alone entity. Prior to the separation on December 20, 2012, the consolidated financial statements of Prothena have been prepared on a "carve-out" basis from the consolidated financial statements of Elan to represent the financial position and performance of Prothena as if the Company had existed on a stand-alone basis and as if Financial Accounting Standards Board ("FASB") Accounting Standard Codification ("ASC") Topic 810, "Consolidation" ("ASC 810") had been applied throughout. The accompanying Consolidated Financial Statements prior to December 21, 2012 include only those assets and liabilities that management has determined are specifically identifiable to Prothena and allocations of direct costs and indirect costs attributable to the Company's operations. The indirect costs included in the Company's Consolidated Financial Statements relate to certain centralized support functions that were provided by Elan. All intragroup transactions within the Prothena Business have been eliminated in the Consolidated Financial Statements and are not disclosed.

These Consolidated Financial Statements have been prepared in accordance with the accounting principles generally accepted in the United States of America ("GAAP"). The Consolidated Financial Statements of Prothena Corporation plc are presented in U.S. dollars, which is the functional currency of the Company. The financial information for all periods prior to the Separation and Distribution were prepared by aggregating financial information from the components of Prothena as described above. All financial information presented after December 20, 2012 includes the accounts of the Company and its wholly-owned subsidiaries. All intercompany balances and transactions have been

eliminated in consolidation.

Prior to December 21, 2012, the centralized support functions provided to the Company by Elan included, but were not limited to, accounting, information technology, taxation, legal, corporate strategy, investor relations, corporate governance and other professional services, employee benefit administration, including equity award and pension services, and cash and treasury management. Centralized support costs allocated to the Prothena business for the years ended December 31, 2012 and 2011 were \$7.7 million and \$4.0 million, respectively. These costs were allocated to the Company for the purposes of preparing the Consolidated Financial Statements based on estimated usage of the resources by the Prothena Business. The estimated usage of the central support resources allocated to the Prothena Business was determined by estimating its portion of the most

Prothena Corporation plc  
Notes (continued)

appropriate driver for each category of central support costs such as headcount or labor hours, depending on the nature of the costs. The Company believes that such allocations were made on a reasonable basis, but may not necessarily be indicative of the costs that would have been incurred if the Prothena Business had operated on a standalone basis.

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

Certain amounts in the Consolidated Financial Statements have been reclassified to conform to the current year presentation.

Use of Estimates

The preparation of the 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

Cash and Cash Equivalents

The Company considers all highly liquid investments held at financial institutions, such as commercial paper, money market funds, and other money market securities with original maturities of three months or less at date of purchase to be cash equivalents.

Property and Equipment, net

Property and equipment, net are stated at cost less accumulated depreciation and amortization. Depreciation and amortization is computed using the straight-line method over the estimated useful lives of the related assets.

Maintenance and repairs are charged to expense as incurred, and improvements and betterments are capitalized. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the balance sheet and any resulting gain or loss is reflected in operations in the period realized. Depreciation and amortization periods for the Company's property, plant and equipment are as follows:

	Useful Life
Machinery and equipment	4-7 years
Leasehold improvements	Shorter of expected useful life or lease term
Purchased computer software	4 years

Impairment of Long-lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable or the estimated useful life is no longer appropriate. If circumstances require that a long-lived asset be tested for possible impairment, the Company compares the undiscounted cash flows expected to be generated by the asset to the carrying amount of the asset. If the carrying amount of the long-lived asset is not recoverable on an undiscounted cash flow basis, an impairment is recognized to the extent that the carrying amount exceeds its fair value. The Company determines fair value using the income approach based on the present value of expected future cash flows. The Company's cash flow assumptions consider historical and forecasted revenue and operating costs and other relevant factors. There were no impairment charges recorded during the years ended December 31, 2013 and 2012.

Revenue

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.  
Advance payments

Prothena Corporation plc  
Notes (continued)

received in excess of amounts earned are classified as deferred revenue until earned. Up-front fees are deferred and amortized to the income statement over the performance period. The performance period is the period over which the Company expects to provide services as determined by the contract provisions.

The Company recognizes revenue from the delivery of research and development services. Revenue is recognized when all of the following criteria are met: persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered and the contractually specified acceptance criteria have been met, the fee is fixed or determinable, and collectibility is reasonably assured. If sales arrangements contain multiple elements, the Company evaluates whether the components of each arrangement represent separate units of accounting.

#### Research and Development

Research and development costs are expensed as incurred and include, but are not limited to, salary and benefits, share-based compensation, clinical trial activities, drug development and manufacturing, prior to FDA approval and third-party service fees, including clinical research organizations and investigative sites. Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided to the Company by its vendors on their actual costs incurred. The objective of the Company's accrual policy is to match the recording of the expenses in our Consolidated Financial Statements to the actual services received and efforts expended. As such, expense accruals related to clinical trials are recognized based on our estimate of the degree of completion of the events specified in the specific clinical study or trial contract. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the Consolidated Financial Statements as prepaid or accrued research and development. Amounts due may be fixed fee, fee for service, and may include upfront payments, monthly payments, and payments upon the completion of milestones or receipt of deliverables.

#### Acquired In-Process Research and Development Expense

The Company has acquired and may continue to acquire the rights to develop and commercialize new drug candidates from third parties. The up-front payments to acquire license, product or rights, as well as any future milestone payments, are immediately expensed as research and development provided that the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has no alternative future use.

#### Share-based Compensation

To determine the fair value of share-based payment awards, the Company uses the Black-Scholes option-pricing model. The determination of fair value using the Black-Scholes option-pricing model is affected by the Company's share price as well as assumptions regarding a number of complex and subjective variables. Share-based compensation expense is recognized on a straight-line basis over the requisite service period for each award. Further, share-based compensation expense recognized in the Consolidated Statements of Operations is based on awards expected to vest and therefore the amount of expense has been reduced for estimated forfeitures. If actual forfeitures differ from estimates at the time of grant they will be revised in subsequent periods. The Company bases its assumptions on historical data when available or when not available, on a peer group of companies. If factors change and different assumptions are employed in determining the fair value of share-based awards, the share-based compensation expense recorded in future periods may differ significantly from what was recorded in the current period (see Note 8 for further information).

