Prothena Corp plc
Form 10-K
March 29, 2013
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2012

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to .

Commission file 001-35676

Prothena Corporation plc

(Exact name of registrant as specified in its charter)

Ireland	**43-1256213**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
650 Gateway Boulevard South San Francisco, California	**94080**
(Address of principal executive offices)	**(Zip Code)**

Registrant s telephone number, including area code: **(650) 837-8550**

Securities registered pursuant to Section 12(b) of the Act

Title of Each Class	**Name of Each Exchange on Which Registered**
Ordinary Shares, par value $0.01 per share	**The NASDAQ Global Market**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ¨ No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule12b-2 of the Exchange Act.:

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company x

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

The number of shares of common stock outstanding as of February 28, 2013 was 17,679,182.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s definitive Proxy Statement for its 2013 Annual Stockholders Meeting are incorporated by reference into Part III of this Annual Report on Form 10-K, to be filed within 120 days of the registrant s fiscal year ended December 31, 2012.

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PROTHENA CORPORATION plc

Form 10K ANNUAL REPORT

For the Fiscal Year Ended December 31, 2012

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

In this Annual Report, except as otherwise indicated or unless the context otherwise requires, all references to we, our, us, Prothena or the Company refer to Prothena Corporation plc, an Irish public limited company, together with its consolidated subsidiaries. References in this Annual Report to Elan refer to Elan Corporation, plc and its consolidated subsidiaries (other than, for all periods following the separation and distribution, Prothena). All references to we, our, us, Prothena or the Company in the context of historical results refer to the Prothena Busin (as defined herein). Except as otherwise indicated or unless the context otherwise requires, the information included in this Annual Report, including the combined financial statements of Prothena, which are comprised of the assets and liabilities of the Prothena Business, assumes the completion of all the transactions referred to in this Annual Report in connection with the separation of the Prothena Business from Elan (including the issuance of Prothena ordinary shares to Elan immediately following the separation and distribution).

This Annual Report on Form 10-K and the documents incorporated herein by reference contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the safe harbor created by those sections. These statements relate to future events or our future financial performance. Forward-looking statements may include words such as may, will, should, expect, plan, intend, anticipate, believe, estimate, pr continue or other wording indicating future results or expectations. Forward-looking statements are subject to risks and uncertainties, and actual events or results may differ materially. Factors that could cause our actual results to differ materially include, but are not limited to, those discussed under Risk Factors in this report. We also face risks and uncertainties relating to our business including:

- our ability to obtain additional financing;
- our history of operating losses;
- tax treatment of our separation from Elan and subsequent distribution of our ordinary shares;
- restrictions on our taking certain actions due to tax rules and covenants with Elan;
- our ability to successfully complete research and development of our drug candidates and the growth of the markets for those drug candidates;
- our ability to develop and commercialize products before competitors that are superior to the alternatives developed by such competitors;
- our ability to protect our patents and other intellectual property;
- loss of key employees;
- the impact of our separation from Elan and risks relating to our ability to operate effectively as a stand-alone, publicly traded company, including, without limitation:
- our ability to achieve benefits from our separation;

changes in our cost structure, management, financing and business operations;

growth in costs and expenses;

our ability to maintain financial flexibility and sufficient cash, cash equivalents, and investments and other assets capable of being monetized to meet our liquidity requirements;

disruptions in the U.S. and global capital and credit markets;

fluctuations in foreign currency exchange rates;

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

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extensive government regulation;

the volatility of our share price;

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

business disruptions caused by information technology failures; and

the other risks and uncertainties described in Item 1A, Risk Factors.

We undertake no obligation to revise or update any forward-looking statements to reflect any event or circumstance that arises after the date of this report, or to conform such statements to actual results or changes in our expectations, except as required by law.

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated Financial Statements and the Notes thereto appearing elsewhere in this Annual Report on Form 10-K. In addition to the other information in this Annual Report on Form 10-K, investors should carefully consider the following discussion and the information under Risk Factors when evaluating us and our business.

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PART I

Item 1. Business

Overview

We are a biotechnology company focused on the discovery and development of novel antibodies for the potential treatment of a broad range of diseases that involve protein misfolding or cell adhesion. We focus on the discovery and development of potential therapeutic monoclonal antibodies directed specifically to disease causing proteins. These potential therapies have a broad range of indications including AL and AA forms of amyloidosis, Parkinson s disease and related synucleinopathies, and novel cell adhesion targets involved in inflammatory disease and metastatic cancers. We plan to initiate Phase 1 clinical trials in these indications during the first half of 2013, 2014 and 2015, respectively. Our strategy is to apply our extensive expertise in generating novel therapeutic antibodies and work with collaborators having expertise in specific animal models of disease, to identify antibody candidates for clinical development.

We were incorporated in Ireland as a private limited company under the name Neotope Corporation Limited on September 26, 2012. We subsequently re-registered as a public limited company and changed the name of the company to Neotope Corporation plc . On November 1, 2012, our 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 (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 separation and distribution we refer to herein as the Prothena Business). Prior to December 21, 2012, the Prothena Business operated as part of Elan and not as a separate stand-alone entity. After the separation from Elan, and the related distribution of our ordinary shares to Elan s stockholders (which we refer to in this report as the separation and distribution), our ordinary shares began trading on The NASDAQ Global Market under the symbol PRTA on December 21, 2012.

In connection with the separation and distribution, Elan invested cash in us in an amount that, together with the 18% of our outstanding ordinary shares (as calculated immediately following the consummation of such subscription) that a wholly-owned subsidiary of Elan acquired immediately following the separation and distribution, equaled $125.0 million.

Our Approach

We focus on the discovery and development of potential therapeutic monoclonal antibodies directed specifically to disease causing proteins. These potential therapies have a broad range of indications including AL (primary) and AA (secondary) forms of amyloidosis, Parkinson s disease and related synucleinopathies, and novel cell adhesion targets involved in inflammatory disease and metastatic cancers. Our strategy is to apply our extensive expertise in generating novel therapeutic antibodies and work with collaborators having expertise in specific animal models of disease, to identify antibody candidates for clinical development.

An epitope is the molecular target recognized by an antibody. A neo-epitope is a site on a protein that becomes accessible only after modification, such as from cleavage or by misfolding into an abnormal shape. The neo-epitopes we target may occur as part of a disease-associated pathological process. We are developing novel, specific monoclonal antibodies against neo-epitope targets for the potential treatment of patients having a disease associated with the neo-epitope.

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Targeting Neo-epitopes of Misfolded Proteins Associated with Disease

In addition to antibodies directed to neo-epitope targets, we are developing antibodies directed to other targets. For example, we have generated antibodies against novel cell adhesion targets expressed on certain pathogenic Th17 immune cells and tumor cells. One specific cell adhesion protein, called melanoma cell adhesion molecule, or MCAM, interacts with another protein called laminin near blood vessel walls which allows circulating tumor cells and a critical subset of T cells to leave the bloodstream and enter into tissues, sometimes initiating pathogenic processes that result in disease. Antibodies that interfere with the cell adhesion process may be useful for treating a range of inflammatory disease and metastatic cancers.

Targeting Cell Adhesion Involved in Disease Processes

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Research and Development Pipeline

Our research and development pipeline includes three lead therapeutic antibody programs that we will aggressively advance: NEOD001 for the treatment of AL and AA Amyloidosis; PRX002 (*formerly* NEOD002) for the treatment of Parkinson s disease; and PRX003 for the potential treatment of inflammatory disease and metastatic cancers.

Our pipeline also includes two late discovery stage programs for which we are testing efficacy of antibodies in preclinical models of disease: tau antibodies for potential treatment of Alzheimer s disease and antibodies for the potential treatment of type 2 diabetes. We are also generating additional novel antibodies against other targets involved in protein misfolding and cell adhesion for characterization in vivo and in vitro. If promising, these antibodies will advance to preclinical development.

The following table summarizes the status of our research and development pipeline:

Our Lead Programs

NEOD001 for amyloidosis

We are developing NEOD001, a monoclonal antibody targeting AL and AA amyloid for the potential treatment of amyloidosis.

Systemic amyloidoses are a complex group of diseases caused by tissue deposition of misfolded proteins that result in progressive organ damage. The most common type, AL amyloidosis or primary amyloidosis, involves a hematological disorder caused by plasma cells that produce misfolded AL protein resulting in deposits of abnormal AL protein (amyloid), in the tissues and organs of individuals with AL amyloidosis. Although little data are available on amyloidosis populations, AL amyloidosis is a rare disorder with an estimated incidence of 8.9 in 1,000,000 patient years. Only 1,200 to 3,200 new cases of AL amyloidosis are reported each year in the United States. Both the causes and origins of AL amyloidosis remain poorly understood.

Current treatments of patients with AL amyloidosis are organ transplant or treatments aimed at reducing or eliminating the bone marrow disorder, i.e. the plasma cells that are responsible for producing the AL protein, thereby limiting production of amyloid. There are no currently approved treatments for AL amyloidosis that directly target potentially toxic forms of the AL protein.

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A different form of systemic amyloidosis, AA amyloidosis or secondary amyloidosis, occurs secondarily as a result of other illnesses, such as chronic inflammatory diseases (for example, rheumatoid arthritis and ankylosing spondylitis) or chronic infections (for example, tuberculosis or osteomyelitis). In secondary amyloidosis, the depositing amyloid protein is amyloid A protein. Amyloid A protein is a cleaved fragment from the acute phase protein serum amyloid A that is produced in abundance by the liver as a result of chronic inflammation. The treatment of secondary amyloidosis is directed at treating the underlying illness, typically with broad acting anti-inflammatory agents such as tumor necrosis factor, or TNF, inhibitors. It is estimated that there are 8,000 patients in the United States and Europe suffering from AA amyloidosis.

NEOD001 is a monoclonal antibody that specifically targets the amyloid that accumulates in both AL and AA forms of amyloidosis. The antibody was designed to not react with normal serum amyloid and only with the aberrant cleaved form of the protein (amyloid A). This approach has the potential to be a first-in-class agent for this orphan disease with a significant unmet medical need. Together with scientists at the University of Tennessee performing under a Sponsored Research Agreement pursuant to which such scientists perform research at our direction and pursuant to project plans we establish, Prothena scientists have published a number of papers characterizing the mouse version of this antibody. NEOD001 was granted orphan drug designation by the FDA in 2012 and by the European Medicines Agency in 2013. An Investigational New Drug application, or IND, for NEOD001 in systemic amyloidosis (AL and AA forms of amyloidosis) was filed and accepted by the FDA in 2012. We plan to initiate a Phase 1 clinical trial for NEOD001 in this indication during the first half of 2013. The primary objectives of the phase 1 trial are to evaluate safety and tolerability of NEOD001 and determine a recommended dose for testing NEOD001 in phase 2 trials. We anticipate that a phase 2 trial of NEOD001 could be initiated in 2014 assuming a phase 2 recommended dose is identified prior to that date.

PRX002 (formerly NEOD002) for Parkinson s disease

We are developing PRX002, a monoclonal antibody targeting synuclein for the potential treatment of Parkinson s disease and other synucleinopathies. Together with scientists at the University of California, San Diego performing under a Laboratory Services Agreement pursuant to which such scientists perform research at our direction and pursuant to project plans we establish, Prothena scientists have published a number of scientific papers describing effects of these antibodies in preclinical models resembling Parkinson s disease.

Alpha-synuclein is a protein that is a prominent component of Lewy bodies and neurites which are pathological hallmarks of Parkinson s disease, dementia with Lewy bodies multiple system atrophy and certain other neurological disorders, collectively known as synucleinopathies. While the normal function of synuclein is not well understood, the protein normally occurs in an unstructured soluble form. In synucleinopathies, the synuclein protein can misfold and aggregate to form insoluble fibrils that contribute to the pathology of the disease.

Parkinson s disease is a degenerative disorder of the central nervous system. The motor symptoms of Parkinson s disease result from the death of dopamine-generating cells in the substantia nigra, a region of the midbrain.

Early in the course of the disease, the most obvious symptoms are movement-related and include shaking, rigidity, slowness of movement and difficulty with walking and gait. Later, cognitive and behavioral problems may arise, with dementia commonly occurring in the advanced stages of the disease. Other symptoms include sensory, sleep and emotional problems. Parkinson s disease is more common in the elderly, with most cases occurring after the age of 50.

Parkinson s disease is the second most common neurodegenerative disorder after Alzheimer s disease. In the United States, at least 500,000 people are believed to suffer from Parkinson s disease, and about 50,000 new cases are reported annually. Current treatments for Parkinson s disease are effective at managing the early motor symptoms of the disease, mainly through the use of levodopa and dopamine agonists. As the disease progresses

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and dopaminergic neurons continue to be lost, these drugs eventually become ineffective at treating the symptoms. The goal of our approach is to slow down the progressive neurodegenerative consequences of disease, a current unmet need.

There is genetic evidence for a causal role of synuclein in Parkinson s disease. In rare cases of familial forms of Parkinson s disease, there are mutations in the synuclein gene, or duplication and triplications of the gene that may cause synuclein protein to form amyloid-like fibrils that contribute to the disease. There is also increasing evidence that pathogenic forms of synuclein can be propagated and transmitted from neuron to neuron. Recent studies in cellular and animal models suggest that the spread of synuclein-associated neurodegeneration can be disrupted by targeting the pathogenic synuclein.

We have generated proprietary antibodies targeting alpha-synuclein that may slow or reduce the neurodegeneration associated with synuclein misfolding and/or transmission. We have tested the efficacy of these antibodies in various cellular and animal models of synuclein-related disease. We have identified a lead clinical candidate, PRX002, that has advanced into manufacturing and is advancing into preclinical safety testing and anticipate that we will file an IND and initiate a phase 1 trial of PRX002 for Parkinson s disease in 2014.

PRX003 for inflammatory disease and metastatic cancer

We are developing PRX003, a monoclonal antibody targeting MCAM (melanoma cell adhesion molecule) for the potential treatment of inflammatory disease and metastatic cancer.

MCAM is a cell adhesion molecule that allows certain cells travelling in the blood stream to leave the circulation and enter tissues. For example, MCAM is expressed on pathogenic Th-17 expressing immune cells that underlie inflammatory disease and on tumor cells involved in metastatic cancer. MCAM functions like VELCRO hook-and-loop fasteners, allowing these cells to stick to the blood vessel wall and migrate into tissues to initiate their pathogenic process.

Our research in the area of cell adhesion has uncovered unique insights into MCAM function, allowing us to develop specific and novel antibodies that block MCAM s VELCRO-like function as potential therapeutics to prevent disease causing cells from spreading into tissue.

Anti-MCAM antibodies may be useful for treating a variety of inflammatory disease such as rheumatoid arthritis, psoriasis and multiple sclerosis. Inflammatory disease arises from an inappropriate immune response of the body against substances and tissues normally present in the body. In other words, the immune system mistakes some part of the body as a pathogen and attacks its own cells. A substantial portion of the population suffers from these diseases, which are often chronic, debilitating, and life-threatening. There are more than eighty illnesses caused by autoimmunity. It has been estimated that inflammatory disease are among the ten leading causes of death among women in all age groups up to 65 years. Current treatment for many inflammatory disease typically entails use of broad acting immunosuppressive agents that weaken the body s ability to fight infection. Only 3-5% of CD4+ T-cells in the circulation express MCAM, yet these cells appear to be disproportionately involved in propagation of inflammatory disease. Hence, anti-MCAM based therapy may provide a more specific way to target the disease -causing immune cells while not interfering with normal function of the immune system.