Total share-based compensation expense recorded in the Consolidated Financial Statements for the year ended December 31, 2012 was allocated to the Company based on awards from Elan equity plans granted to Elan employees who have, directly or indirectly, provided services to the Company.

With respect to Elan options and RSUs held by Elan employees that became employees of Prothena effective upon the Separation and Distribution:

- unvested Elan options and RSUs that would otherwise have vested within twelve months following the effective date of the Separation and Distribution vested immediately upon the Separation and Distribution, with the RSUs (which by

their terms are settled upon vesting) settled in Elan ordinary shares or Elan ADSs in accordance with their terms;  
• other unvested Elan options and RSUs were forfeited; and  
• all vested Elan options (including options the vesting of which were accelerated as described above) will be required to

39

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Prothena Corporation plc  
Notes (continued)

be exercised for Elan ordinary shares or Elan ADSs within twelve months of the effective date of the Separation and Distribution, or will be forfeited.

However, for Elan employees who are aged 55 or over with at least five years of service and who became employees of the Company, unvested Elan options and RSUs became fully vested and exercisable upon the Separation and Distribution, with the RSUs (which, by their terms, are settled upon vesting) settled in Elan ordinary shares or Elan ADSs in accordance with their terms, and with Elan options being exercisable for one year following the Separation and Distribution. Similarly, unvested Elan options and RSUs held by Dr. Schenk, became fully vested and exercisable upon the Separation and Distribution, with the RSUs (which, by their terms are settled upon vesting) settled in Elan ordinary shares or Elan ADSs in accordance with their terms, and with Elan options being exercisable for two years following the Separation and Distribution.

The Company did not recognize any expense after December 20, 2012 in relation to the existing Elan equity-based awards as the Company's employees are not required to provide service after the Separation and Distribution in order to receive the benefits of the awards. The share-based compensation expense relating to the changes described above is a non-recurring charge that is directly attributable to Elan as part of the Separation and Distribution of the Prothena Business, therefore it was not recorded in the Company's Consolidated Financial Statements after December 20, 2012.

#### Income Taxes

Subsequent to the separation from Elan, Prothena began to file its own U.S. and foreign income tax returns and income taxes are presented in the Consolidated Financial Statements using the asset and liability method prescribed by the accounting guidance for income taxes. Prior to the separation from Elan, income taxes as presented in the Consolidated Financial Statements represented current and deferred income taxes of Elan attributed to the Company in a manner that is systematic, rational and consistent with the asset and liability method prescribed by the accounting guidance for income taxes. The Company's income tax provision prior to the separation from Elan was prepared under the "separate return method." The separate return method applies the accounting guidance for income taxes to the standalone Consolidated Financial Statements as if the Company was a separate taxpayer and a standalone enterprise. Deferred tax assets ("DTAs") and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using the enacted tax rates projected to be in effect for the year in which the differences are expected to reverse. Net deferred tax assets are recorded to the extent the Company believes that these assets will more likely than not be realized. In making such determination, all available positive and negative evidence is considered, including scheduled reversals of deferred tax liabilities, projected future taxable income, tax planning strategies and recent financial operations.

Significant estimates are required in determining the Company's provision for income taxes. Some of these estimates are based on management's interpretations of jurisdiction-specific tax laws or regulations. Various internal and external factors may have favorable or unfavorable effects on the future effective income tax rate of the business. These factors include, but are not limited to, changes in tax laws, regulations and/or rates, changing interpretations of existing tax laws or regulations, changes in estimates of prior years' items, past and future levels of R&D spending and changes in overall levels of income before taxes.

The tax benefit from an uncertain tax position is recognized only if it is more likely than not the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such positions are then measured based on the largest benefit that has a greater than 50% likelihood of being realized upon settlement. Changes in recognition or measurement are reflected in the period in which the change in judgment occurs. Interest and penalties related to unrecognized tax benefits are accounted for in income tax expense.

#### Net Loss Per Share

Basic net loss per share is calculated by dividing net loss by the weighted-average number of ordinary shares outstanding during the period. Diluted net loss per share is equal to basic net loss per share as the Company had no potentially dilutive securities outstanding for any of the periods presented. Prior to the separation and distribution, the

Company operated as part of Elan and not as a separate entity. As a result, the Company did not have any ordinary shares outstanding prior to December 21, 2012. The calculation of basic and diluted net loss per share assumes that the 14,497,929 shares issued to Elan shareholders in connection with the separation from Elan have been outstanding for all periods presented and that the 3,182,253 shares purchased by Elan upon separation have been outstanding since December 20, 2012.



Prothena Corporation plc  
Notes (continued)

Net loss per share was determined as follows during the years ended December 31 (in thousands, except per share amounts):

	2013	2012
	\$	\$
Net loss	(40,996 )	(41,411 )
Weighted-average ordinary shares outstanding	18,615	14,593

Basic and diluted net loss per share (2.20 ) (2.84 )

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

	2013	2012
	\$	\$
Stock options to purchase ordinary shares	1,974	1,005

## Comprehensive Loss

Comprehensive loss is comprised of net loss and other comprehensive income (loss). The Company has no components of other comprehensive income (loss). Therefore net loss equals comprehensive loss for all periods presented and, accordingly, the Consolidated Statements of Comprehensive 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. All of its long-lived assets were held in the United States. Revenue recorded in the Statements of Operations consists of fees earned from the provision of nonclinical research support to Elan, primarily in the areas of safety, toxicology and regulatory. The fees charged to Elan were calculated based on the expenses incurred by the Company in the provision of those R&D services, plus a contractually determined mark-up of those expenses.

The Company utilizes a third party manufacturer 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.

## 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 would be presented as a reduction of a deferred tax asset for a net operating loss carryforward, a similar tax loss or a tax credit carryforward if such settlement is required or expected in the event the uncertain tax position is disallowed. The new guidance becomes effective for the Company on January 1, 2015 and will be applied prospectively to unrecognized tax benefits that exist at the effective date with retrospective applications permitted. The Company has presented in these Consolidated Financial Statements its unrecognized tax

benefits as a reduction in its deferred tax assets as of December 31, 2013.

41

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Prothena Corporation plc  
Notes (continued)

### 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 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 \$153.3 million and \$103.5 million in money market funds included in cash and cash equivalents at December 31, 2013 and 2012, respectively. The Company did not have any investment holdings prior to the separation and distribution of the Prothena Business from Elan on December 20, 2012.

There were no other-than-temporary impairments during the years ended December 31, 2013 and 2012.

### 4. Composition of Certain Balance Sheet Items

#### Property and Equipment, net

Property and equipment, net consisted of the following at December 31 (in thousands):

	2013	2012
	\$	\$
Machinery and equipment	5,649	5,449
Leasehold improvements	1,927	1,651
Purchased computer software	85	85
	7,661	7,185
Less: accumulated depreciation and amortization	(4,289	) (3,743
Property and equipment, net	3,372	3,442

Depreciation expense was \$660,000 and \$447,000 for the years ended December 31, 2013 and 2012, respectively.

#### Other Current Liabilities

Other current liabilities consisted of the following at December 31 (in thousands):

Prothena Corporation plc  
Notes (continued)

	2013	2012
	\$	\$
Payroll and related expenses	2,800	1,592
Professional services	616	27
Accrued offering costs	82	—
Deferred rent	138	51
Other	254	—
Other current liabilities	3,890	1,670

## 5. Commitments and Contingencies

## Building Lease

In March 2010, Elan entered into a lease agreement for certain premises within a building in South San Francisco, California with a commencement date in November 2010 and a ten year lease term. In connection with the separation and distribution, this lease agreement was assigned to Prothena Biosciences Inc.

The lease, as amended, provides for approximately 50,400 of rentable square feet at a base rent that increases annually. Under the terms of this November 30, 2013 amendment, the Company can take occupancy of or sublease the additional space immediately, but is not obligated to begin paying rent or related operating expenses for the additional space until April 1, 2015, subject to certain adjustments if the additional space is sublet prior to that date. Rent for the additional space is at the same rate per rentable square foot as its existing premises and includes certain additional tenancy improvement allowances reimbursable by the landlord. The Company expects to incur an additional \$4.6 million in rent and lease-related operating expenses over the seven-year lease term, which expires on November 30, 2020.

Future minimum rental commitments under operating leases as of December 31, 2013, are as follows (in thousands):

Due in:	\$
2014	1,302
2015	1,756
2016	1,930
2017	2,009
2018	2,089
Thereafter	4,230
Total future minimum rental commitments	13,316

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 \$1,277,000 and \$1,289,000 for the years ended December 31, 2013 and 2012, 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



Prothena Corporation plc  
Notes (continued)

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 December 31, 2013 and 2012.

#### Commitments

As of December 31, 2013, the Company had non-cancelable purchase commitments to suppliers for \$2.7 million of which \$758,000 is included in accrued current liabilities, and contractual obligations under license agreements of \$1.1 million. The following is a summary of the Company's non-cancelable purchase commitments and contractual obligations as of December 31, 2013 (in thousands):

	Total	2014	2015	2016	2017	2018	Thereafter
	\$	\$	\$	\$	\$	\$	\$
Purchase Obligations	2,723	2,723	—	—	—	—	—
Contractual obligations under license agreements	1,070	85	85	85	85	85	645
Total	3,793	2,808	85	85	85	85	645

#### 6. Significant Agreements

##### License, Development, and Commercialization Agreement with Roche

On December 11, 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." The effectiveness of the License Agreement is subject to the completion of the customary regulatory clearances, including the expiration of the applicable Hart-Scott-Rodino ("HSR") waiting period. Upon the effectiveness of the License Agreement, the Company will grant 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 Licensed Products and an option to co-promote PRX002. During the term 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™ technology to increase delivery of therapeutic antibodies to the brain. The License Agreement provides that Roche will make an upfront payment to the Company of \$30.0 million and a near-term clinical milestone payment of \$15.0 million. 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 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.

After the Company files an investigational new drug application with the U.S. Food and Drug Administration for PRX002, 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

Prothena Corporation plc  
Notes (continued)

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 United States in the Parkinson's disease indication. If the Company exercises such option, it may also elect to co-promote additional Licensed Products in the United States approved for Parkinson's disease. Outside the United States, 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.

See Note 16 "Collaboration with Roche" for further detail.

## 7. Shareholders' Equity

### Ordinary Shares

As of December 31, 2013, the Company had 100,000,000 ordinary shares authorized for issuance with a par value of \$0.01 per share and 21,856,261 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 December 31, 2013, the Company had 10,000 Euro Deferred Shares authorized for issuance with a nominal value of €22 per share, 1,750 Euro Deferred Shares were issued and no shares are outstanding at December 31, 2013 as the issued Euro Deferred Shares were redeemed upon the separation on December 20, 2012. 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.

### Issuance of Ordinary Shares

On December 20, 2012, in connection with the Separation and Distribution, the Company issued 14,496,929 ordinary shares to holders of record of Elan ordinary shares and Elan American Depository Shares. Concurrently, the Company issued 3,182,253 ordinary shares to Elan for cash consideration of \$26.0 million.

### October 2013 Offering



In October 2013 the Company completed an underwritten public offering of an aggregate of 6,796,500 of its ordinary shares at a public offering price of \$22.00 per share, which consisted of 4,177,079 newly issued ordinary shares sold by the Company

45

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Prothena Corporation plc  
Notes (continued)

and 2,619,421 ordinary shares sold by Janssen Pharmaceutical, a wholly-owned subsidiary of Johnson & Johnson, as selling shareholder. The Company received aggregate net proceeds of approximately \$84.5 million, after deducting the underwriting discount and estimated offering costs. The Company did not receive any proceeds from the sale of 2,619,421 ordinary shares sold, which represented Janssen Pharmaceutical's entire shareholding in Prothena. During the year ended December 31, 2013 underwriting discounts and offering costs of \$7.4 million were recorded as an offset to the proceeds and recorded in additional paid in capital.