MCAM antibodies may also be useful for treating metastatic cancers, including melanoma. Melanoma is a malignant tumor of melanocytes, a potentially dangerous form of skin cancer. It was estimated that doctors in the United States would diagnose about 76,250 new cases of melanoma in 2012, with approximately 9,000 melanoma-related deaths that are usually related to metastatic spread of the tumors. Normal melanocytes do not express MCAM, but expression is turned on and continues to increase as the cells become more malignant. Treatment with anti-MCAM antibodies may help patients with melanoma by inhibiting the growth and spread of the tumor.

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We have generated monoclonal antibodies that selectively block MCAM-mediated cell adhesion. Our antibodies are currently being tested in animal models of inflammatory disease and metastatic cancer. Based on early results from these studies, we have identified a lead clinical candidate, PRX003, and intend to advance this antibody into manufacturing and preclinical safety testing. We anticipate that we will file an IND and initiate a phase 1 trial of PRX003 in 2015.

Our Discovery Programs

Tau antibodies for Alzheimer s disease

We are developing antibodies targeting tau for the potential treatment of Alzheimer s disease and other tauopathies.

Tau proteins are proteins that stabilize microtubules. They are abundant in neurons of the central nervous system and are less common elsewhere in the body. When tau proteins are defective, they often misfold and aggregate to form neurofibrillary tangles. Tau sequestered in neurofibrillary tangles no longer has the ability to stabilize microtubules properly and is thought to be linked to the progressive neurodegeneration characteristic of several neurological diseases known as tauopathies. Tauopathies are a class of neurodegenerative diseases associated with the pathological aggregation of tau protein in the human brain. The best-known of these illnesses is Alzheimer s disease, wherein tau protein is deposited within neurons.

Alzheimer s disease is a degenerative brain disease that slowly destroys memory and thinking skills. It can begin with simple forgetfulness, but may rapidly progress into more advanced symptoms, including confusion, profound memory loss, language disturbances, personality and behavior changes, impaired judgment and dementia. Alzheimer s disease primarily affects older people, and in most cases, readily apparent symptoms appear after age 60. It is estimated that more than 5 million Americans and more than 35 million people worldwide, at the age of 60 years or older, suffer from some form of dementia. Although some patients may live up to 20 years after being diagnosed with Alzheimer s disease, the average life expectancy after diagnosis is eight to ten years. No current therapy alters the progressive and eventually fatal neurodegenerative consequences of these conditions.

Recent experimental data from multiple laboratories show that pathogenic forms of tau can be propagated and spread between neurons. It has further been demonstrated that administration of tau antibodies in animal models with tauopathies can potentially interrupt tau propagation and the resulting neurodegenerative effects of this process.

We have generated and tested in vivo a variety of proprietary tau antibodies. We are currently selecting optimal candidates for their ability to block propagation and toxicity associated with misfolded forms in animal models of tauopathies. These studies will help us to identify a potential clinical candidate to advance into manufacturing and preclinical safety testing and we anticipate that, if successful, we will file an IND with a tau clinical candidate in 2015.

Antibodies for Type 2 diabetes

We are developing antibodies to protect against loss of insulin producing beta cells of the pancreas for the potential treatment of type 2 diabetes.

Type 2 diabetes is a metabolic disorder characterized by high blood glucose in the context of insulin resistance and relative insulin deficiency. Type 2 diabetes makes up about 90% of cases of diabetes, and obesity is thought to be the primary cause of type 2 diabetes in people who are genetically predisposed to the disease. Rates of diabetes have increased markedly over the last 50 years in parallel with obesity. Type 2 diabetes is a global health problem affecting more than 300 million people worldwide. Long-term complications from high blood sugar can include heart disease, strokes, diabetic retinopathy where eyesight is affected, kidney failure which may require dialysis, and poor circulation of limbs leading to amputations.

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Type 2 diabetes is initially managed by increasing exercise and dietary modification. If blood glucose levels are not adequately lowered by these measures, medications may be needed. In type 2 diabetes, patients become increasingly unable to adequately regulate blood glucose levels and current therapies such as metformin and insulin only target this hyperglycemia. In many cases, the progressive loss of insulin producing beta cells of the pancreas leads to dependence upon injected insulin to manage blood glucose levels. Current therapies do not target the fundamental mechanism by which these beta cells are lost in disease.

We have generated unique antibodies and are currently testing the hypothesis that treatment with these antibodies may reduce the progressive increase in glucose levels in animal models of type 2 diabetes. If successful, these studies will help us identify a potential clinical candidate to advance into manufacturing and preclinical safety testing and we anticipate that, if successful, we will file an IND with a type 2 diabetes clinical candidate in 2015.

Our Strategy

We will advance novel and proprietary therapeutic antibodies discovered by our scientists internally. Our goal is to be a leading biotechnology company focused on discovery and development of novel antibodies for the potential treatment of a broad range of diseases that involve protein misfolding or cell adhesion. Key elements of our strategy to achieve this goal are:

Continue to discover potential therapeutic antibodies directed against novel targets involved in protein misfolding and cell adhesion. We will continue to leverage our core scientific expertise and proprietary technology to develop innovative antibody-based therapeutics for the potential treatment of a range of diseases. Once we formulate a novel hypothesis or approach to a known target, we generate antibodies against that target. Specific and selective antibodies are characterized in vitro, then used to test the initial hypothesis in vivo using animal models of disease. We typically rely on the use of animal models that have been extensively developed by external laboratories, as we have already done with three of our programs: AL amyloidosis, Parkinson s disease and tau for Alzheimer s disease. We plan to maintain a broad and diverse pipeline of antibodies with multiple potential indications.

Quickly translate our research discoveries into clinical development. Once we establish in vivo proof of concept for our antibody candidates, we use animal models to identify potential clinical candidates to rapidly advance to manufacturing and preclinical testing. We have contracted with Boehringer Ingelheim for cell line development and antibody drug substance production. In 2012, we filed an Investigational Drug Application with the FDA for NEOD001 in AL and AA amyloidosis and we plan to initiate a Phase 1 clinical trial of NEOD001 in amyloidosis patients during the first half of 2013.

Establish early clinical proof of concept with our therapeutic antibodies. We will leverage our insight of pathology in diseases involving protein misfolding and cell adhesion to employ biomarker endpoints as a way to detect signals of clinical efficacy early in the clinical development process. We may elect to start clinical testing of our antibodies in smaller indications having more well-established endpoints in order to demonstrate proof of concept as a basis for further investment in clinical trials, potentially in larger indications, by us or potential partners.

Strategically collaborate or out-license select programs. We intend to seek to collaborate or license certain potentially therapeutic antibody products to biotechnology or pharmaceutical companies for preclinical and clinical development and commercialization. For certain product opportunities, we may choose to proceed with further clinical development independently in order to create long term value. We intend to seek strategic alliances in which we would provide our research and development services for our collaborators as part of our plan to generate revenue.

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Highly leverage external talent and resources.

We plan to maintain strong talent internally having expertise in our core areas of focus and as needed to execute efficiently on our clinical development and business objectives. We will leverage outsourcing to meet our operational and business needs while maintaining flexibility as those needs may change over time. We plan to continue to rely on the very extensive experience of our management team to execute on our objectives.

Collaborate with scientific and clinical experts in disease areas of interest.

We collaborate with highly regarded scientists having expertise in our disease areas of interest to test and characterize our potential therapeutic antibody candidates. We also collaborate with leading clinical experts in our disease areas of interest for feedback and guidance on our programs. In addition, we engage a number of consultants having specific functional and/or disease area expertise to execute our preclinical and clinical development programs.

Regulation

We anticipate that if we commercialize any products, the U.S. market will be our most important market. For this reason, the factors discussed below, in Government Regulation, Product Approval and Orphan Drugs place emphasis on requirements in the United States.

Government Regulation

The pharmaceutical industry is subject to significant regulation by international, national, state and local governmental regulatory agencies. Pharmaceutical product registration is primarily concerned with the safety, efficacy and quality of new drugs and devices and, in some countries, their pricing. A product must generally undergo extensive clinical trials before it can be approved for marketing. The process of developing a new pharmaceutical product, from idea to commercialization, can take in excess of 10 years.

Governmental authorities, including the FDA and comparable regulatory authorities in other countries, regulate the design, development, testing, manufacturing and marketing of pharmaceutical products. Non-compliance with applicable requirements can result in fines and other judicially imposed sanctions, including product seizures, import restrictions, injunctive actions and criminal prosecutions of both companies and individuals. In addition, administrative remedies can involve requests to recall violative products; the refusal of the government to enter into supply contracts; or the refusal to approve pending product approval applications for drugs, biological products or medical devices until manufacturing or other alleged deficiencies are brought into compliance. The FDA also has the authority to cause the withdrawal of approval of a marketed product or to impose labeling restrictions.

The pricing of pharmaceutical products is regulated in many countries and the mechanism of price regulation varies. In the United States, while there are limited indirect federal government price controls over private sector purchases of drugs, it is not possible to predict future regulatory action on the pricing of pharmaceutical products.

Product Approval

Preclinical tests assess the potential safety and efficacy of a product candidate in animal models. The results of these studies must be submitted to the FDA as part of an Investigational New Drug Application before human testing may proceed.

The clinical trial process can take three to ten years or more to complete, and there can be no assurance that the data collected will demonstrate that the product is safe or effective or, in the case of a biologic product, pure and potent, or will provide sufficient data to support FDA approval of the product. The FDA may place clinical

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trials on hold at any point in this process if, among other reasons, it concludes that clinical subjects are being exposed to an unacceptable health risk. Trials may also be terminated by institutional review boards, which must review and approve all research involving human subjects. Side effects or adverse events that are reported during clinical trials can delay, impede or prevent marketing authorization.

The results of the preclinical and clinical testing, along with information regarding the manufacturing of the product and proposed product labeling, are evaluated and, if determined appropriate, submitted to the FDA through a license application such as a New Drug Application, or NDA, or a Biologics License Application, or BLA. In certain cases, an Abbreviated New Drug Application, or ANDA, can be filed in lieu of filing an NDA.

There can be no marketing in the United States of any drug, biologic or device for which a marketing application is required until the application is approved by the FDA. Until an application is actually approved, there can be no assurance that the information requested and submitted will be considered adequate by the FDA. Additionally, any significant change in the approved product or in how it is manufactured, including changes in formulation or the site of manufacture, generally require prior FDA approval. The packaging and labeling of all products developed by us are also subject to FDA approval and ongoing regulation.

Whether or not FDA approval has been obtained, approval of a pharmaceutical product by comparable regulatory authorities in other countries outside the United States must be obtained prior to the marketing of the product in those countries. The approval procedure varies from country to country. It can involve additional testing and the time required can differ from that required for FDA approval. Although there are procedures for unified filings for EU countries, in general, most other countries have their own procedures and requirements.

Once a product has been approved, significant legal and regulatory requirements apply in order to market a product. In the United States, these include, among other things, requirements related to adverse event and other reporting, product advertising and promotion, and ongoing adherence to cGMP requirements, as well as the need to submit appropriate new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process.

The FDA also enforces the requirements of the Prescription Drug Marketing Act, which, among other things, imposes various requirements in connection with the distribution of product samples to physicians. Sales, marketing and scientific/educational grant programs must comply with the Medicare-Medicaid Anti-Fraud and Abuse Act, as amended, the False Claims Act, as amended, and similar state laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, as amended. We are also subject to Section 6002 of the Affordable Care Act, or ACA, commonly known as the Physician Payment Sunshine Act, or Sunshine Act, which regulates disclosure of payments to healthcare professionals and providers.

The FCPA and UK Bribery Act prohibit companies and their representatives from offering, promising, authorizing or making payments to foreign officials (and certain private individuals under the U.K. Bribery Act) for the purpose of obtaining or retaining business abroad. In many countries, the healthcare professionals we interact with may meet the definition of a foreign government official for purposes of the FCPA. Failure to comply with domestic or foreign laws could result in various adverse consequences, including possible delay in approval or refusal to approve a product, recalls, seizures, withdrawal of an approved product from the market, the imposition of civil or criminal sanctions and the prosecution of executives overseeing our international operations.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally defined as a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting an NDA. After the

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FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA applicant to receive FDA approval for a particular active ingredient to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the United States for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug for the same orphan indication, except in limited circumstances, such as a showing of clinical superiority to the product with orphan.

Patents and Intellectual Property Rights

We aggressively strive to protect the proprietary technology that we believe is important to our business, including seeking and maintaining domestic and international patents intended to cover our products and compositions, their methods of use and processes for their manufacture and any other inventions that may be commercially important to the development of our business. We also rely on trade secrets to protect aspects of our business. Our competitive position depends on our ability to obtain patents on our technologies and our potential products, to defend our patents, to protect our trade secrets and to operate without infringing valid and enforceable patents or trade secrets of others. We seek licenses from others as appropriate to enhance or maintain our competitive position.

We own or hold licenses to a number of issued patents and US pending patent applications, as well as foreign patents and pending Patent Corporation Treaty applications and foreign counterparts.

In connection with our program targeting AL and AA amyloid for the potential treatment of amyloidosis, we own US Patent No. 7,928,203, which is a composition of matter patent and expires in 2029 and US Patent No. 8,268,973, which is a composition of matter patent and expires in 2028. We also have ownership rights in US Patent No. 8,124,081, which is a method of treatment patent and expires in 2020. In addition, we jointly own with the University of Tennessee patent applications pending in the United States, Australia, Brazil, China, Colombia, Eurasia, Europe, Hong Kong, Indonesia, Israel, India, Japan, South Korea, Mexico, Norway, New Zealand, Philippines, Singapore and South Africa, and have exclusively licensed the University of Tennessee s joint ownership interest in these patent applications. Under our exclusive, sublicensable, worldwide license agreement with the University of Tennessee entered into on December 8, 2008, we paid to the University of Tennessee an annual maintenance fee of $10,000 on each of the first two anniversaries of execution of the license agreement, and have paid, and are required to continue to pay, $25,000 on each anniversary thereafter. In addition, we have paid a license issue fee of $10,000, and we are required to pay to the University of Tennessee an amount equal to 1% of net sales of any product covered by any applicable patent, plus certain additional royalties in the event that all or a portion of the license is sublicensed. To date, we have not paid or incurred any royalties to the University of Tennessee under our license agreement. The license agreement will continue in effect on a country-by-country basis for the longer of (i) a period of twenty years from the date of execution of the license agreement, or (ii) in each country in which a valid claim for any licensed patent or patent application exists, expiration of such valid claim. The University of Tennessee may terminate the agreement prior to the end of its term if we are adjudicated by a court of competent jurisdiction to be insolvent, if we are dissolved or are declared bankrupt, upon our failure to make payment under the agreement within 120 days of notice of such failure or upon our material breach of the agreement, which breach has not been cured within sixty days of written notice of such breach. We may terminate the agreement prior to the end of its term upon three months written notice to the University of Tennessee or upon material breach of the agreement by the University of Tennessee, which breach has not been cured within sixty days of written notice of such breach.

We also hold exclusive, royalty-free sublicenses from affiliates of Elan under US and foreign patent rights owned by Janssen Alzheimer Immunotherapy relating to immunotherapeutic approaches targeting misfolding proteins other than amyloid beta peptide. In connection with our program targeting synuclein for the potential treatment of Parkinson s disease and other synucleinopathies, we own or hold an exclusive, royalty-free license from affiliates of Elan to US Patent No. 7,910,333, which is a composition of matter patent and expires in 2024,

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and we own or hold non-exclusive royalty-free licenses from affiliates of Elan under patent rights relating to research tools such as animal models and assay technology in support of our programs relating to synucleinopathies and Alzheimer s disease. In addition, we jointly own with the University of California San Diego US Patent Nos. 7,919,088, 8,092,801 and 8,147,833, which are method of treatment patents and expire in 2025, 2029 and 2027, respectively.