## 8. Share-Based Compensation

The following table summarizes share-based compensation expense for the years ended December 31 (in thousands):

	2013	2012
	\$	\$
Research and development - direct	980	6,093
General and administrative - direct	2,148	5
Total direct expense	3,128	6,098
General and administrative — allocated	—	1,445
	3,128	7,543

The following table summarizes share-based compensation expense by type of award for the years ended December 31 (in thousands):

	2013	2012
	\$	\$
Restricted stock units	—	3,477
Stock options <sup>(1)</sup>	3,128	2,598
Employee Equity Purchase Plan		23
Total direct	3,128	6,098
Share-based compensation expense-allocated	—	1,445
	3,128	7,543

<sup>(1)</sup> Includes \$0.3 million of share-based compensation expense for the year ended December 31, 2013 related to an option granted to a consultant.

## The Prothena Corporation plc 2012 Long Term Incentive Plan

The 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 year ended December 31, 2013, the Company granted 1,978,000 share options under its LTIP. The Company's options generally vest over four years. As of December 31, 2013, 676,500 ordinary shares remain available for grant and options to purchase 1,973,500 ordinary shares granted from the LTIP were outstanding with a weighted-average exercise price of approximately \$7.50 per share.

## 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 models

Prothena Corporation plc  
Notes (continued)

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

Share-based compensation expense will continue to have an adverse impact on the Company's reported results of operations, although it will have no impact on its overall financial position. The amount of unearned share-based compensation currently estimated to be expensed from now through the year 2016 related to unvested share-based payment awards at December 31, 2013 is \$7.3 million. The weighted-average period over which the unearned share-based compensation is expected to be recognized is 2.6 years. If there are any modifications or cancellations of the underlying unvested securities, the Company may be required to accelerate, increase or cancel any remaining unearned share-based compensation expense. Future share-based compensation expense and unearned share-based compensation will increase to the extent that the Company grants additional equity awards.

Share-based compensation expense recorded in these consolidated financial statements for the year ended December 31, 2013 was based on awards from Prothena's LTIP granted to Prothena employees.

The fair value of the options granted to employees during the year ended December 31, 2013 is estimated as of the grant date using the Black-Scholes option-pricing model assuming the weighted-average assumptions listed in the following table:

	Year Ended December 31, 2013
Expected volatility	84.0%
Risk-free interest rate	1.2%
Expected dividend yield	—%
Expected life (in years)	6.0
Weighted average grant date fair value	\$5.22

The following table summarizes the Company's share option activity during the year ended December 31, 2013:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
		\$		\$
Outstanding at December 31, 2012	—	—	0	—
Granted	1,978,000	7.50		
Canceled	(4,500)	) 6.41		
Outstanding at December 31, 2013	1,973,500	7.50	9.2	37,528
Vested and expected to vest at December 31, 2013	1,822,838	7.47	9.2	34,728

Vested at December 31, 2013   —   —   0   —

The following table summarizes information about the Company's share options outstanding as of December 31, 2013:

47

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Prothena Corporation plc  
Notes (continued)

Range of Exercise Prices		Options Outstanding			Options Exercisable	
		Number of Options	Weighted - Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
\$6.03	\$6.03	454,500	9.08	\$6.03	—	\$—
6.41	6.41	857,000	9.08	6.41	—	—
6.65	6.65	50,000	9.21	6.65	—	—
6.73	6.73	366,000	9.25	6.73	—	—
8.21	9.75	103,500	9.41	9.62	—	—
16.42	16.42	50,000	9.56	16.42	—	—
17.63	17.63	9,000	9.58	17.63	—	—
20.04	20.04	13,500	9.75	20.04	—	—
20.17	20.17	40,000	9.67	20.17	—	—
24.26	24.26	30,000	9.84	24.26	—	—
\$6.03	\$24.26	1,973,500	9.17	\$7.50	—	\$—

## Elan's Share-based Compensation Awards

Prior to the Separation and Distribution of the Prothena Business on December 20, 2012, the Company's employees had received share-based compensation awards under Elan's equity compensation plans and, therefore, the following disclosures pertain to share-based compensation expense that was allocated to the Prothena Business related to Elan's share-based equity awards. Elan's equity award program provided for the issuance of stock options, RSUs and other equity awards to its employees, including employees that have directly and indirectly provided service to the Prothena Business. The share-based payment compensation expense recorded in the Consolidated Financial Statements for the year ended December 31, 2012 includes all of the share-based payment expenses directly attributable to the Prothena Business and an allocation of indirect expenses that have been deemed attributable to the Prothena Business. The Company did not recognize any expense after December 20, 2012 in relation to the existing Elan equity-based awards as the Company's employees are not required to provide service after the Separation and Distribution in order to receive the benefits of the awards. The share-based compensation expense relating to the changes described below is a non-recurring charge that is directly attributable to Elan as part of the Separation and Distribution of the Prothena Business, and therefore was not recorded in the Company's Consolidated Financial Statements after December 20, 2012.

## Share-based Compensation Expense

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

## Restricted Share Units

Elan granted RSUs to its employees, including employees that have directly and indirectly provided service to the Prothena Business. The RSUs generally vest between one and three years from the grant date and shares are issued to RSU holders as soon as practicable following vesting. The fair value of services received by the Prothena Business in return for the RSUs is measured by reference to the fair value of the underlying shares at grant date. The total fair value expensed over the vesting terms of RSUs that became fully vested was \$506,000 in 2012.

Prothena Corporation plc  
Notes (continued)

### Share Options

Share options are granted at the price equal to the market value at the date of grant and will expire on a date not later than 10 years after their grant. Options generally vest between one and four years from the grant date.

Equity-settled share-based payments expense recognized in the “Carve-out” Combined Financial Statements are based on the fair value of the awards measured at the date of grant. The graded-vesting attribution method is used for recognizing share-based compensation expense over the requisite service period for each separately vesting tranche of award as though the awards were, in substance, multiple awards.

The fair value of share options is calculated using a binomial option-pricing model, taking into account the relevant terms and conditions. The binomial option-pricing model is used to estimate the fair value of the Company’s share options because it better reflects the possibility of exercise before the end of the options’ life. The binomial option-pricing model also integrates possible variations in model inputs, such as risk-free interest rates and other inputs, which may change over the life of the options. The amount recognized as an expense is adjusted each period to reflect actual and estimated future levels of vesting.