We also own patent applications relating to AL and AA, synuclein, MCAM and various discovery programs that are pending in the United States and other countries, which, if issued, would have expiration dates in the range of 2020 through 2032, excluding any available patent term adjustment.

Competition

The pharmaceutical industry is highly competitive. Our principal competitors consist of major international companies, all of which are larger and have greater financial resources, technical staff, manufacturing, R&D and marketing capabilities than we have. We also compete with smaller research companies and generic drug and biosimilar manufacturers. The degree of competition varies for each of our programs.

A drug may be subject to competition from alternative therapies during the period of patent protection or regulatory exclusivity and thereafter it may be subject to further competition from generic products or biosimilars. Governmental and other pressures toward the dispensing of generic products or biosimilars may rapidly and significantly reduce, slow or reverse the growth, sales and profitability of any product not protected by patents or regulatory exclusivity, and may adversely affect our future results and financial condition. If we successfully discover, develop and commercialize any products, the launch of competitive products, including generic or biosimilar versions of any such products, may have a material adverse effect on our revenues and results of operations.

Our competitive position depends in part upon our ability to discover and develop innovative and cost-effective new products. If we fail to discover and develop new products, our business, financial condition and results of operations will be materially and adversely affected.

Product Supply

While supplies of raw materials and clinical supplies of our main product candidate are generally available in quantities adequate to meet the needs of our business, we are dependent on Boehringer Ingelheim to manufacture our clinical supplies of NEOD001. An inability to obtain product supply could have a material adverse effect on our business, financial condition and results of operations.

Research and Development

Our research and development expenses totaled $34.1 million, $24.2 million and $9.8 million in 2012, 2011 and 2010, respectively. For more information, see Management s Discussion and Analysis of Financial Condition and Results of Operations.

We are performing certain research and development services for Elan and we intend to pursue opportunities to perform research and development services for unrelated parties with whom we are otherwise collaborating, using compensation arrangements that are consistent with industry arrangements between unrelated parties. We also may earn income through licensing agreements and other types of transactions.

Employees

As of December 31, 2012, we had 30 employees, of whom approximately 23 were engaged in research and development activities and the remainder working in general and administrative areas.

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Information about Segment and Geographic Revenue

Information about segment and geographic revenue is set forth in Note 2 of the Notes to Consolidated Financial Statements under Item 8 of this Annual Report on Form 10-K.

Available information

Our registration statement on Form 10 and our current reports on Form 8-K, and all amendments to those reports, filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge on our website at www.prothena.com as soon as reasonably practicable after we file such reports with the Securities and Exchange Commission, or the SEC. Information contained in, or accessible through, our website is not incorporated by reference into and does not form a part of this report.

Our periodic and current reports, registration statements, proxy and information statements and other information are available for inspection and copying at the SEC s Public Reference Room at 100 F Street, NE, Washington, DC 20549 or may be obtained by calling the SEC at 1-800-SEC-0330.The SEC also maintains a website containing such information available free of charge to the public at http://www.sec.gov.

Item 1A. Risk Factors

You should carefully consider the risks described below, together with all of the other information included in this Annual Report on Form 10-K, in considering our business and prospects. Set forth below and elsewhere in this report and in other documents we file with the 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. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. Each of these risk factors could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our common stock.

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 $41.4 million, $29.7 million and $12.5 million for the years ended December 31, 2012, 2011 and 2010, respectively. We expect to continue to incur substantial losses for the foreseeable future as we:

- conduct our planned Phase 1 clinical trial for NEOD001 and initiate additional clinical trials, if supported by the results of the Phase 1 trial;
- complete preclinical development of other product candidates and initiate clinical trials, if supported by positive preclinical data;
- pursue our early stage research and seek to identify additional drug candidates and potentially acquire rights from third parties to drug candidates through licenses, acquisitions or other means; and
- add operational, financial and management information systems and other personnel.

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

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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, 2012, we had cash and cash equivalents of approximately $124.9 million. Although we expect that our existing cash and cash equivalents will be sufficient to support us through 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:

- the timing of initiation, progress, results and costs of our clinical trials;
- the results of our research and preclinical studies;
- the costs of clinical manufacturing and of establishing commercial manufacturing arrangements;
- the costs of preparing, filing, and prosecuting patent applications and maintaining, enforcing, and defending intellectual property-related claims;
- the costs and timing of capital asset purchases;
- our ability to establish research collaborations and strategic collaborations and 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 this expectation 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. Our future capital requirements will depend on numerous factors, including, the timing of initiation, progress, results and costs of our clinical trials; the results of our research and preclinical studies; the costs of clinical manufacturing and of establishing commercial manufacturing arrangements; the costs of preparing, filing, and prosecuting patent applications and maintaining, enforcing, and defending intellectual property-related claims; the costs and timing of capital asset purchases; our ability to establish research collaborations and strategic collaborations and licensing or other arrangements; the costs to satisfy our obligations under potential future collaborations; and the timing, receipt, and amount of revenues or royalties, if any, from any approved drug candidates.

In order to develop and obtain regulatory approval for our potential products we will need to raise substantial additional funds through public or private equity offerings, debt financings, strategic alliances, joint ventures and licensing 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. If adequate funds are not available on a timely basis, we may be required to:

- terminate or delay clinical trials or other development for one or more of our drug candidates;

delay arrangements for activities that may be necessary to commercialize our drug candidates; or

curtail or eliminate our drug research and development programs that are designed to identify new drug candidates or cease operations.

We are not able to provide specific estimates of the timelines or total costs to complete the Phase 1 clinical trial for NEOD001. In the pharmaceutical industry, the research and development process is lengthy and involves a high degree of risk and uncertainty. This process is conducted in various stages and, during each stage, there is a substantial risk that potential products in our research and development pipeline will experience difficulties, delays or failures. This makes it difficult to estimate the total costs to complete the Phase 1 clinical trial for

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NEOD001, or any potential future drug candidates, and to estimate the anticipated completion date with any degree of accuracy, and raises concerns that attempts to provide estimates of timing may be misleading by implying a greater degree of certainty than actually exists.

We may seek to raise any necessary funds through public or private equity offerings, debt financings, strategic alliances, joint ventures and licensing arrangements. We may not be able to obtain additional financing on terms favorable to us, if at all. General market conditions may make it very difficult for us to seek financing from the capital markets. 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.

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

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

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.

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 no drug candidates in clinical trials. We may not be able to successfully discover, develop, obtain regulatory approval for or commercialize any drug candidates.

The success of our business depends substantially upon our ability to discover, develop, obtain regulatory approval for and commercialize our drug candidates successfully. Our research and development programs are prone to the significant and likely risks of failure inherent in drug development. We intend to continue to invest most of our time and financial resources in our research and development programs. Although we expect to conduct at least one Phase 1 clinical trial in an orphan indication during the next two years, we currently do not, and may never, have any drug candidates in clinical trials. In addition, we have not identified product 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

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

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

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

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

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

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

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

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

- conditions imposed on us by the FDA or any foreign regulatory authority regarding the scope or design of our clinical trials;
- delays in obtaining, or our inability to obtain, required approvals from institutional review boards, or IRBs, or other reviewing entities at clinical sites selected for participation in our clinical trials;

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

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

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- 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 begin 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 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.

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.

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Both before and after marketing approval, our drug candidates are or would be subject to ongoing regulatory requirements, 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 and record keeping related to the drug are subject to extensive regulatory requirements. If we fail to comply with the regulatory requirements of the FDA and other applicable U.S. and foreign regulatory authorities, we could be subject to administrative or judicially imposed sanctions, including:

- restrictions on the products or manufacturing processes;
- warning letters;
- civil or criminal penalties;
- fines;
- injunctions;
- product seizures or detentions;
- import 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.

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.

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,

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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 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.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell an approved product, 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. 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 adequate coverage and 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. These third-party payors are increasingly attempting to contain healthcare costs by demanding price discounts or

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rebates and limiting both coverage and the amounts that they will pay for new drugs, and, as a result, they may not cover or provide adequate payment for our drug candidates. We might need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any future products to such payors satisfaction. Such studies might require us to commit a significant amount of management time and financial and other resources. Our future products might not ultimately be considered cost-effective. Adequate third-party reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development.

U.S. and foreign governments continue to propose and pass legislation designed to reduce the cost of healthcare. For example, in some foreign markets, the government controls the pricing and profitability of prescription pharmaceuticals. 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. Cost control initiatives could decrease the price that we would receive for any products in the future, which would limit our revenue and profitability. Accordingly, legislation and regulations affecting the pricing of pharmaceuticals might change before our drug candidates are approved for marketing. Adoption of such legislation could further limit reimbursement for pharmaceuticals.

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, 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, reimbursement coverage, 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.

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

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

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

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

Risks Related to Our Dependence on Third Parties

We will 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 will need to 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 will reduce our control over these activities. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. Although we have and will enter into agreements with these third parties, we will be responsible for confirming that our clinical trials are conducted in accordance with their general investigational plans and protocols. Moreover, the FDA requires us to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the trial

participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities and requirements. To date, we believe our consultants, contract research organizations and other similar entities with which we are

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working have performed well; however, if these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be required to replace them. Although we believe that there are a number of other third-party contractors we could engage to continue these activities, it may result in a delay of our planned clinical trials. Accordingly, we may be delayed in obtaining regulatory approvals for our drug candidates and may be delayed in our efforts to successfully develop our drug candidates.

If we do not establish 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 leading pharmaceutical and 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 third-party manufacturers 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 will rely on a third-party manufacturer to supply, store, and distribute drug supplies for our planned clinical trials 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 unannounced inspection by the FDA and corresponding state and foreign agencies to ensure strict compliance with current Good Manufacturing Practice, or cGMP, 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.

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

To date, our drug candidates have been manufactured in small quantities for preclinical 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.

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 the intellectual property relating to our drug candidates, or if we infringe the rights of others, our ability to successfully commercialize our drug candidates will be harmed.

We own or hold licenses to a number of issued patents and U.S. pending patent applications, as well as foreign patents and pending Patent Corporation Treaty applications and foreign counterparts. In connection with our program targeting AL and AA amyloid for the potential treatment of amyloidosis, we have ownership rights in patents expiring between 2020 and 2029. In connection with our program targeting synuclein for the potential treatment of Parkinson s disease and other synucleinopathies, we have ownership rights and licenses related to patents expiring between 2024 and 2029. We also own patent applications relating to AL and AA, synuclein, MCAM and various discovery programs that are pending in the United States and other countries, which, if issued, would have expiration dates in the range of 2020 through 2032, excluding any available patent term adjustment. See Business Patents and Intellectual Property Rights for a detailed description of our owned and licensed intellectual property rights.

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

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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. 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 US Patent and Trademark Office, or the USPTO, for the entire time prior to issuance as a US 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 US and foreign patents or published applications that affect our business either by blocking our ability to commercialize our drugs or by covering similar technologies.

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 intend to 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.

We intend to enter into licenses that will give us rights to third-party intellectual property that is necessary or useful for our business. We expect that any such licensors may be able to terminate any agreements with us in the event we breach the applicable license agreement and fail to cure the breach within a specified period of time. Under potential license agreements we may be obligated to pay the licensor fees, which may include annual license fees, royalties, a percentage of revenues associated with the licensed technology and a percentage of sublicensing revenue. In addition, under most such agreements, we will be required to diligently pursue the development of products using the licensed technology.

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 obtain patents in the future and allege that the use of our technologies infringes these patent claims or that we are employing their proprietary technology without authorization. Elan is involved in litigation with the Alzheimer s Institute of America, or AIA. While the lawsuit was dismissed with prejudice, AIA appealed the result and if the appeal is successful, AIA may institute suit against us related to our research activities. If we become involved in this matter it may distract our management and result in substantial costs, although Elan is contractually obligated pursuant to the terms of the Demerger Agreement to reimburse us for our expenses and indemnify us for any damages.

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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.

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 Relating to the Separation and the Distribution

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

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

- greater strategic focus of financial resources and management s efforts;

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direct and differentiated access to capital resources;

enhanced investor ability to evaluate our financial performance and strategy against our peer group; and

improved ability to align management incentive compensation with our performance by issuing Prothena stock options.

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

the regulatory and other managerial challenges of operating as an independent public company may distract our management team from focusing on our business and strategic priorities;

we will require substantial ongoing cash investment for the foreseeable future, we will no longer be supported by the revenue and cash flows of Elan s business and we may not be able to issue debt or equity on terms acceptable to us or at all;

our ability to differentiate our company against our peer group and attract early stage biotechnology investors is largely dependent on the success of our research and development programs, which are at an early stage; and

we expect to pay our key executives less cash compensation than what they were paid at Elan, so even if we are able to provide potential equity compensation tied specifically to our business, we may not be able to attract and retain employees as desired.

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

If the IRS successfully challenges the tax-free treatment of the separation and distribution, our U.S. shareholders may incur substantial U.S. federal income tax liability.

Elan received an opinion on the closing date of the separation and distribution from each of Cadwalader, Wickersham & Taft LLP and KPMG LLP to the effect that the separation and distribution should qualify as a reorganization under section 368(a)(1)(D) of the Code, and the distribution, as such, should qualify as a distribution of our ordinary shares to Elan shareholders under section 355 of the Code. If the separation and distribution are so treated, our shareholders who received our ordinary shares in connection with the separation and distribution should not recognize any gain for U.S. federal income tax purposes on the receipt of our ordinary shares therefrom, except with respect to cash received in lieu of fractional Prothena ordinary shares. However, Elan did not seek a ruling from the IRS addressing the separation and distribution and related transactions. It also should be noted that there is a lack of binding administrative and judicial authority addressing the qualification under sections 355 and 368(a)(1)(D) of the Code of transactions substantially similar to the separation and distribution and related transactions. As a result, the IRS could subsequently assert, and a court could determine, that the separation and distribution constitute a taxable transaction for U.S. federal income tax purposes. If the distribution of our ordinary shares fails to qualify as a tax-free transaction to our shareholders for U.S. federal income tax purposes, our shareholders who received our ordinary shares in connection with the separation and distribution could be taxed on the full value of the Prothena ordinary shares received, without reduction for any portion of such shareholders tax basis in Elan ordinary shares and/or Elan ADSs, since distributions generally are presumed to be taxable dividends for U.S. federal income tax purposes.

In addition, under the Tax Matters Agreement, we generally are required to indemnify Elan against any tax-related losses Elan incurs to the extent such losses are attributable to any action, misrepresentation or omission of Prothena or any of its affiliates.

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The tax consequences of the separation and distribution are complicated and depend on your individual situation. You should consult your own tax advisor as to the specific tax consequences of the distribution to you, including the effect of any U.S. federal, state or local or non-U.S. tax laws and of any changes in applicable tax laws.

Our ability to operate our business effectively may suffer if we do not establish our own financial, administrative and other support functions in order to operate as a separate, stand-alone company, and the transition services Elan has agreed to provide may not be sufficient for our needs.

Prior to the separation, our business was operated by Elan as part of its broader corporate organization rather than as a standalone company. Historically, we have relied on financial, administrative and other resources, including the business relationships, of Elan to support the operation of our business. In conjunction with our separation from Elan, we will need to expand our financial, administrative and other support systems or contract with third parties to replace some of Elan s systems. We will also need to maintain our own credit and banking relationships and perform our own financial and operational functions. We have entered into separation-related agreements with Elan, and Elan has agreed to provide transition services for up to six months following the separation. However, after the expiration of these transition services, we may not be able to adequately replace those resources or replace them at the same cost. We also may not be able to successfully put in place the financial, operational and managerial resources necessary to operate as a public company or that we will be able to be profitable doing so. Any failure or significant downtime in our own financial or administrative systems or in Elan s financial or administrative systems during the transition period could impact our results or prevent us from performing other administrative services and financial reporting on a timely basis and could materially harm our business, financial condition and results of operations.

Our accounting and other management systems and resources may not be adequately prepared to meet the financial reporting and other requirements to which we are subject as a publicly traded company. If we are unable to achieve and maintain effective internal controls, our business, financial position and results of operations could be adversely affected.

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 Securities Exchange Act of 1934, as amended, or the Exchange Act. We are subject to the reporting and other obligations under 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. 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 will place significant demands on our management and administrative and operational resources, including accounting resources.

To comply with these requirements, we expect that we will need to upgrade our systems, including information technology, implement additional financial and management controls, reporting systems and procedures and hire additional legal, accounting and finance staff. We expect to incur additional annual expenses for the purpose of addressing these requirements, and those expenses may be significant. If we are unable to upgrade our financial and management controls, reporting systems, information technology and procedures in a timely and effective fashion, our ability to comply with our financial reporting requirements and other rules that apply to reporting companies could be impaired. In addition, if we are unable to conclude that our internal control over financial reporting is effective, we could lose investor confidence in the accuracy and completeness of our financial reports.

Our management will be responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is a process designed to provide reasonable

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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 achieve and 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.

The historical financial information we have included in this Annual 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 when we are an independent company. 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; and
- 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 expect to incur in the future as a result of our separation 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 NASDAQ and SEC rules. Prior to the separation and distribution, our 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 likely to be less than the comparable expenses we expect to incur as a separate publicly traded company, which are estimated to be between $2 million and $4 million higher per year than the annualized allocated expenses for the latest interim period, based on currently anticipated activities. Therefore, our financial statements may not be indicative of our future performance as an independent company. For additional information about our past financial performance and the basis of presentation of our financial statements, please see Selected Financial Data, Management s Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and the notes thereto included elsewhere in this Annual Report.

In addition, we will 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 in Ireland. There can be no assurance that these costs will not exceed the costs historically borne by Elan and those allocated to us in connection with the separation.

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

We have entered into certain agreements with Elan, including the Demerger Agreement, Tax Matters Agreement, Transitional Services Agreement, Research and Development Services Agreement and the Subscription and Registration Rights Agreement, which set forth the main terms of the separation and provide a

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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.

We expect that we will be treated as a passive foreign investment company, which could result in adverse U.S. federal income tax consequences to our U.S. shareholders.

Special U.S. federal income tax rules apply to U.S. holders owning stock of a passive foreign investment company, or PFIC. A non-U.S. corporation will be treated as a PFIC for any taxable year in which, after taking into account the income and assets of the corporation and certain subsidiaries pursuant to the applicable look through rules, either (i) 75 percent or more of such corporation s gross income is passive income, or (ii) 50 percent or more of the average value of such corporation s assets are considered passive assets (generally, assets that generate passive income). Passive income generally includes dividends, interest, royalties, rents, annuities, net gains from the sale or exchange of property producing such income and net foreign currency gains. Cash and assets readily convertible into cash are categorized as passive assets. For purposes of determining whether a non-U.S. corporation will be considered a PFIC, the corporation will be treated as holding its proportionate share of the assets, and receiving directly its proportionate share of the income, of any other corporation in which such non-U.S. corporation owns, directly or indirectly, more than 25 percent (by value) of the stock.

While the determination of PFIC status for any taxable year is very fact specific and generally cannot be made until the close of the taxable year in question, we expect to be treated as a PFIC immediately after the distribution and to remain a PFIC in the immediate future. If we are classified as a PFIC in any taxable year during which a U.S. holder holds our ordinary shares, we generally would continue to be treated as a PFIC as to such holder in all succeeding taxable years, regardless of whether we continue to meet the PFIC income test or PFIC asset test discussed above. In such case, subject to the discussion below of the mark-to-market election, a U.S. holder of our ordinary shares would be subject to increased tax liability (generally including an interest charge) upon the sale or other disposition of our ordinary shares or upon the receipt of certain distributions that constitute excess distributions under the PFIC rules (generally, the portion of any distributions received by such holder on our ordinary shares in a taxable year in excess of 125% of the average annual distributions received in the preceding three taxable years or, if shorter, such holder s holding period for our ordinary shares).

If we are or become a PFIC, and our ordinary shares are treated as marketable stock for purposes of the PFIC rules, a U.S. holder of our ordinary shares generally could make a mark-to-market election to elect out of the PFIC rules described above regarding excess distributions and recognized gains. In such case, a U.S. holder generally would include in income, as ordinary income, for each taxable year that we are a PFIC the excess, if any, of the fair market value of such holders of our ordinary shares at the end of such taxable year over such holder s adjusted tax basis in such ordinary shares, and generally would be allowed to take an ordinary loss in respect of the excess, if any, of such holder s adjusted tax basis in our ordinary shares over their fair market value at the end of the taxable year (but only to the extent of the net amount of previously included income as a result of the mark-to-market election). A U.S. holder s tax basis in our ordinary shares would be adjusted to reflect any such income or loss amounts. Any gain recognized on the sale or other disposition of our ordinary shares would be treated as ordinary income, and any loss recognized would be treated as ordinary loss to the extent of any net mark-to-market income for prior taxable years. The reduced rates of taxation applicable to qualified dividend income under current law generally would not apply.

The mark-to-market election is available only for marketable stock, which is stock that is regularly traded other than in *de minimis* quantities on at least 15 days during each calendar quarter for any calendar year on a qualified exchange or other market as defined in the applicable Treasury regulations. Once made, the election cannot be revoked without the consent of the IRS, unless the shares cease to be marketable. Because a mark-to-market election may not be available for equity interests in any lower-tier PFICs that we own, a U.S. holder of our ordinary shares may continue to be subject to the PFIC rules with respect to such holder s indirect interest in any investments held by us that are treated as an equity interest in a PFIC for U.S. federal income tax purposes.

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In addition to the mark-to-market election, a U.S. holder of our ordinary shares may, subject to certain limitations, avoid the PFIC rules described above regarding excess distributions and recognized gains by making a timely qualified electing fund, or QEF, election to be taxed currently on such holder s pro rata portion of the PFIC s net capital gains (as long-term capital gain) and other earnings and profits (as ordinary income). However, this option would not be available to U.S. holders of our ordinary shares because we do not intend to prepare, or share, the information that would enable holders to make a QEF election.

You should consult your own tax advisor as to the specific tax consequences to you of our expected PFIC classification.

If there is any change to Irish tax law or the anticipated tax treatment of the distribution was challenged by the Revenue Commissioners of Ireland, relevant Irish holders of our ordinary shares may incur a charge to Irish tax as a result of receiving shares in connection with the distribution.

Statements contained in this Annual Report concerning the taxation of Irish holders of our ordinary shares are based on current Irish tax law and the published practice of the Revenue Commissioners of Ireland as of the date of this Annual Report, either of which is subject to change, possibly with retrospective effect.

The taxation of the distribution depends on the individual circumstances of the Irish holders of our ordinary. Therefore any investors who are in any doubt as to their tax position (from an Irish perspective) as a result of receiving our ordinary shares in connection with the separation and distribution should consult their own independent tax advisers.

No specific confirmation as to the tax treatment of the separation and distribution for relevant Irish holders of our ordinary shares will be sought by Elan. In the event of a successful challenge, Irish holders of our ordinary shares may incur a charge to Irish tax as a result of receiving our ordinary shares in connection with the separation and distribution.

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

Certain of our executive officers and directors are former officers and employees of Elan and thus have professional relationships with Elan s executive officers and directors. Our Chairman of the Board, Lars Ekman, is Elan s former President of Research and Development and a former member of Elan s Board of Directors. Our Chief Executive Officer and director, Dale Schenk, has held the position of EVP and Chief Scientific Officer for Elan. Our director, Shane Cooke, is a former director of Elan and Elan s former Chief Financial Officer, Executive Vice President and Head of Elan Drug Technologies. Our director, Richard T. Collier, is Elan s former Executive Vice President and General Counsel. Our Head of Corporate and Business Development and Secretary, Tara Nickerson, has held the position of Vice President and Head of Business Development for Elan Pharmaceuticals, Inc., a subsidiary of Elan. Our Chief Scientific Officer and Head of Research and Development, Gene Kinney, has held the position of SVP, Pharmacological Sciences for Elan. Our controller and chief accounting officer, John Randall Fawcett, has held the position of Senior Director, Financial Analysis & Planning for Elan. In addition, certain of our other employees and directors have a meaningful financial interest in Elan as a result of their ownership of Elan ordinary shares, options and other equity awards. These relationships may create, or may create the appearance of, conflicts of interest when these directors and officers face decisions that could have different implications for Elan than for us.

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 Jumpstart Our Business Startups Act, or the JOBS Act. The JOBS Act contains provisions that, among other things, relax certain reporting requirements for emerging

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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.

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 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.

Risks Related to Our Ordinary Shares

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

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

- our ability to obtain financing as needed;
- progress in and results from our planned clinical trials;
- 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;

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

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

public concern over our drug candidates;

litigation;

future sales of our ordinary shares;

general market conditions;

changes in the structure of healthcare payment systems;

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

economic and other external factors or other disasters or crises;

period-to-period fluctuations in our financial results;

overall fluctuations in U.S. equity markets;

the sale of our shares by some Elan shareholders because our business profile and market capitalization may not fit their investment objectives;

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

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

the operating and stock 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; and

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.

We rely on permitted exemptions from certain SEC and NASDAQ corporate governance standards, which may afford less protection to the holders of our ordinary shares.

NASDAQ and SEC rules and regulations generally require all members of the audit committee of a listed company to be independent directors as defined thereunder; furthermore, NASDAQ rules also generally require that the compensation committee and the nominating committee of listed companies consist solely of independent directors, and that the majority of a listed company s board of directors be independent directors as defined thereunder. However, these rules are subject to certain phase-in periods for newly listed companies. We rely on the phase-in periods for the audit committee, compensation committee and nominating committee that allows each of our committees to include (i) a minimum of one independent member for up to 90 days after our NASDAQ listing and (ii) thereafter a minority of members who are not independent directors until one year following our NASDAQ listing. Furthermore, we rely on the phase-in period for our board of directors to include (i) a minimum of one independent director for up to 90 days after our NASDAQ listing and (ii) thereafter a minimum of two independent directors for up to one year after our NASDAQ listing. Our reliance on these phase-in periods may adversely affect the level of independent oversight over the management of our company and therefore afford less protection to the holders of our ordinary shares.

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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.

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 by for acquisitions, capital market transactions or otherwise. We will need to raise additional capital. 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 grant stock option awards to our directors, officers and employees, which would dilute your ownership stake in us. The number of shares authorized under our equity plan is 2,650,000.

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

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

In addition, at December 31, 2012, a wholly-owned subsidiary of Elan held 18% of our outstanding ordinary shares. The ordinary shares held by a wholly-owned subsidiary of Elan are restricted securities, and Elan has agreed to cause the disposition of our ordinary shares as soon as a disposition is warranted consistent with the business purposes for Elan s retention of our ordinary shares. We have agreed that, upon the request of Elan, we will use our reasonable best efforts to effect a registration under applicable federal and state securities laws of any of our ordinary shares acquired by Elan. The sales of significant amounts of our ordinary shares or the perception in the market that this will occur may result in the lowering of the market price of our ordinary shares.

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 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 US federal or state court based on civil liability, whether or not based solely on US federal or state securities laws, would not automatically be enforceable in Ireland.

As an Irish company, we are governed by the Irish Companies Acts, which differ in some material respects from laws generally applicable to US corporations and shareholders, including, among others, differences relating to interested director and officer transactions and shareholder lawsuits. Likewise, the duties of directors

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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 rules. Under the Irish takeover rules, our board of directors is not permitted to take any action that might frustrate an offer for our shares once our board of directors 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 of directors has reason to believe an offer is or may be imminent. These provisions may give the board of directors 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.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We occupy approximately 36,500 square feet of leased office and laboratory space located in South San Francisco, California. The term of our lease extends into 2020. We believe that our facility is sufficient to meet our current needs and that suitable additional space will be available as and when needed on acceptable terms.

Item 3. Legal Proceedings

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

Item 4. Mine Safety and Disclosures

Not applicable.

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PART II

Item 5. Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our ordinary shares have been traded on The NASDAQ Global Market, or NASDAQ, under the symbol PRTA since December 21, 2012. The following table sets forth, for the period beginning December 21, 2012 through December 31, 2012, the high and low intraday prices per share of our common stock as reported by NASDAQ.

Year ended December 31, 2012	High	Low
Fourth Quarter (beginning December 21, 2012)	$ 8.10	$ 6.60

On March 12, 2013, the closing price of our common stock was $6.60.

Dividend Policy

Prothena is a newly formed entity and, therefore, has not paid dividends in the past and does not anticipate paying dividends in the foreseeable future. Any future determination to pay dividends will be at the discretion of the Board of Directors and will be dependent upon Prothena s financial condition, results of operations, capital requirements and such other factors as the Board of Directors deems relevant.

Under Irish law, dividends and distributions may only be made from distributable reserves. Distributable reserves generally means accumulated realized profits less accumulated realized losses and includes reserves created by way of capital reduction. In addition, no distribution or dividend may be made unless the net assets of Prothena are equal to, or in excess of, the aggregate of Prothena s called up share capital plus undistributable reserves and the distribution does not reduce Prothena s net assets below such aggregate. Undistributable reserves include the share premium account, the capital redemption reserve fund and the amount by which Prothena s accumulated unrealized profits, so far as not previously utilized by any capitalization, exceed Prothena accumulated unrealized losses, so far as not previously written off in a reduction or reorganization of capital.

The determination as to whether or not Prothena has sufficient distributable reserves to fund a dividend must be made by reference to the relevant accounts of Prothena. The relevant accounts are either the last set of unconsolidated annual audited financial statements or other financial statements properly prepared in accordance with the Companies Acts, which give a true and fair view of Prothena s unconsolidated financial position and accord with accepted accounting practice. The relevant accounts must be filed in the Companies Registration Office (the official public registry for companies in Ireland).

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

Stockholders

There were approximately 1,647 stockholders of record of our ordinary shares as of March 12, 2013. Because many of our shares are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

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Equity Compensation Plan Information

The information under the caption Equity Compensation Plan Information in our 2013 Proxy Statement is incorporated herein by reference.

Performance Graph

The graph below compares the cumulative total return to security holders of our ordinary shares with the comparable cumulative returns of the NASDAQ Composite and Biotechnology Indexes. The graph assumes the investment of $100 on December 21, 2012, the date on which our ordinary shares began trading on The NASDAQ Global Market, through December 31, 2012. Points on the graph represent the performance as of end of each business day.

The information under the heading Performance Graph shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.

Cumulative Total Return as of	12/21/12	12/24/12	12/26/12	12/27/12	12/28/12	12/31/12
Prothena Corporation plc	100.00	94.44	94.44	95.83	95.42	101.81
NASDAQ Composite Index	100.00	99.72	98.98	98.84	97.99	99.95
NASDAQ Biotechnology Index	100.00	99.93	98.87	98.74	97.69	99.28

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As our stock had only been traded publicly for six trading days as of December 31, 2012, information surrounding stockholder returns in comparison to the NASDAQ Biotechnology and NASDAQ Composite Indices may not be meaningful to investors.

Irish Law Matters

As we are an Irish public limited company, the following matters of Irish law are relevant to the holders of our ordinary shares.