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

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

The fair value of options granted during the year December 31, 2012 was estimated using the binomial option-pricing model with the following weighted-average assumptions:

	Year Ended December 31, 2012	
Expected volatility	60.1	%
Risk-free interest rate	0.9	%
Expected dividend yield	—	%
Expected life <sup>(1)</sup>	4.9 - 6.8	
Weighted average fair value	\$6.66	

The expected life of options granted, as derived from the output of the binomial model, ranged from 4.9 to 6.8 years <sup>(1)</sup>in 2012. The contractual life of the options, which is not more than 10 years from the date of grant, was used as an input into the binomial model.

### Employee Equity Purchase Plan

Elan operates an EEPP for eligible employees, including employees that have directly and indirectly provided service to the Company. The fair value of options issued under the EEPP is calculated using the Black-Scholes option-pricing model, taking into account the relevant terms and conditions. Options issued under the EEPP have relatively short contractual lives, or must be exercised within a short period of time after the vesting date, and the input factors identified above do not apply. Therefore, the Black-Scholes option-pricing model produces a fair value that is substantially the same as a more complex binomial option-pricing model for the EEPP. The amount recognized as an expense is adjusted each period to reflect actual and estimated future levels of vesting. The weighted-average fair value of options granted under the EEPP to employees that have directly and indirectly provided service to the Company during the year ended December 31, 2012 was \$4.46.

The estimated fair values of options granted under the EEPP to employees that provided directly attributable service to the Company in the year ended December 31, were calculated using the following inputs into the Black-Scholes option-pricing model:

49

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Prothena Corporation plc  
Notes (continued)

	2012	
Weighted-average share price	\$13.97	
Weighted-average exercise price	\$11.88	
Expected volatility <sup>(1)</sup>	60.5%	
Expected life (months)	6.0	
Expected dividend yield	—	%
Risk-free interest rate	0.09%	

(1) The expected volatility was determined based on the implied volatility of traded options on Elan's ordinary shares.

## 9. Income Taxes

Subsequent to the separation from Elan, the Company began to file its own U.S. and foreign income tax returns and income taxes are presented in the Consolidated Financial Statements using the asset and liability method prescribed by the accounting guidance for income taxes. Prior to the separation from Elan, income taxes as presented in the Consolidated Financial Statements represented current and deferred income taxes of Elan attributed to the Company in a manner that is systematic, rational and consistent with the asset and liability method prescribed by the accounting guidance for income taxes. The Company's income tax provision prior to the separation from Elan was prepared under the "separate return method." The separate return method applies the accounting guidance for income taxes to the standalone financial statements as if Prothena were a separate taxpayer and a standalone enterprise.

Loss before provision for income taxes by country for the years ended December 31, 2013 and 2012 is summarized as follows (in thousands):

	2013		2012	
	\$		\$	
Ireland	(42,523	)	(35,898	)
United States	1,942		(5,507	)
Loss before provision for income taxes	(40,581	)	(41,405	)

Components of the provision for income taxes for the years ended December 31, 2013 and 2012 consisted of the following (in thousands):

	2013		2012	
	\$		\$	
Current:				
U.S. Federal	958		26	
U.S. State	(5	)	—	
Ireland	—		—	
Total current provision	953		26	
Deferred:				
U.S. Federal	(538	)	(20	)
U.S. State	—		—	
Ireland	—		—	
Total deferred provision (benefit)	(538	)	(20	)
Total provision for income taxes	415		6	

The provision for income taxes differs from the statutory tax rate 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.

Following is a reconciliation



Prothena Corporation plc  
Notes (continued)

between income taxes computed at the Irish statutory tax rate and the provision for income taxes for for the years ended December 31, 2013 and 2012 (in thousands):

	2013		2012
	\$		\$
Taxes at the Irish statutory tax rate of 12.5%	(5,073	)	(5,176
Income at rates other than the Irish statutory rate	(3,169	)	4
Change in valuation allowance	10,365		5,176
Share-based payments	164		—
Tax credits	(1,921	)	—
Other	49		2
Provision for income taxes	415		6

Deferred income taxes reflect the net tax effect of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's net deferred tax assets as of December 31, 2013 and 2012 are as follows (in thousands):

	2013		2012
	\$		\$
Deferred tax assets:			
Net operating loss carry forwards	15,457		8,917
Tax credits	1,310		—
Accruals	1,149		79
Share-based compensation	779		—
Gross deferred tax assets	18,695		8,996
Valuation allowance	(17,798	)	(8,917
Net deferred tax assets	897		79
Deferred tax liability	—		(6
Net deferred tax assets	897		73

Recognition of deferred tax assets is appropriate when realization of such assets is more likely than not. Based upon the weight of available evidence, especially the uncertainties surrounding the realization of deferred tax assets through future taxable income, the Company believes it is not yet more likely than not that the deferred tax assets will be fully realizable. Accordingly, the Company has provided a valuation allowance of \$17.8 million against its deferred tax assets as of December 31, 2013 in relation to deferred tax assets arising from tax credits and net operating losses. The net increase of \$8.9 million in the valuation allowance during the year ended December 31, 2013 was primarily due to current year net operating losses and tax credits.

As of December 31, 2013, certain of the Company's Irish subsidiaries had net operating loss carryovers of \$97.2 million which can be carried forward indefinitely but are limited to the same trade/trades. In addition, as of December 31, 2013, the Company had state net operating loss carryforwards of approximately \$37.5 million available to reduce future taxable income for the Company's U.S. subsidiary, if any. If not utilized, the state net operating loss carryforward begins expiring in 2032.

The Company also has federal research and development credits carryforwards of \$0.8 million and California research and development credit carryforwards of \$0.5 million, respectively, at December 31, 2013. The federal research and development credit carryforwards will expire starting in 2033 if not utilized. The California tax credits can be carried forward indefinitely.