Irish Restrictions on Import and Export of Capital

Except as indicated below, there are no restrictions on non-residents of Ireland dealing in Irish domestic securities, which includes ordinary shares of Irish companies. Dividends and redemption proceeds also continue to be freely transferable to non-resident holders of such securities. The Financial Transfers Act, 1992 gives power to the Minister for Finance of Ireland to restrict financial transfers between Ireland and other countries and persons. Financial transfers are broadly defined and include all transfers that would be movements of capital or payments within the meaning of the treaties governing the member states of the European Union. The acquisition or disposal of interests in shares issued by an Irish incorporated company and associated payments falls within this definition. In addition, dividends or payments on redemption or purchase of shares and payments on a liquidation of an Irish incorporated company would fall within this definition. At present the Financial Transfers Act, 1992 prohibits financial transfers involving the late Slobodan Milosevic and associated persons, Burma (Myanmar), Belarus, certain persons indicted by the International Criminal Tribunal for the former Yugoslavia, the late Osama bin Laden, Al-Qaida, the Taliban of Afghanistan, Democratic Republic of Congo, Democratic People s Republic of Korea (North Korea), Iran, Iraq, Côte d Ivoire, Lebanon, Liberia, Zimbabwe, Sudan, Somalia, Republic of Guinea, Afghanistan, Egypt, Eritrea, Libya, Syria, Tunisia, certain known terrorists and terrorist groups, and countries that harbor certain terrorist groups, without the prior permission of the Central Bank of Ireland.

Irish Taxes Applicable to U.S. Holders

Withholding Tax on Dividends.

While we have no current plans to pay dividends, dividends on our ordinary shares would generally be subject to Irish Dividend Withholding Tax, or DWT, at the standard rate of income tax (currently 20%), unless an exemption applies.

Dividends on our ordinary shares that are owned by residents of the United States and held beneficially through the Depositary Trust Company, or DTC, will not be subject to DWT provided that the address of the beneficial owner of the ordinary shares in the records of the broker is in the United States.

Dividends on our ordinary shares that are owned by residents of the United States and held directly (outside of DTC) will not be subject to DWT provided that the shareholder has completed the appropriate Irish DWT form and this form remains valid. Such shareholders must provide the appropriate Irish DWT form to our transfer agent at least seven business days before the record date for the first dividend payment to which they are entitled.

If any shareholder who is resident in the United States receives a dividend subject to DWT, he or she should generally be able to make an application for a refund from the Irish Revenue Commissioners on the prescribed form.

While the United States/Ireland Double Tax Treaty contains provisions regarding withholding, due to the wide scope of the exemptions from DWT available under Irish domestic law, it would generally be unnecessary for a United States resident shareholder to rely on the treaty provisions.

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Income Tax on Dividends.

A shareholder who is neither resident nor ordinarily resident in Ireland and who is entitled to an exemption from DWT generally has no additional liability to Irish income tax or to the universal social charge on a dividend from us unless that shareholder holds their ordinary shares in connection with a trade or business carried on by such shareholder in Ireland through a branch or agency.

A shareholder who is neither resident nor ordinarily resident in Ireland and who is not entitled to an exemption from DWT generally has no additional liability to Irish income tax or to the universal social charge on a dividend from us. The DWT deducted by us discharges the liability to Irish income tax and to the universal social charge. This however is not the case where the shareholder holds their ordinary shares in connection with a trade or business carried on by such shareholder in Ireland through a branch or agency.

Irish Tax on Capital Gains.

A shareholder who is neither resident nor ordinarily resident in Ireland and does not hold their shares in connection with a trade or business carried on by such shareholder in Ireland through a branch or agency should not be within the charge to Irish tax on capital on a disposal of our shares.

Capital Acquisitions Tax.

Irish Capital Acquisitions Tax, or CAT, is comprised principally of gift tax and inheritance tax. CAT could apply to a gift or inheritance of our ordinary shares irrespective of the place of residence, ordinary residence or domicile of the parties. This is because our ordinary shares are regarded as property situated in Ireland as our share register must be held in Ireland. The person who receives the gift or inheritance has primary liability for CAT.

CAT is levied at a rate of 33% above certain tax-free thresholds. The appropriate tax-free threshold is dependent upon (i) the relationship between the donor and the donee and (ii) the aggregation of the values of previous gifts and inheritances received by the donee from persons within the same category of relationship for CAT purposes. Gifts and inheritances passing between spouses are exempt from CAT. Our shareholders should consult their own tax advisers as to whether CAT is creditable or deductible in computing any domestic tax liabilities.

Stamp Duty.

Irish stamp duty may be payable in respect of transfers of our ordinary shares (currently at the rate of 1% of the price paid or the market value of the shares acquired, if greater).

Shares Held Through DTC

A transfers of our ordinary shares from a seller who holds shares through DTC, to a buyer who holds the acquired shares through DTC should not be subject to Irish stamp duty.

Shares Held Outside of DTC or Transferred Into or Out of DTC

A transfer of our ordinary shares (i) by a seller who holds shares outside of DTC to any buyer, or (ii) by a seller who holds the shares through DTC to a buyer who holds the acquired shares outside of DTC, may be subject to Irish stamp duty.

Shareholders wishing to transfer their shares into or out of DTC may do so without giving rise to Irish stamp duty provided that there is no change in the beneficial ownership of such shares and the transfer into or out of DTC is not effected in contemplation of a subsequent sale of such shares to a third party. In order to benefit from

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this exemption from Irish stamp duty, the seller must confirm to us that there is no change in the ultimate beneficial ownership of the shares as a result of the transfer and there is no agreement for the sale of the shares by the beneficial owner to a third party being contemplated.

Item 6. Selected Consolidated Financial Data

The following selected consolidated financial information has been derived from our audited consolidated financial statements. The information set forth below is not necessarily indicative of results of future operations and should not be relied upon as an indicator of our future performance. The selected consolidated financial data should be read in conjunction with Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operations and the Consolidated Financial Statements and notes thereto included in Item 8 of this Annual Report on Form 10-K in order to fully understand factors that may affect the comparability of the information presented below.

Our historical results of operations presented below may not be reflective of our financial position, results of operations and cash flows had we operated as a stand-alone public company during all periods presented. Prior to December 21, 2012, the Prothena Business operated as part of Elan and not as a separate stand-alone entity. Our Combined Financial Statements prior to December 21, 2012 have been prepared on a carve-out basis from the consolidated financial statements of Elan to represent our financial position and performance as if we had existed on a stand-alone basis during each of the fiscal years presented in the Consolidated Financial Statements. Central support costs have been allocated to us for the purposes of preparing the Consolidated Financial Statements based on estimated usage of the resources by us. The estimated usage of the central support resources allocated to us has been determined by estimating our portion of the most appropriate driver of each category of central support costs such as headcount or labor hours, depending on the nature of the costs. We believe that such allocations have been made on a reasonable basis, but may not necessarily be indicative of all of the costs that would have been incurred if we had operated on a standalone basis.

The following tables set forth our selected consolidated financial data for the periods indicated below (amounts in thousands except for per share amounts).

	Years Ended December 31,			
	2012	2011	2010	2009
Consolidated Statement of Operations Data:				
Revenue	$ 2,658	$ 507	$ 1,243	$ 2,505
Operating expenses:				
Research and development expenses	34,139	24,172	9,787	2,933
General and administrative expenses	9,929	5,579	3,618	683
Total operating expenses	44,068	29,751	13,405	3,616
Loss from operations	(41,410)	(29,244)	(12,162)	(1,111)
Interest income	5			
Net loss before income taxes	(41,405)	(29,244)	(12,162)	(1,111)
Provision for income taxes	6	426	320	47
Net loss	$ (41,411)	$ (29,670)	$ (12,482)	$ (1,158)
Basic and diluted net loss per share (1)	$ (2.84)	$ (2.05)	$ (0.86)	$ (0.08)
Shares used to compute basic and diluted net loss per share	14,593	14,497	14,497	14,497
Consolidated Balance Sheet Data:				
Cash and cash equivalents (1)	$ 124,860	$	$	$
Total assets	129,283	3,618	3,278	779
Other non-current liabilities	1,055	1,650	1,384	728
Total liabilities	2,799	10,054	3,249	1,617

Shareholders and parent company equity	126,484	(6,436)	(30)	(838)	

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(1) Prior to the separation and distribution completed on December 20, 2012, we operated as part of Elan and not as a separate stand-alone entity. As a result, we did not have any ordinary shares outstanding and cash and cash equivalents prior to December 21, 2012. The calculation of basic and diluted net loss per share assumes that the 14,497,000 shares issued to Elan shareholders in connection with the separation from Elan have been outstanding for all periods presented and that the 3,182,000 shares purchased by Elan upon separation have been outstanding since December 20, 2012.

Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis is intended to provide you with an understanding of our historical performance and financial condition during the years ended December 31, 2012, 2011 and 2010. You should read this discussion in conjunction with Consolidated Financial Statements and the notes to those statements.

Overview

We are a biotechnology company focused on the discovery and development of novel antibodies for the potential treatment of a broad range of diseases that involve protein misfolding or cell adhesion. We focus on the discovery and development of potential therapeutic monoclonal antibodies directed specifically to disease causing proteins. These potential therapies have a broad range of indications including AL and AA forms of amyloidosis, Parkinson s disease and related synucleinopathies, and novel cell adhesion targets involved in autoimmune disease and metastatic cancers. We plan to initiate Phase 1 clinical trials in these indications during the first half of 2013, 2014, and 2015, respectively. Our strategy is to apply our extensive expertise in generating novel therapeutic antibodies and work with collaborators having expertise in specific animal models of disease, to identify antibody candidates for clinical development.

We are a newly formed, public limited company incorporated in Ireland. Prothena s business consists of a substantial portion of Elan s former drug discovery business platform, including Neotope Biosciences Limited (and its wholly-owned subsidiary Prothena Biosciences, Inc.) and Onclave Therapeutics Limited, each former wholly-owned subsidiaries of Elan (which for the period prior to separation and distribution we refer to herein as the Prothena Business). Effective December 21, 2012, the Prothena Business separated from Elan. Our financial statements for these periods prior to December 21, 2012 have been derived from Elan s historical accounting records and reflect significant allocations of direct costs and expenses. All of the allocations and estimates in these financial statements are based on assumptions that we believe are reasonable. However, the financial statements do not necessarily represent our financial position or results of operations had we been operating as a separate independent entity. See Critical Accounting Policies and Estimates below as well as Note 2 of Notes to the Consolidated Financial Statements included in Item 8 of this report.

The Separation and Distribution

Elan s board of directors and its management team from time to time assess the optimal alignment of Elan s assets, and in particular the benefits and risks of maintaining both a late-stage products development business and an early-stage discovery business and the income statement dynamics such businesses present to the marketplace and Elan shareholders. On August 13, 2012, Elan announced that its board of directors had approved the separation of Elan and its drug discovery business into two independent, publicly traded companies: Elan and Prothena. On December 7, 2012, the Elan board of directors approved a deemed *in specie* distribution by Prothena issuing directly to the holders of Elan ordinary shares and Elan ADSs, on a pro rata basis, Prothena ordinary shares representing 99.99% of Prothena s outstanding shares (with the remaining 0.01% of Prothena s outstanding shares, which were previously issued to the original incorporators of Prothena and which we refer to as the incorporator shares, being mandatorily redeemed by Prothena after the related demerger). On December 12, 2012, shareholders of Elan voted to approve the *in specie* distribution as required by Elan s Articles of Association. On December 20, 2012, each holder of Elan ordinary shares or ADSs received 1 Prothena ordinary share for every 41 Elan ordinary shares or Elan ADSs held at the close of business on the record date for the distribution, subject to certain conditions.

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Immediately after the separation and distribution, a wholly-owned subsidiary of Elan acquired newly-issued ordinary shares of Prothena, representing 18% of the outstanding ordinary shares of Prothena (as calculated immediately following the acquisition), for a cash payment to Prothena of $26.0 million. Immediately after the consummation of this purchase, the incorporator shares were mandatorily redeemed by Prothena pursuant to their terms for their initial subscription price, and cancelled. Immediately following the separation and distribution and Elan s purchase of Prothena ordinary shares, Elan shareholders owned directly 82% of the outstanding ordinary shares of Prothena, and Elan owned the remaining 18%.

Basis of Presentation and Preparation of the Financial Statements

Our business consists of a substantial portion of Elan s former drug discovery business platform, including Neotope Biosciences Limited (and its wholly-owned subsidiary Prothena Biosciences, Inc.) and Onclave Therapeutics Limited, each former wholly-owned subsidiaries of Elan, and related tangible assets and liabilities (which for the period prior to separation and distribution we refer to herein as the Prothena Business).

Prior to December 21, 2012, the Prothena Business has historically operated as part of Elan and not as a separate stand-alone entity. Our Consolidated Financial Statements have been prepared on a carve-out basis from the consolidated financial statements of Elan to represent our financial position and performance as if we had existed on a stand-alone basis during each of the fiscal years presented in the Consolidated Financial Statements.

Central support costs have been allocated to us for the purposes of preparing the Consolidated Financial Statements based on estimated usage of the resources by us. The estimated usage of the central support resources allocated to us has been determined by estimating our portion of the most appropriate driver of each category of central support costs such as headcount or labor hours, depending on the nature of the costs. We believe that such allocations have been made on a reasonable basis, but may not necessarily be indicative of the costs that would have been incurred if we had operated on a standalone basis. For additional information regarding the basis of preparation, refer to Note 2 of Notes to the Consolidated Financial Statements included in Item 8 of this report.

Critical Accounting Policies and Estimates

Management s discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions the reported amounts of assets, liabilities, revenues, expenses and related disclosures. Actual results could differ from these estimates. We believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our financial statements.

Carve-out of the results of operations, financial condition and cash flows of the Prothena Business

Prior to December 21, 2012, the Prothena Business has historically operated as part of Elan and not as a separate stand-alone entity. Our Consolidated Financial Statements have been prepared on a carve-out basis from the consolidated financial statements of Elan to represent the financial position and performance of Prothena as if we had existed on a stand-alone basis during each of the fiscal years presented in the Consolidated Financial Statements; and as if Financial Accounting Standards Board, or FASB, Accounting Standard Codification, or ASC, Topic 810, Consolidation, had been applied throughout. The Consolidated Financial Statements have been prepared in conformity with accounting principles generally accepted in the United States of America (US GAAP), by aggregating financial information from the components of Prothena described in Note 1 of the Notes to Consolidated Financial Statements , included in Item 8 of this report.

The accompanying Consolidated Financial Statements 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 our operations. Indirect costs relate to certain support functions that were provided on a

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centralized basis within Elan. The support functions provided to us by Elan included, but were not limited to: accounting, information technology, taxation, legal, corporate strategy, investor relations, corporate governance and other professional services, employee benefit administration, including equity award and pension services, and cash and treasury management. Central support costs of our business for the years ended December 31, 2012, 2011 and 2010 were $7.7 million, $4.0 million and $2.8 million, respectively. These costs have been allocated to us for the purposes of preparing the Consolidated Financial Statements based on estimated usage of the resources by us. The estimated usage of the central support resources allocated to us has been determined by estimating our portion of the most appropriate driver of each category of central support costs such as headcount or labor hours, depending on the nature of the costs. We believe that such allocations have been made on a reasonable basis, but may not necessarily be indicative of the costs that would have been incurred if we had operated on a standalone basis.

Share-Based Compensation

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

Total share-based compensation expense for the years ended December 31, 2012, 2011 and 2010 was $7.5 million, $3.6 million and $1.9 million, respectively. This expense was allocated to us based on awards from Elan equity plans granted to Elan employees who have, directly or indirectly, provided services to Prothena. We will not recognize any expense going forward in relation to the existing Elan equity-based awards as our employees are not required to provide service after the separation and distribution in order to receive the awards.

Results of Operations

Results for the years ended December 31, 2012, 2011 and 2010

	Years Ended December 31,		
	2012	2011	2010
	(in thousands)		
Revenue	$ 2,658	$ 507	$ 1,243
Operating expenses:			
Research and development expenses	34,139	24,172	9,787
General and administrative expenses	9,929	5,579	3,618
Total operating expenses	44,068	29,751	13,405
Loss from operations	(41,410)	(29,244)	(12,162)
Interest income	5		
Loss before income taxes	(41,405)	(29,244)	(12,162)
Provision for income taxes	6	426	320
Net loss	$ (41,411)	$ (29,670)	$ (12,482)

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Revenue

Revenue for the years ended December 31, 2012, 2011 and 2010 was comprised of fees earned from the provision of R&D services to Elan.

Total revenues increased $2.2 million, or 424%, from 2011 to 2012, primarily by an expansion of the scope of the research and development services provided to Elan.

Total revenues decreased by $0.7 million, or 59%, from 2010 to 2011, primarily by a reduction of the scope of the research and development services provided to Elan.

Operating Expenses

Total operating expenses consist of research and development, or R&D, expense and general and administrative, or G&A, expense. For the years ended December 31, 2012, 2011, and 2010, total operating expenses were $44.1 million, $29.8 million and $13.4 million, respectively. R&D expenses primarily consist of expenses for the early discovery efforts on pathology-biology based misfolding protein targets in chronic degenerative diseases, and research costs we incurred in providing research services to Elan s ELND005 program. These expenses primarily consist of employee and related costs, and spending associated with external research. G&A expense primarily consists of professional services expenses, management compensation expenses and certain central support costs that had been allocated to us by Elan based on estimated usage of resources by us. For additional information regarding the allocation of central general and administrative expenses, please refer to Note 1 of the Notes to Consolidated Financial Statements included elsewhere in Item 8 of this report.

Research and Development Expenses

R&D expenses increased by $10.0 million, or 41%, in 2012 compared to 2011 and by $14.4 million, or 147%, in 2011 compared to 2010. The increases were primarily due to increases in share-based compensation expense, headcount attributable to Prothena programs and external expenses related to PRX002 (formerly NEOD002) and MCAM, offset by decreases in NEOD001 related costs.

Our research activities are aimed at developing new drug products. Our development activities involve the translation of our research into potential new drugs. R&D expenses include personnel, materials, equipment and facilities costs that are allocated to clearly related R&D activities.

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete development of our product candidates. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress and expense of our drug discovery efforts and other research and development activities;
- the potential benefits of our product candidates over other therapies;
- clinical trial results; and
- the terms and timing of regulatory approvals.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or other regulatory authority were to require us to conduct clinical trials

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beyond those which we currently anticipate will be required for the completion of clinical development of a product candidate or if we experience significant delays in enrollment in any clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

The following table sets forth the R&D expenses for our major program (specifically, any program where an Investigational New Drug Application has been filed with the FDA), NEOD001, and other R&D expenses for the years ended December 31, 2012, 2011 and 2010, and the cumulative amounts to date (in thousands):

	Years Ended December 31,			Cumulative to date
	2012	2011	2010	
NEOD001 (1)	$ 7,995	$ 11,322	$ 2,281	$ 23,439
Other R&D (2)	26,144	12,850	7,506	
	$ 34,139	$ 24,172	$ 9,787	

(1) Cumulative R&D costs to date for NEOD001 include the costs incurred from the date when the program has been separately tracked in preclinical development. Expenditures in early discovery stage are not tracked by program and accordingly have been excluded from this cumulative amount.

(2) Other R&D is comprised of preclinical development and discovery programs that have not yet resulted in an Investigational New Drug Application filing with the FDA, and research costs we incurred in providing research services to Elan s ELND005 program.

We have not disclosed specific estimates of the timelines or total costs to complete the development of our NEOD001 drug candidate. In the pharmaceutical industry, the R&D process is lengthy and involves a high degree of risk and uncertainty. This process is conducted in various stages and, during each stage there is a substantial risk that potential products in our R&D pipeline will experience difficulties, delays or failures. This makes it very difficult for us to estimate the total costs to complete the development of our NEOD001 drug candidate, or any potential future drug candidates, or to estimate the anticipated completion dates with any degree of accuracy, and raises concerns that attempts to provide estimates of timing may be misleading by implying a greater degree of certainty than actually exists. As a result of the significant risks and uncertainties in predicting the outcomes and the timelines for our individual projects, we cannot estimate with any certainty when or if material net cash inflows from our NEOD001 drug candidate, or any potential future drug candidates, will occur.

General and Administrative Expenses

G&A expenses increased by $4.4 million, or 78% in 2012 compared to 2011 and by $2.0 million, or 54%, in 2011 compared to 2010. The increases were primarily due to increases in support costs allocated to the Prothena business by Elan. Generally, we anticipate that our G&A expenses will change in concert with changes in our R&D activities.

Taxation

Our operations were historically included in Elan s consolidated U.S. federal and state income tax returns and in returns of certain Elan foreign subsidiaries. The current and deferred tax provision calculations have been prepared as if we were a separate taxable entity and consistent with the asset and liability method prescribed by Income Taxes (ASC 740). The current and deferred tax provision and the related tax disclosures are not necessarily representative of the tax provision/ (benefit) that may arise for the Company in the future.

The tax provision for the years ended December 31, 2012, 2011 and 2010 was $6,000, $426,000 and $320,000, respectively. The tax provision reflects U.S. Federal and State taxes and the availability of Irish tax losses. No material deferred tax assets, or DTAs, have been recognized on the balance sheet.

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Liquidity and Capital Resources

Overview

Prior to the separation, our operating and capital resource requirements were funded by Elan. As part of the separation and distribution, Elan made a cash investment in us of $99.0 million, which we expect to be used to fund working capital expenses and for other general corporate purposes. Additionally, a wholly-owned subsidiary of Elan made a cash payment of $26.0 million to acquire 18% of our outstanding ordinary shares (as calculated immediately following the acquisition). As of December 31, 2012, we had $124.9 million in cash and cash equivalents, which we believe will provide us with sufficient liquidity and capital resources to meet our cash needs for the next twelve months.

We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development of our current product candidates. Our future capital requirements will depend on numerous factors, including, the timing of initiation, progress, results and costs of our clinical trials; the results of our research and preclinical studies; the costs of clinical manufacturing and of establishing commercial manufacturing arrangements; the costs of preparing, filing, and prosecuting patent applications and maintaining, enforcing, and defending intellectual property-related claims; the costs and timing of capital asset purchases; our ability to establish research collaborations and strategic collaborations and licensing or other arrangements; the costs to satisfy our obligations under potential future collaborations; and the timing, receipt, and amount of revenues or royalties, if any, from any approved drug candidates. In order to develop and obtain regulatory approval for our potential products we will need to raise substantial additional funds through public or private equity offerings, debt financings, strategic alliances, joint ventures and licensing arrangements. We cannot assume that such additional financing will be available on acceptable terms, if at all, and such financing may only be available on terms dilutive to our shareholders.

Cash Flows for the Years Ended December 31, 2012, 2011 and 2010

The following table summarizes, for the periods indicated, selected items in our consolidated statements of cash flows (in thousands):

	Year Ended December 31,		
	2012	2011	2010
Cash used in operating activities	$ (42,072)	$ (19,697)	$ (9,083)
Cash used in investing activities	(1,301)	(595)	(2,607)
Cash provided by financing activities	168,233	20,292	11,690
Net increase(decrease) in cash and cash equivalents	$ 124,860	$	$

Cash Used in Operating Activities

Net cash used in operating activities was $42.1 million, $19.7 million and $9.1 million in 2012, 2011 and 2010, respectively, in each case consisting primarily of net losses (adjusted to exclude non-cash charges) and changes in working capital accounts.

Cash Used in Investing Activities

Net cash used in investing activities was $1.3 million in 2012, consisting of purchases of property and equipment. Net cash used in investing activities was $0.6 million in 2011, consisting of purchases of property and equipment and computer software. Net cash used in investing activities was $2.6 million in 2010, primarily consisting of purchases of property and equipment.

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Cash Provided by Financing Activities

Net cash provided by financing activities was $168.2 million in 2012, primarily consisting of funding provided by Elan and the sale of newly issued ordinary shares to Elan. Net cash provided by financing activities was $20.3 million and $11.7 million in 2011 and 2010, respectively, reflecting funding provided by Elan.

Off-Balance Sheet Arrangements

At December 31, 2012, we were not a party to any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources.

Contractual Obligations

The following table sets out, at December 31, 2012, our main contractual obligations due by period. These represent the major contractual, future payments that may be made by us. The table does not include items such as future investments in financial assets.

	Total	Less than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
			(in thousands)		
Operating lease obligations	$ 11,175	$ 1,155	$ 2,603	$ 2,848	$ 4,569
Purchase obligations (1)	1,298	1,298			
Total contractual obligations	$ 12,473	$ 2,453	$ 2,603	$ 2,848	$ 4,569

(1) Includes all open purchase orders as of December 31, 2012 for suppliers.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Foreign Currency Risk

We do not have any foreign exchange risk as the U.S. dollar is the only currency in which we conduct business.

Interest Rate Sensitivity

Our exposure to interest rate risk is limited to our cash equivalents, which consist of accounts maintained in money market funds. We have assessed that there is no material exposure to interest rate risk given the nature of money market funds. In general, money market funds are not subject to market risk because the interest paid on such funds fluctuates with the prevailing interest rate.

In the future, we anticipate that our exposure to interest rate risk will primarily be related to our investment portfolio. We intend to invest any surplus funds in accordance with a policy approved by our board of directors which will specify the categories, allocations, and ratings of securities we may consider for investment. The primary objectives of our investment policy will be to preserve principal and maintain proper liquidity to meet our operating requirements. Our investment policy will also specify credit quality standards for our investments and limits the amount of credit exposure to any single issue, issuer or type of investment.

Credit Risk

All of our accounts receivables are due from a single customer (Elan) to whom we provide R&D services. Due to their substantial financial resources, we do not believe that our credit risk is significant.

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Item 8. Financial Statements and Supplementary Data

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Report of Independent Registered Public Accounting Firm

The Board of Directors

Prothena Corporation plc:

We have audited the accompanying consolidated balance sheet of Prothena Corporation plc (and subsidiaries) as of December 31, 2012, and the related consolidated statements of operations, shareholders equity and cash flows for the year then ended. These consolidated financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Prothena Corporation plc (and subsidiaries) as of December 31, 2012, and the results of their operations and their cash flows for the year then ended in conformity with U.S. generally accepted accounting principles.

/s/ KPMG LLP

San Francisco, California

March 28, 2013

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Report of Independent Registered Public Accounting Firm

To the Board of Directors of Prothena Corporation plc

We have audited the accompanying consolidated financial statements of Prothena Corporation plc, formerly referred to as the carve-out combined financial statements of the Prothena Business (formerly the Neotope Business), which comprises the carve-out combined balance sheet as at December 31, 2011 and the carve-out combined statements of operations, parent company equity and cash flows for each of the years in the two-year period ended December 31, 2011 (together and hereinafter, the Combined Financial Statements). These Combined Financial Statements are the responsibility of the management of Prothena Corporation, plc. Our responsibility is to express an opinion on these Combined Financial Statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the Combined Financial Statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the Combined Financial Statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the Combined Financial Statements referred to above present fairly, in all material respects, the financial position of the Prothena Business as at December 31, 2011 and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2011, in accordance with U.S. generally accepted accounting principles.

/s/ KPMG

Chartered Accountants

Dublin, Ireland

October 1, 2012, except for the retrospective inclusion of basic and diluted net loss per share disclosures for each of the years in the two-year period ended December 31, 2011, as to which the date is March 28, 2013

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Prothena Corporation plc

Consolidated Balance Sheets

As of December 31, 2012 and 2011

(in thousands, except par value)

	2012	2011
ASSETS		
Current assets:		
Cash and cash equivalents	$ 124,860	$
Receivables from related party	223	
Deferred tax assets	73	
Prepaid and other current assets	685	124
Total current assets	125,841	124
Non-current assets:		
Property and equipment, net	3,393	2,539
Intangible assets, net	49	70
Other non-current assets		885
Total non-current assets	3,442	3,494
Total assets	$ 129,283	$ 3,618
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$	$ 380
Accrued research and development expenses	47	5,542
Income taxes payable	27	
Other current liabilities	1,670	2,482
Total current liabilities	1,744	8,404
Non-current liabilities	1,055	1,650
Total liabilities	2,799	10,054
Shareholders equity		
Ordinary shares, $0.01 par value; 100,000 shares authorized; 17,679 and 0 shares issued and outstanding at December 31, 2012 and 2011, respectively	177	
Additional paid-in capital	126,652	
Accumulated deficit	(345)	
Parent company equity		(6,436)
Total shareholders equity (deficit)	126,484	(6,436)
Total liabilities and shareholders equity	$ 129,283	$ 3,618

See accompanying notes to Consolidated Financial Statements.

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Prothena Corporation plc

Consolidated Statements of Operations

For the Years Ended December 31, 2012, 2011 and 2010

(in thousands, except per share data)

	2012	2011	2010
Revenue related party	$ 2,658	$ 507	$ 1,243
Operating expenses:			
Research and development expenses	34,139	24,172	9,787
General and administrative expenses	9,929	5,579	3,618
Total operating expenses	44,068	29,751	13,405
Loss from operations	(41,410)	(29,244)	(12,162)
Interest income	5		
Loss before income taxes	(41,405)	(29,244)	(12,162)
Provision for income taxes	6	426	320
Net and comprehensive loss	$ (41,411)	$ (29,670)	$ (12,482)
Basic and diluted net loss per share	$ (2.84)	$ (2.05)	$ (0.86)
Shares used to compute basic and diluted net loss per share	14,593	14,497	14,497

See accompanying notes to Consolidated Financial Statements.

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Prothena Corporation plc

Consolidated Statements of Cash Flows

For the Years Ended December 31, 2012, 2011 and 2010

(in thousands)

	2012	2011	2010
Cash flows from operating activities:			
Net loss	$ (41,411)	$ (29,670)	$ (12,482)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	468	391	191
Share-based compensation	6,098	2,972	1,600
Changes in operating assets and liabilities:			
Receivables from related party	(223)		
Other assets	(467)	(146)	(83)
Accounts payable, accruals and other liabilities	(6,537)	6,756	1,691
Net cash used in operating activities	(42,072)	(19,697)	(9,083)
Cash flows from investing activities:			
Purchase of property and equipment	(1,301)	(510)	(2,565)
Purchase of intangible assets		(85)	(42)
Net cash used in investing activities	(1,301)	(595)	(2,607)
Cash flows from financing activities:			
Proceeds from funding provided by Elan	145,233	20,292	11,690
Repayment of funding provided by Elan	(3,000)		
Proceeds from issuance of ordinary shares to Elan	26,000		
Net cash provided by financing activities	168,233	20,292	11,690
Net increase in cash and cash equivalents	124,860		
Cash and cash equivalents at beginning of year			
Cash and cash equivalents at end of year	$ 124,860	$	$

See accompanying notes to Consolidated Financial Statements.