Cumulative unremitted earnings of the Company's U.S. subsidiary total approximately \$1.5 million at December 31, 2013. The majority of the Company's U.S. subsidiary's cash balance at December 31, 2013 is committed for its working capital needs. No taxes have been provided for the unremitted earnings as any tax basis differences relating to investments in this overseas subsidiary are considered to be permanent in duration. Unremitted earnings may be

subject to Irish taxes (potentially at a rate of 12.5%) if they were to be distributed as dividends. However, as of December 31, 2013 the Company's net operating losses in Ireland

Prothena Corporation plc  
Notes (continued)

are sufficient to offset any potential dividend income received from its U.S. subsidiary.

A reconciliation of the beginning and ending amounts of unrecognized tax benefits is as follows (in thousands):

Gross Unrecognized Tax Benefits at December 31, 2012	\$ —
Additions for tax positions taken in a prior year	—
Additions for tax positions taken in the current year	480
Reductions for tax positions taken in the prior year due to settlement	—
Reductions for tax positions taken in the prior year due to statutes lapsing	—
Gross Unrecognized Tax Benefits at December 31, 2013	\$ 480

If recognized, none of our unrecognized tax benefits as of December 31, 2013 would reduce our annual effective tax rate but would result in a corresponding adjustment to our deferred tax valuation allowance. As of December 31, 2013, we have not recorded a liability for potential interest or penalties. We also do not expect our unrecognized tax benefits to change significantly over the next 12 months.

The major taxing jurisdictions for the Company are Ireland and the United States. The tax years 2012 to 2013 remain subject to examination by the U.S. taxing authorities and the tax years 2008 to 2013 remain subject to examination by the Irish taxing authorities.

#### 10. Employee Retirement Plan

##### Prothena 401K Retirement Plan

In December 2012 (effective January 1, 2013), the Company established a qualified retirement plan under section 401(k) of the Internal Revenue Code ("IRC") under which participants may contribute up to 100% of their eligible compensation, subject to maximum deferral limits specified by the IRC. In addition, the Company contributes 3% of each participating employee's eligible compensation, subject to limits specified by the IRC, on a quarterly basis. Further, the Company may make a discretionary matching and/or profit sharing contribution as determined solely by the Company. The Company did not record any expense in the year ended December 31, 2012 as no contributions, matching or profit sharing contributions were made under the 401(k) plan. The Company recorded total expense for matching contributions of \$293,000 for the year ended December 31, 2013.

##### Elan Pharmaceuticals 401(k) Retirement Savings Plan

Elan maintains a 401(k) retirement savings plan for its employees based in the United States, including employees that directly and indirectly provided service to the Prothena Business prior to the Separation and Distribution. The Prothena Business recorded total expense for matching contributions of \$127,000 for the year ended December 31, 2012.

#### 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 in December 2013 and such 3,182,253 ordinary shares were held by an indirect wholly owned subsidiary of Perrigo on December 31, 2013.

On January 17, 2014 the Company filed a registration statement on Form S-3 with the Securities and Exchange Commission (Registration No. 333-193416). This registration statement relates to the resale by the selling shareholder of up to 3,182,253 of the Company's ordinary shares, which represented approximately 14.6% of the ordinary shares issued and outstanding prior to the original date of filing of the registration statement (see Note 16).

As described elsewhere in these consolidated financial statements, the results of operations of the Prothena business for the time period prior to the separation include transactions with Elan. All of the revenue recognized by the Company for the years ended December 31, 2013, 2012 and 2011 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

52

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Prothena Corporation plc  
Notes (continued)

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.

TSA expenses recognized during the years ended December 31, 2013, and 2012, respectively were \$480,000 and \$nil, respectively, of which \$117,000 was included in R&D expenses and \$363,000 was included in G&A expenses for year ended December 31, 2013. The TSA expired on December 31, 2013.

R&D Services Agreement<sup>(1)</sup>

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.

There was also a number of other material agreements including the Subscription and Registration Rights Agreement which documented the relationship between Elan and Prothena for the 18% stake and a Tax Matters

<sup>(1)</sup> Agreement under which tax liabilities relating to taxable periods before and after the separation and distribution will be computed and apportioned between the parties, and responsibility for payment of those tax liabilities (including any taxes attributable to the separation and distribution) will be allocated between Elan and Prothena.





Prothena Corporation plc  
Notes (continued)

## 12. Employees

The number of persons employed by the Group as of December 31, 2013 was 39 employees, of whom approximately 27 were engaged in research and development activities and the remainder working in general and administrative areas. At December 31, 2012 there were 30 employees, of whom approximately 23 were engaged in research and development activities.

The financial results prior to December 21, 2012 were based on a carve out of Elan's financials, employee compensation and benefits was attributed to the Prothena Business based on the allocation of expenses to Prothena programs. Since employees were not dedicated to the Prothena Business it is not possible to directly determine remuneration for Prothena employees. The remuneration to employees related to the Prothena Business during the year ended December 31, 2012 is estimated to be approximately \$7.0 million, post-retirement benefits is estimated to be approximately \$0.1 million and share-based compensation is estimated to be approximately \$7.5 million of which, Dr. Schenk received remuneration of approximately \$0.9 million, post-retirement benefits of approximately \$7,500 and share-based compensation of approximately \$2.0 million.

## 13. Director Remuneration

The following table sets forth information concerning the directors emoluments (in thousands):

	2013	2012
Fees for services as director	284	—
Other emoluments <sup>(1)</sup>	462	—
Equity awards <sup>(2)</sup>	3,724	—
Total	\$4,471	\$0

<sup>(1)</sup> Other emoluments represent amounts paid to executive director in connection with the management of the affairs of the group.

<sup>(2)</sup> The amounts in the "Equity Award" row reflect the aggregate grant date fair value computed in accordance with FASB ASC Topic 718. The assumptions made in the valuation of the awards are discussed in Note 8, "Share Based Compensation" of "Notes to Consolidated Financial Statements". These amounts do not correspond to the actual value that may be recognized by the directors.

## 14. Auditors' Remuneration

The following table provides information regarding the fees incurred by KPMG LLP and KPMG Ireland during the years ended December 31, 2013 and 2012. All fees described below were approved by the audit committee.