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Prothena Corporation plc

Consolidated Statements of Shareholders Equity

For the Years Ended December 31, 2012, 2011 and 2010

(in thousands)

	Ordinary Shares		Additional Paid-In Capital	Accumulated Deficit	Parent Company Equity	Total Stockholders Equity (Deficit)
	Shares	Amount				
Balances at December 31, 2009		**$**	**$**	**$**	**$ (838)**	**$ (838)**
Net loss					(12,482)	(12,482)
Share-based compensation					1,600	1,600
Net funding provided by Elan					11,690	11,690
Balances at December 31, 2010					**(30)**	**(30)**
Net loss					(29,670)	(29,670)
Share-based compensation					2,972	2,972
Net funding provided by Elan					20,292	20,292
Balances at December 31, 2011					**(6,436)**	**(6,436)**
Contribution of net assets to Prothena and issuance of ordinary shares	14,497	145	100,684		(100,829)	
Issuance of ordinary shares to Elan	3,182	32	25,968			26,000
Net loss				(345)	(41,066)	(41,411)
Share-based compensation					6,098	6,098
Net funding provided by Elan					142,233	142,233
Balances at December 31, 2012	**17,679**	**$ 177**	**$ 126,652**	**$ (345)**	**$**	**$ 126,484**

See accompanying notes to Consolidated Financial Statements.

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Prothena Corporation plc

Notes to Consolidated Financial Statements

1. Organization

Description of Business

Prothena Corporation plc (Prothena or the Company) is a newly formed, public limited company incorporated in Ireland. Prothena is a biotechnology company focused on the discovery and development of novel antibodies for the potential treatment of a broad range of diseases that involve protein misfolding or cell adhesion. The Company is focused on the discovery and development of potential therapeutic monoclonal antibodies directed specifically to disease causing proteins. These potential therapies have a broad range of indications including AL and AA forms of amyloidosis, Parkinson s disease and related synucleinopathies, and novel cell adhesion targets involved in autoimmune disease and metastatic cancers. The Company plans to initiate Phase 1 clinical trials in these indications during the first half of 2013, 2014 and 2015, respectively. The Company s strategy is to apply its extensive expertise in generating novel therapeutic antibodies and work with collaborators having expertise in specific animal models of disease, to identify antibody candidates for clinical development.

Prothena s business consists of a substantial portion of Elan s former drug discovery business platform, including Neotope Biosciences Limited (and its wholly-owned subsidiary Prothena Biosciences, Inc.) and Onclave Therapeutics Limited, each former wholly-owned subsidiaries of Elan (which for the period prior to separation and distribution we refer to herein as the Prothena Business). Effective December 20, 2012, the Prothena Business separated from Elan.

Basis of Preparation and Presentation of Financial Information

The Prothena Business has historically operated as part of Elan and not as a separate stand-alone entity. Prior to the separation on December 20, 2012, the 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, 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 our operations. The indirect costs included in our 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 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.

The centralized support functions provided to us by Elan included, but were not limited to, accounting, information technology, taxation, legal, corporate strategy, investor relations, corporate governance and other professional services, employee benefit administration, including equity award and pension services, and cash and treasury management. Centralized support costs allocated to the Prothena business for the years ended

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December 31, 2012, 2011 and 2010 were $7.7 million, $4.0 million and $2.8 million, respectively. These costs have been allocated to us for the purposes of preparing the Consolidated Financial Statements based on estimated usage of the resources by us. The estimated usage of the central support resources allocated to us has been determined by estimating our portion of the most appropriate driver of each category of central support costs such as headcount or labor hours, depending on the nature of the costs. We believe that such allocations have been made on a reasonable basis, but may not necessarily be indicative of the costs that would have been incurred if we had operated on a standalone basis.

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 has 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.

Liquidity and Business Risks

As part of the separation and distribution process described above, Elan made a net cash investment in the Prothena Business of $99.0 million. Elan also made a $26.0 million cash payment to Prothena to purchase 18% of the outstanding ordinary shares of Prothena (as calculated immediately following the purchase). As of December 31, 2012, Prothena has $124.9 million in cash and cash equivalents. Management believes that the Company s cash and cash equivalents at December 31, 2012 will be sufficient to meet the Company s obligations for at least the next twelve months based on management s current business plans. If the Company elects to increase its spending on development programs significantly above current long-term plans or enters into potential licenses and 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 equity or debt financings, loans and collaborative agreements with corporate partners.

The Company is subject to a number of risks, including: its ability to successfully commercialize its product candidates, if approved; the uncertainty of the Company s research and development efforts resulting in future successful commercial products; obtaining regulatory approval for new products; significant competition from larger organizations; reliance on the proprietary technology of others; dependence on key personnel; uncertain patent protection; dependence on corporate partners and collaborators; and possible restrictions on reimbursement from governmental agencies and healthcare organizations, as well as other changes in the health care industry.

The Company is dependent on Boehringer Ingelheim to manufacture its clinical supplies of NEOD001, a monoclonal antibody. An inability to obtain product supply could have a material adverse impact on the Company s business, financial condition and results of operations.

Use of Estimates

The preparation of the Consolidated Financial Statements in conformity with U.S. 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.

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2. Summary of 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

Property and equipment are stated at cost less accumulated depreciation. Depreciation is computed using the straight-line method based on estimated useful lives as follows:

Leasehold improvements	Shorter of expected useful life or lease term
Property and equipment	3-10 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. 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.

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 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.

Research and Development

Research and development costs are expensed as incurred.

Share-based Compensation

To determine the fair value of share-based payment awards, the Company uses a binomial option-pricing model for its stock options and the Black-Scholes option-pricing model for its EEPP awards. The determination of fair value using an option-pricing model is affected by the Company s stock 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 7 for further information).

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Total share-based compensation expense recorded in these consolidated financial statements for the years ended December 31, 2012, 2011 and 2010 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 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 will not recognize any expense going forward 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 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 financial statements.

Income Taxes

The operations of the Prothena Business were historically included in Elan s consolidated U.S. federal and state income tax returns and in tax returns of certain Elan foreign subsidiaries. Income taxes reflected in these financial statements have been calculated as if the business were a separate taxable group for the periods presented and consistent with the asset and liability method prescribed by ASC 740 Income Taxes, (ASC 740).

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. DTAs are recognized for the expected future tax consequences, for all deductible temporary differences and operating loss carry-forwards. A valuation allowance is required for DTAs if, based on available evidence, it is more likely than not that all or some of the asset will not be realized due to the inability to generate sufficient future taxable income.

Significant estimates are required in determining our 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.

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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 14,497,000 shares issued to Elan shareholders in connection with the separation from Elan have been outstanding for all periods presented and that the 3,182,000 shares purchased by Elan upon separation have been outstanding since December 20, 2012.

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

	Years Ended December 31,		
	2012	2011	2010
Net loss	$ (41,411)	$ (29,670)	$ (12,482)
Weighted average ordinary shares outstanding	14,593	14,497	14,497
Basic and diluted net loss per share	$ (2.84)	$ (2.05)	$ (0.86)

Comprehensive Loss

Comprehensive loss is comprised of net loss and other comprehensive income (loss). The Company has no components of other comprehensive income (loss), and accordingly, net loss equals comprehensive loss for all periods presented.

Segment, Geographical and Customer Concentration

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. All of the Company s principal operations and decision-making functions are located in the United States.

The Company s revenues have been from Ireland for all periods presented, while all of its assets were held in the United States. Revenue recorded in the statements of operations consists of fees earned from the provision of non-clinical research support to Elan, primarily in the areas of safety, toxicology and regulatory. The fees charged to Elan were calculated based on the expenses incurred by the Company in the provision of those R&D services, plus a contractually determined mark-up of those expenses.

Recent Accounting Pronouncements

In May 2011, the FASB issued ASU No. 2011-04, Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs , which results in common fair value measurement and disclosure requirements in U.S. GAAP and IFRS. The amendments change the wording used to describe many of the requirements in U.S. GAAP for measuring fair

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value and for disclosing information about fair value measurements. Some of the amendments clarify the FASB s intent about the application of existing fair value measurement requirements while other amendments change a particular principle or requirement for measuring fair value or for disclosing information about fair value measurements. The adoption of ASU 2011-04 impacts the Company s disclosures but did not have a material impact on it s financial position, results of operations or cash flows. This standard was adopted by the Company during the year ended December 31, 2011.

3. Fair Value Measurements

Fair value is the amount at which a financial instrument could be exchanged in an arms-length transaction between informed and willing parties, other than in a forced or liquidation sale. The following financial instruments are not measured at fair value on the Company s consolidated balance sheet at December 31, 2012, but require disclosure of their fair values: accounts receivable, accounts payable and accrued expenses. The estimated fair value of such instruments at December 31, 2012 approximates their carrying value as reported on the consolidated balance sheet. The fair values of such financial instruments are determined using the income approach based on the present value of estimated future cash flows. There have been no changes in the Company s valuation technique during the year ended December 31, 2012. The fair value of all of these instruments would be categorized as Level 2 of the fair value hierarchy.

The fair value of financial assets and liabilities is measured under a framework that establishes levels which are defined as follows: Level 1 fair value is determined from observable, quoted prices in active markets for identical assets or liabilities. Level 2 fair value is determined from quoted prices for similar items in active markets or quoted prices for identical or similar items in markets that are not active. Level 3 fair value is determined using the entity s own assumptions about the inputs that market participants would use in pricing an asset or liability. The Company did not have any investment holdings prior to the separation and distribution from Elan on December 20, 2012. The Company s level 2 securities are valued using third-party pricing sources, which consisted of $103.5 million in money market funds included in cash and cash equivalents at December 31, 2012. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, issuer credit spreads, benchmark securities, prepayment/default projections based on historical data and other observable inputs. The Company validates the prices provided by its third-party pricing services by understanding the models used, obtaining market values from other pricing sources, analyzing pricing data in certain instances and confirming those securities traded in active markets.

There were no other-than-temporary impairments during the years ended December 31, 2012, 2011 and 2010.

4. Composition of Certain Balance Sheet Items

Property and Equipment

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

	2012	2011
Machinery and equipment	$ 5,449	$ 2,313
Leasehold improvements	1,651	794
Less: accumulated depreciation and amortization	(3,707)	(568)
Property and equipment, net	$ 3,393	$ 2,539

Depreciation expense was $447,000, $377,000 and $190,000 for the years ended December 31, 2012, 2011, and 2010, respectively.

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Intangible Assets

Intangible assets consisted of the following at December 31 (in thousands):

	2012	2011
Purchased computer software	$ 85	$ 85
Less: accumulated amortization	(36)	(15)
Intangible assets, net	$ 49	$ 70

Intangible assets are amortized on a straight line basis over their expected life, which we estimate to be four years. Amortization expense was $21,000, $14,000 and $1,000 for the years ended December 31, 2012, 2011, and 2010, respectively. The estimated aggregate amortization expense for 2013, 2014 and 2015 is $21,000, $21,000 and $7,000, respectively.

Other Non-current Assets

Certain employees that provided services to the Prothena Business prior to the separation and distribution participated in Elan s deferred compensation plans. Other non-current assets at December 31, 2011 are primarily comprised of assets relating to these plans. These plan assets, and the associated obligation to plan participants, were retained by Elan at the time of the separation and distribution.

Other Current Liabilities

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

	2012	2011
Payroll and related taxes	$ 1,592	$ 2,097
Deferred rent	51	51
G&A accruals	27	97
Deferred compensation		166
Other accruals		71
	$ 1,670	$ 2,482

Non-current Liabilities

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

	2012	2011
Deferred rent	$ 1,055	$ 932
Deferred compensation		718
	$ 1,055	$ 1,650

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. The lease, as amended, provides for approximately 36,500 of rentable square feet at a base rent that increases annually. In connection with the separation and distribution, this lease agreement was assigned to Prothena Biosciences, Inc. Rental payments on operating leases are charged to expense on a straight-line basis over the period of the lease.

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Future minimum rental commitments under the operating lease were as follows at December 31, 2012 (in thousands):

Due in:	
2013	$ 1,155
2014	1,261
2015	1,342
2016	1,396
2017	1,452
thereafter	4,569
Total	$ 11,175

Rent expense for years ended December 31, 2012, 2011 and 2010 was $1,317,000, $1,530,000, and $551,000, respectively.

Purchase Commitments

The Company had commitments to suppliers for purchases totaling $1,298,000 at December 31, 2012.

6. Shareholder s Equity

Ordinary Shares

At December 31, 2012, the Company had 100,000,000 ordinary shares authorized for issuance with a par value of $0.01 per share and 17,679,182 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.

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.

Euro Deferred Shares

At December 31, 2012, the Company had 10,000 euro deferred shares authorized for issuance with a nominal value of 22 per share, 1,750 shares were issued and no shares are outstanding at December 31, 2012 as the issued 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.

7. Share-Based Compensation Expense

The Prothena Corporation plc 2012 Long Term Incentive Plan

The Company s 2012 Long Term Incentive Plan (LTIP) provides for the issuance of common share-based awards, including restricted shares, restricted share units, share options, share appreciation rights and other equity-based awards, to its employees, officers, directors and consultants. Under the plan, the Company is authorized to issue a total of 2,650,000 shares. As of December 31, 2012, the Company has not issued any share-based equity awards to its employees under the Company s LTIP.

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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 share options, RSUs and other equity awards to its employees, including employees that have directly and indirectly provided service to the Prothena Business. The share-based payment compensation expense recognized in these Consolidated Financial Statements includes all of the share-based payment expenses directly attributable to the Prothena Business and an allocation of indirect expenses that have been deemed attributable to the Prothena Business for all periods presented. The Company will not recognize any expense going forward in relation to the existing Elan equity-based awards as its employees are not required to provide service after the separation and distribution in order to receive the awards.

The following table summarizes share-based compensation expense recognized in 2012, 2011 and 2010 (in thousands):

		2012	2011	2010
Research and development expenses	direct	$ 6,093	$ 2,819	$ 1,600
General and administrative expenses	direct	5	153	
Total direct expense		6,098	2,972	1,600
General and administrative expenses	allocated	1,445	594	303
		$ 7,543	$ 3,566	$ 1,903

Share-based Compensation Expense

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

The following table summarizes share-based compensation expense related to award type (in thousands):

		2012	2011	2010
RSUs		$ 3,477	$ 1,708	$ 930
Stock options		2,598	1,247	656
EEPP		23	17	14
Share-based compensation expense	direct	6,098	2,972	1,600
Share-based compensation expense	allocated	1,445	594	303
		$ 7,543	$ 3,566	$ 1,903

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

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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, $1,069,000 and $650,000 in 2012, 2011 and 2010, respectively.

The non-vested RSUs relating to the employees that provided directly attributable service to the Prothena Business are summarized as follows (in thousands, except fair value amounts):

	RSUs	Weighted-Average Grant Date Fair Value
Non-vested at December 31, 2010	229	$ 9.67
Granted	195	6.80
Vested	(132)	9.85
Non-vested at December 31, 2011	292	$ 7.67
Granted	166	13.19
Vested	(348)	9.44
Forfeited	(110)	10.10
Non-vested at December 31, 2012		$

Stock Options

Stock 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.

The following table summarizes the number of options outstanding as of December 31 that were held by the employees that provided directly attributable service to the Prothena Business (in thousands):

	2012	2011
1996 Plan	46	96
1999 Plan	35	57
2006 Long Term Incentive Plan	924	671
Total	1,005	824

The total stock options outstanding, vested and expected to vest, and exercisable that are held by the employees that provided directly attributable service to the Prothena Business are summarized as follows:

	Options (In thousands)	WAEP (1)	Weighted Average Remaining Contractual Life (In years)	Aggregate Intrinsic Value (In thousands)
Outstanding at December 31, 2010	627	$ 16.70		
Granted	324	6.82		
Exercised	(60)	7.41		
Expired	(67)	57.33		

Outstanding at December 31, 2011	824	$ 10.21			
Granted	398	13.17			
Exercised	(127)	6.59			
Forfeited	(84)	12.66			
Expired	(6)	14.07			
Outstanding, exercisable and vested at December 31, 2012	1,005	$ 11.17	6.8	$	1,424

(1) Weighted-average exercise price

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The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value (the difference between Elan s closing share price on the last trading day of 2012 and the exercise price, multiplied by the number of in-the-money options) that would have been received by direct option holders had all these option holders exercised their options on December 31, 2012. This amount changes based on the fair market value of Elan s ordinary shares. The total intrinsic value of options exercised in 2012 was $765,000. The total fair value expensed over the vesting terms of options that became fully vested in 2012, 2011 and 2010 was $505,000, $1,232,000 and $597,000, respectively.