## KPMG LLP

	Year Ended December 31,	
	2013	2012
Audit Fees <sup>(1)</sup>	\$450,200	\$232,000
Tax Fees <sup>(2)</sup>	20,820	—
Total Fees	\$471,020	\$232,000

<sup>(1)</sup> Audit Fees consisted of fees related to comfort letters, consents and our 2012 and 2013 audits and out of pocket expenses, including travel expenses, incurred by KPMG LLP.

<sup>(2)</sup> Tax Fees consisted of fees for 2013 tax consultation and tax compliance services incurred by KPMG LLP.

Prothena Corporation plc  
Notes (continued)

KPMG Ireland

	Year Ended December 31,	
	2013	2012
Audit Fees <sup>(3)</sup>	\$56,800	\$—
Tax Fees <sup>(4)</sup>	27,491	—
Total Fees	\$84,291	\$0

(3) Audit Fees consisted of fees related to statutory audits, comfort letters and consents.

(4) Tax Fees consisted of fees for 2013 tax consultation and tax compliance services incurred by KPMG Ireland.

15. Approval of the Financial Statements

The financial statements were approved by the directors on March 31, 2014.

16. Subsequent Events

Collaboration with Roche

On January 22, 2014 the License Agreement with Roche, which is discussed in more detail in Note 6, became effective following the expiration of the HSR waiting period. Consequently, in consideration for the rights granted to Roche under the License Agreement, a one-time, non-refundable, non-creditable payment of \$30.0 million was received from Roche in February 2014.

The Company is currently in the process of evaluating the accounting treatment for this transaction. Based on its preliminary assessment, the Company has identified the deliverables at the inception of the License Agreement as the license, clinical product supply, supply services, development activities and research activities. Through the Company's analysis, it will assess whether each of the deliverables identified has stand alone value, and how the arrangement consideration should be allocated to the deliverables based on the relative selling price methodology. 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 intends to 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 payments will be evaluated separately as the related contingencies are resolved.

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 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.

Amendment and Restatement of the LTIP

On March 11, 2014, the Board adopted, subject to shareholder approval, the Amended and Restated 2012 Plan. The Amended and Restated 2012 Plan constitutes an amendment and restatement of the LTIP. The effectiveness of the Amended and Restated 2012 Plan is subject to approval by the Company's shareholders and is recommended by the Board.

The Amended and Restated 2012 Plan amends and restates the 2012 Plan as set forth below:

- Increases the aggregate number of ordinary shares available for issuance under the 2012 Plan by 2,900,000 ordinary shares, to a total of 5,550,000 ordinary shares;



Prothena Corporation plc  
Notes (continued)

Allows the Company to grant cash incentive compensation (in addition to equity incentive compensation permitted under the 2012 Plan) that are intended to qualify as performance-based compensation exempt from the deduction limitation under Section 162(m) of the Code;

Applies annual limits on the number of ordinary shares (750,000 ordinary shares) and dollar amounts (\$5,000,000) of awards that may be granted to an individual in any one calendar year;

Eliminates the provision that permits ordinary shares subject to stock options that are withheld or surrendered to satisfy the exercise price or tax obligations of any stock options or SARs to be used again for new grants under the Amended and Restated 2012 Plan; and

Provides that Full Value Awards (as defined below) made to employees or consultants will become vested over a period of not less than three years following the date of grant (or in the case of awards subject to performance-based vesting, over a period of not less than one year measured from the beginning of the period over which performance is evaluated), provided that such vesting may be accelerated upon certain terminations of service or a change in control.

## Prothena Corporation plc

Parent Company Balance Sheet  
 As of 31 December 2013 and 2012  
 (in thousands, except par value)

	2013	2012
	\$	\$
Assets		
Current assets:		
Cash and cash equivalents	109,282	26,000
Other current assets	45	—
Total current assets	109,327	26,000
Non-current assets:		
Investments in subsidiaries	102,649	100,829
Total non-current assets	102,649	100,829
Total assets	211,976	126,829
Liabilities and shareholders' equity		
Total Current Liabilities	766	—
Shareholders' equity		
Ordinary shares, \$0.01 par value; 100,000 shares authorised; 21,856 and 17,679 shares issued and outstanding at 31 December 2013 and 2012 respectively	219	177
Additional paid-in capital	214,191	126,652
Accumulated deficit	(3,200)	—
Total shareholders' equity (deficit)	211,210	126,829
Total liabilities and shareholders' equity	211,976	126,829
See accompanying notes to the Parent Company Financial Statements.		

/s/ Dale B. Schenk      /s/Shane Cooke

Dale B. Schenk      Shane Cooke      March 31, 2014  
 Director      Director

## Prothena Corporation plc

Parent Company Statement of Cash Flows  
for the Years Ended 31 December 2013 and 2012  
(in thousands)

	2013	2012
	\$	\$
Cash flows from operating activities:		
Net loss	(3,200	) —
Adjustments to reconcile net loss to cash used in operating activities:		
Share-based compensation	1,308	—
Changes in operating assets and liabilities:		
Other assets	(45	) —
Accounts payable, accruals and other liabilities	766	—
Cash flows from operating activities	(1,171	) —
Cash flows from investing activities:		
Investments in subsidiaries	—	(100,829 )
Net cash used in investing activities	—	(100,829 )
Cash flows from financing activities:		
Proceeds from funding provided by Elan	—	100,829
Proceeds from issuance of ordinary shares by Elan	—	26,000
Proceeds from issuance of ordinary shares in public offering, net	84,453	—
Net cash provided by financing activities	84,453	126,829
Net increase in cash and cash equivalents	83,282	26,000
Cash and cash equivalents at beginning of year	26,000	—
Cash and cash equivalents at end of year	109,282	26,000

See accompanying notes to the Parent Company Financial Statements.

## Prothena Corporation plc

Parent Company Statement of Shareholders' Equity  
for the Years Ended 31 December 2013 and 2012  
(in thousands, except share data)

	Ordinary Shares		Additional Paid-in Capital	Accumulated Deficit	Parent Company Equity	Total Shareholders' Equity (Deficit)
	Number	Amount				
		\$	\$	\$	\$	\$
Balance at incorporation	—	—	—	—	—	—
Contribution of net assets to Prothena and issuance of ordinary shares	14,496,929	145	100,684	—	—	100,829
Issuance of ordinary shares to Elan	3,182,253	32	25,968	—	—	26,000
Net loss				—	—	—
Balance at 31 December 2012	17,679,182	177	126,652	—	—	126,829
Issuance of ordinary shares in public offering, net of issuance costs	4,177,079	42	84,411	—	—	84,453
Share-based compensation	—	—	3,128	—	—	3,128
Net Loss	—	—		(3,200 )	—	(3,200 )
Balance at 31 December 2013	21,856,261	219	214,191	(3,200 )	—	211,210

See accompanying notes to the Parent Company Financial Statements.

Attributable loss of the company

The profit attributable to shareholders dealt with in the financial statements of the company for the period ended 31 December 2013 was \$3.2 million (2012: \$NIL). As permitted by Section 148(8) of the Companies Act, 1963, the statement of comprehensive income for the company has not been separately presented in these financial statements.

Prothena Corporation plc

Notes

Forming part of the Parent Company Financial Statements

## 1. Summary of Significant Accounting Policies

### Basis of Preparation

The directors have elected to prepare the Parent Company Financial Statements in accordance with Section 1 of the Companies (Miscellaneous Provisions) Act 2009 (as amended), which provides that a true and fair view of the state of affairs and profit or loss of the group may be given by preparing the financial statements in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”), as defined in Section 1 of the Companies (Miscellaneous Provisions) Act 2009 (as amended), to the extent that the use of those principles in the preparation of the financial statements does not contravene any provision of the Companies Acts, 1963-2013 or of any regulations made thereunder.

### Functional Currency

Items included in the balance sheet are measured using the currency of the primary economic environment in which the Company operates (the “functional currency”). The balance sheet is presented in United States dollars, which is the Company’s functional currency. Transactions in foreign currencies are recorded at the rate ruling at the date of the transaction. The resulting monetary assets and liabilities are translated at the balance sheet rate with the resulting gains or losses reflected in the profit and loss account.

### Profit and Loss Account

In accordance with Section 148(8) of the Companies Act, 1963 and Section 7(1A) of the Companies (Amendment) Act, 1986, the Company has availed of the exemption from presenting the individual profit and loss account. The Company’s profit for the period from September 26, 2012 (the date of incorporation) to December 31, 2012 was \$Nil. The net loss for the year ended December 31, 2013 was \$3.2 million.

### Financial Assets

The Company’s investment in subsidiary was recorded at cost which equaled fair value on December 20, 2012 (the day immediately preceding the effective date of the separation and distribution referred to in Note 3 below), based on the Company’s market capitalization at that time. This initial valuation is the Company’s cost basis for its investment in its subsidiaries. The investment is tested for impairment if circumstances or indicators suggest that impairment may exist.

### Taxation

Current tax is provided on the Company’s taxable profits, at amounts expected to be paid, using the tax rates and laws that have been enacted or substantially enacted by the balance sheet date.

Deferred tax is accounted for in respect of all timing differences that have originated but not reversed at the balance sheet date. Provision is made at the tax rates that are expected to apply in the periods in which the timing differences are expected to reverse. Timing differences arise from the inclusion of items in income and expenditure in tax computations in periods different from those in which they are included in the financial statements.



A deferred tax asset is only recognized when it is more likely than not the asset will be recoverable in the foreseeable future out of suitable taxable profits from which the underlying timing differences can be recovered.

Prothena Corporation plc

Notes

Forming part of the Parent Company Financial Statements (continued)

## 2. History and Description of the Company

The Company was incorporated in Ireland as a private limited company under the name “Neotope Corporation Limited” on September 26, 2012. The Company was subsequently re-registered as a public limited company and changed the name of the company to “Neotope Corporation plc”. On November 1, 2012, the Company’s shareholders resolved to change the name of the company to “Prothena Corporation plc”, and this was approved by the Irish Registrar of Companies on November 7, 2012.

Prothena’s business consists of a substantial portion of Elan Corporation, plc’s (now Elan Corporation Limited, a wholly owned subsidiary of Perrigo Company plc, “Elan”) former drug discovery business platform, including Neotope Biosciences Limited and Onclave Therapeutics Limited, each former wholly-owned subsidiaries of Elan (which for the period prior to the separation and distribution is 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 of the Prothena Business from Elan, and the related distribution of its ordinary shares to Elan’s shareholders (which is refer to in this report as the “separation and distribution”), its 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.

## 3. Financial Fixed Assets

Investment in Subsidiaries for the years ended December 31, (in thousands):

	2013	2012
	\$	\$
Beginning Cost	100,829	—
Investment in Neotope Biosciences Ltd	—	100,829
Shares based compensation for Prothena Biosciences Inc	1,820	—
Ending Cost	102,649	100,829

In 2012, the Company acquired 100% of the ordinary share capital of Neotope Biosciences Limited, a research and development company incorporated in the Republic of Ireland. The principal activity of Prothena Corporation plc is an investment holding company. The Company’s investment in Neotope Biosciences Limited was recorded at fair value of \$100,829,000 on December 20, 2012 (date of the separation and distribution) based on the market price of the Prothena Corporation plc ordinary shares at the time of the separation and distribution. This initial valuation became the Company’s cost basis in Neotope Biosciences Limited. Prothena Corporation plc is the 100% parent of Neotope Biosciences Limited, Onclave Therapeutics Limited (both incorporated in the Republic of Ireland) and Prothena Biosciences Inc (incorporated in the United States), all of whom are engaged in research and development activities.

## 4. Employees

The Company had no employees as of December 31, 2013 and 2012, respectively.

## 5. Auditors Remuneration

KPMG Ireland received \$3,000 for the statutory audit of Prothena Corporation plc for the period ended 31 December 2013.



Prothena Corporation plc

Notes

Forming part of the Parent Company Financial Statements (continued)

6. Other Current Liabilities

Other current liabilities composition for the years ended December 31, (in thousands):

	2013	2012
	\$	\$
Trade payable	229	—
Amounts due to group undertakings	113	—
Accrued liabilities	424	—
Balance at the end of the year	766	—

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