At December 31, 2012, the range of exercise prices and weighted-average remaining contractual life of outstanding and exercisable options were as follows:

	Options Outstanding and Exercisable		
	Options Outstanding (in thousands)	Weighted Average Remaining Contractual Life (in years)	WAEP
$ 4.92 - $ 9.26	418	7.5	$ 6.80
$10.77 - $25.95	587	6.4	$ 14.28
$ 4.92 - $25.95	1,005	6.8	$ 11.17

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 stock options is calculated using a binomial option-pricing model and the fair value of options issued under the EEPP is calculated using the Black-Scholes option-pricing model, taking into account the relevant terms and conditions. The binomial option-pricing model is used to estimate the fair value of our stock 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. 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 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.

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The estimated weighted-average grant date fair values of the individual options granted to the employees that provided directly attributable service to the Company during the years ended December 31, 2012, 2011 and 2010 were $6.66, $2.99 and $3.86, respectively. The fair value of options granted during these years was estimated using the binomial option-pricing model with the following weighted-average assumptions:

	2012	2011	2010
Risk-free interest rate	0.89%	1.71%	2.09%
Expected volatility	60.1%	49.3%	66.0%
Expected dividend yield			
Expected life (1)			

(1) The expected lives of options granted in 2012, as derived from the output of the binomial model, ranged from 4.9 years to 6.8 years (2011: 4.8 years to 7.4 years; 2010: 4.8 years to 7.5 years). The contractual life of the options, which is not later than 10 years from the date of grant, is 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 years ended December 31, 2012, 2011 and 2010 were $4.46, $2.30 and $1.84, respectively.

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

	2012	2011	2010
Weighted-average share price	$ 13.97	$ 8.00	$ 5.61
Weighted-average exercise price	$ 11.88	$ 6.80	$ 4.77
Expected volatility (1)	60.5%	49.7%	63.9%
Expected life (months)	6.0	6.0	6.0
Expected dividend yield			
Risk-free interest rate	0.09%	0.16%	0.21%

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

8. 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.

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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, $120,000 and $0 for the years ended December 31, 2012, 2011 and 2010, respectively.

9. Income Taxes

The Company is incorporated in Ireland, but has operations and is subject to taxation in both the United States and Ireland. Its operating results were historically included in Elan s consolidated U.S. federal and state income tax returns and in the tax returns of certain foreign subsidiaries of Elan. Income taxes reflected in these Consolidated Financial Statements have been calculated as if the Company operated as a separate taxable group in Ireland for all periods presented and consistent with the asset and liability method prescribed by ASC 740. No current tax liabilities have been recognized on the balance sheet as it is assumed that they have been settled as they arose.

Loss before income taxes by region for each of the fiscal periods presented is summarized as follows (in thousands):

	2012	2011	2010
Ireland	$ (35,898)	$ (27,620)	$ (12,366)
United States	(5,507)	(1,624)	204
Loss before provision for income taxes	$ (41,405)	$ (29,244)	$ (12,162)

Components of income tax expense for each of the fiscal periods presented consisted of the following (in thousands):

	2012	2011	2010
Irish corporation tax current	$	$	$
Irish corporation tax deferred			
U.S. taxes current	26	426	320
U.S. taxes deferred	(20)		
Provision for income taxes	$ 6	$ 426	$ 320

The provision for income taxes differs from the statutory tax rate applicable to Ireland primarily due to Irish net operating losses and U.S. share-based compensation. Following is a reconciliation between income taxes computed at the standard Irish statutory tax rate which is the statutory rate relevant to the Company and the provision for income taxes for the years ended December 31, 2012, 2011 and 2010, respectively (in thousands):

	2012	2011	2010
Taxes at the Irish standard tax rate of 12.5%	$ (5,176)	$ (3,656)	$ (1,520)
U.S. income at rates other than the Irish standard rate	4	613	383
Losses for which no deferred tax asset is recognized	5,176	3,656	1,520
Share-based payments		205	166
R&D tax credit		(392)	(229)
Other	2		
Provision for income taxes	$ 6	$ 426	$ 320

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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 our net deferred tax assets as of December 31, 2012 and 2011 are as follows (in thousands):

	2012	2011
Total deferred tax liabilities	$ (6)	$
Deferred tax assets:		
Net operating losses	8,917	5,983
R&D tax credit		679
Accruals	79	
Share-based compensation expense		1,004
Total deferred tax assets	$ 8,990	$ 7,666
Valuation allowance	$ (8,917)	$ (7,666)
Net deferred tax asset/ (liability)	$ 73	$

At December 31, 2012 a valuation allowance of $8,916,730 has been recognized in relation to deferred tax assets arising on Irish net operating losses, as the recoverability of the deferred tax assets is uncertain. The valuation allowance recorded against the deferred tax assets as of December 31, 2011 was $7,665,445. The net increase in the valuation allowance during the year ended December 31, 2012 was primarily due to Irish net operating losses.

At December 31, 2012, certain of Prothena s Irish subsidiaries had net operating loss carryovers of $71,333,842. These can be carried forward indefinitely but are limited to the same trade/trades.

The major taxing jurisdictions for Prothena are Ireland and the United States. The tax years 2008 to 2012 remain subject to examination by the respective taxing authorities of each jurisdiction. The Company has no material uncertain tax provisions

Cumulative unremitted earnings of the Company s U.S. subsidiary total approximately $10,000 at December 31, 2012. No taxes have been provided for the unremitted earnings as any tax basis differences relating to investments in these overseas subsidiaries are considered to be permanent in duration. Unremitted earnings may be liable to overseas taxes (potentially at a rate of 12.5%) if they were to be distributed as dividends.

10. Related Parties

Prior to December 20, 2012, the Prothena Business operated as part of Elan and not as a separate stand-alone entity. Effective December 20, 2012, the Prothena Business separated from Elan. In connection with the plan of separation, Elan acquired an 18% interest in the Company (as calculated immediately following the acquisition).

As described elsewhere in these consolidated financial statements, the results of operations of the Prothena business for the time period prior to the separation include transactions with Elan. All of the revenue recognized by the Company for each of the three years ended December 31, 2012, 2011 and 2010 consist of fees arising from R&D services provided to Elan. Additionally, the results of operations for this time period include certain costs allocated from Elan to the Company for centralized support services.

The Company has entered into certain agreements with Elan, including the Transitional Services Agreement and the R&D services Agreement.

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Transitional Services Agreement

In December 2012, the Company entered into a Transitional Services Agreement (TSA) with Elan under which Elan will provide to the Company, and the Company will provide to Elan, specified services to help ensure an orderly transition following the separation and distribution. The services provided by Elan under the Transitional Services Agreement will include chemistry, manufacturing and controls/quality assurance, information services, IT services, facilities services, company secretarial services, finance services, legal services, compliance services and human relations services. The services provided by the Company will include finance services and product support services and assisting in reviewing proposed Elan publications related to work done at Elan prior to separation.

The Company expects that the TSA will remain in effect until the expiration of the last time period for the performance of services thereunder, which in no event shall be later than December 31, 2013.

Both the Company and Elan will be permitted to terminate the TSA (to the extent it relates to any particular transitional service) if the other party breaches any of its significant obligations under the agreement and does not cure such breach within 20 business days of receiving written notice from the other party. In addition, either party may terminate the TSA if a receiver, examiner or administrator is appointed with respect to any of the other party s assets, the other company is struck off the Register of Companies in its jurisdiction of organization or at the option of such party with respect to a particular transition service if such party is the service recipient.

The payment terms of the agreement generally provide that the Company will pay Elan for the time spent by each Elan employee providing the services, which will be calculated by the portion of the employee s time dedicated to the provision of the services, plus 40%. The time for each employee will be calculated using one of two specified rates per annum depending on the employee s wage band. There will be a fixed monthly charge for IT services of $75,000 for so long as those services are provided. Similarly, Elan will pay the Company for the time spent by each of the Company s employee providing services to Elan, which will be an agreed percentage of the employee s time, based on the cost of providing those services plus 40% and including, as applicable, any fees for any services from Elan or the Company provided by third party providers and invoiced to the recipient at cost. The services from the Company will also be calculated using one of two specified rates per annum depending on the employee s wage band. There will also be a fixed monthly charge of $6,000 to account for lab space and capital equipment used by Elan.

R&D Services Agreement

In December 2012, The Company entered into a Research and Development Services Agreement (RDSA) with Elan pursuant to which the Company will provide certain R&D services to Elan. The RDSA will, among other things, set out the scope of the services, the consideration to be paid for the services and the general principles around ownership of intellectual property as it relates to the services. The RDSA is expected to be in effect for a period of not less than two years. Either party is entitled to terminate the RDSA at any time by notice in writing to the other party if there has been a material breach by the other party or if the other party becomes insolvent or if the other party is in breach of any of its confidentiality obligations under the agreement.

The services provided for under the RDSA include support for the ELND005 and ELND002 programs (which include the provision of expert advice and opinion in the areas of nonclinical safety/toxicology and pharmacology, regulatory support for nonclinical sections of pertinent documents, conducting and interpreting externally conducted nonclinical studies, and support in respect of the identification and maintenance of nonclinical expert advisors as required). These services will be substantially similar to research services performed by the Company for Elan prior to the separation and distribution.

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

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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.

11. Selected Quarterly Financial Information (unaudited)

The following is a summary of quarterly results of operations for the years ended December 31, 2012 and 2011 (in thousands, except per share data):

	Year Ended December 31, 2012			
	Q1	Q2	Q3	Q4
Revenues	$ 404	$ 735	$ 944	$ 575
Operating expense	11,215	10,446	9,612	12,795
Net loss	(10,811)	(9,711)	(8,668)	(12,221)
Basic and diluted net loss per share	(0.75)	(0.67)	(0.60)	(0.82)

	Year Ended December 31, 2011			
	Q1	Q2	Q3	Q4
Revenues	$ 130	$ 100	$ 150	$ 127
Operating expense	5,616	7,239	7,334	9,562
Net loss	(5,597)	(7,300)	(7,220)	(9,553)
Basic and diluted net loss per share	(0.39)	(0.50)	(0.50)	(0.66)

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2012. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2012, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management s Report on Internal Control over Financial Reporting

This report does not include a report of management s assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

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Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended December 31, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information under the captions Proposal No. 1 Election of Directors, Section 16(a) Beneficial Ownership Reporting Compliance, Compensation Discussion and Analysis, Report of the Audit Committee of the Board of Directors and Certain Relationships and Related Transactions in our 2013 Proxy Statement is incorporated herein by reference.

Item 11. Executive Compensation

The information under the captions Compensation Committee Interlocks and Insider Participation, Risk Assessment and Compensation Practices, Compensation Discussion and Analysis and Report of the Compensation Committee of the Board of Directors on Executive Compensation in our 2013 Proxy Statement is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information under the captions Security Ownership of Certain Beneficial Owners and Management, Equity Compensation Plan Information, Section 16(a) Beneficial Ownership Reporting Compliance and Compensation Discussion and Analysis in our 2013 Proxy Statement is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information under the captions Proposal No. 1 Election of Directors and Certain Relationships and Related Transactions in our 2013 Proxy Statement is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

The information under the caption Proposal No. 2 Ratification of Selection of Independent Registered Public Accounting Firm in our 2013 Proxy Statement is incorporated herein by reference.

With the exception of the information specifically incorporated by reference in Part II and Part III to this Annual Report on Form 10-K from our 2013 Proxy Statement, our 2013 Proxy Statement shall not be deemed to be filed as part of this report.

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PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) Financial Statements

The financial statements filed as part of this report are listed on the index to consolidated financial statements included in Part II, Item 8 of this report.

(b) Financial Statement Schedules

Financial statement schedules have been omitted because the required information is not present or not present in the amounts sufficient to require submission of the schedule or because the information required is included in the consolidated financial statements or notes thereto.

(c) Exhibits

The following exhibits are incorporated by reference or filed herewith.

Exhibit No.	Description
2.1	Demerger Agreement, dated as of November 8, 2012 between Elan Corporation, plc and Prothena Corporation plc. (1)
2.2	Amended and Restated Intellectual Property License and Contribution Agreement, dated December 20, 2012, by and among Neotope Biosciences Limited, Elan Pharma International Limited, and Elan Pharmaceuticals, Inc. (2)
2.3	Intellectual Property License and Conveyance Agreement, dated December 20, 2012, by and among Neotope Biosciences Limited, Elan Pharma International Limited and Elan Pharmaceuticals, Inc. (3)
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10.1	Tax Matters Agreement, dated December 20, 2012, by and between Elan Corporation, plc and Prothena Corporation plc (5)
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10.5#	Form of Deed of Indemnity (9)
10.6	Lease Agreement, dated as of March 18, 2010 between Are-San Francisco No. 33, LLC and Elan Pharmaceuticals, Inc. (10)
10.7	First Amendment to Lease, dated as of November 18, 2011 between Are-San Francisco No. 33, LLC and Elan Pharmaceuticals, Inc. (11)
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10.11#	Prothena Corporation plc 2012 Long Term Incentive Plan (15)
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10.19#	Offer letter, dated March 19, 2013, between Prothena Biosciences Inc and Martin Koller (21)
10.20#	Offer letter, dated December 14, 2012, between Prothena Biosciences Inc and Tara Nickerson
21.1	List of Subsidiaries
24.1	Power of Attorney (included on signature page hereto)
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(1) Filed as Exhibit 2.1 to Amendment No. 2 to Registrant s Registration Statement on Form 10 filed with the SEC on November 30, 2012, and incorporated herein by reference.
(2) Filed as Exhibit 2.1 to Registrant s Current Report on Form 8-K filed with the SEC on December 21, 2012, and incorporated herein by reference.
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(20) Filed as Exhibit 10.1 to Registrant s Current Report on Form 8-K filed with the SEC on March 28, 2013, and incorporated herein by reference.
(21) Filed as Exhibit 10.2 to Registrant s Current Report on Form 8-K filed with the SEC on March 28, 2013, and incorporated herein by reference.

* Exhibit 32.1 is being furnished and shall not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or otherwise subject to the liability of that section, nor shall such exhibit be deemed to be incorporated by reference in any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as otherwise specifically stated in such filing.

# Indicates management contract or compensatory plan, contract or arrangement.

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SIGNATURES

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

Prothena Corporation plc

Date: March 29, 2013

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

Date: March 29, 2013

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

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POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose individual signature appears below hereby authorizes and appoints Dale B. Schenk and Tran B. Nguyen, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Name	Title	Date
/s/ Dale B. Schenk	President and Chief Executive Officer	March 29, 2013
Dale B. Schenk, Ph.D.	(Principal Executive Officer) and Director	
/s/ Tran B. Nguyen	Chief Financial Officer	March 29, 2013
Tran B. Nguyen	(Principal Accounting and Financial Officer)	
/s/ Lars Ekman	Chairman of the Board	March 29, 2013
Lars Ekman, M.D., Ph.D.		
/s/ Richard T. Collier	Director	March 29, 2013
Richard T. Collier		
/s/ Shane Cooke	Director	March 29, 2013
Shane Cooke		
/s/ Christopher S. Henney	Director	March 29, 2013
Christopher S. Henney, Ph.D., D.Sc.		

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