Prothena Corp plc
Form 10-Q
November 02, 2015

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2015

Or

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

Commission file number: 001-35676

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

Ireland	98-1111119
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

Alexandra House
The Sweepstakes, Ballsbridge
Dublin 4, Ireland

(Address of principal executive offices including Zip Code)
Registrant's telephone number, including area code: 011-353-1-902-3519

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

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

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

The number of ordinary shares outstanding as of October 23, 2015 was 31,522,750.

PROTHENA CORPORATION plc
Form 10-Q – QUARTERLY REPORT
For the Quarter Ended September 30, 2015
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(in thousands, except share and per share data)
(unaudited)

	September 30, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$387,802	$293,579
Receivable from Roche	814	1,729
Receivable from related party	—	30
Deferred tax assets	174	167
Prepaid expenses and other current assets	4,786	3,770
Total current assets	393,576	299,275
Non-current assets:		
Property and equipment, net	2,930	3,121
Deferred tax assets, non-current	2,417	1,720
Other non-current assets	7	—
Total non-current assets	5,354	4,841
Total assets	$398,930	$304,116
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$4,058	$4,722
Accrued research and development	9,522	2,285
Income taxes payable	—	57
Other current liabilities	4,978	4,975
Total current liabilities	18,558	12,039
Non-current liabilities:		
Income taxes payable, non-current	98	98
Deferred rent	2,195	2,090
Other liabilities	126	—
Total non-current liabilities	2,419	2,188
Total liabilities	20,977	14,227
Commitments and contingencies (Note 6)		
Shareholders' equity:		
Euro deferred shares, €22 nominal value:	—	—
Authorized shares — 10,000 at September 30, 2015 and December 31, 2014		
Issued and outstanding shares — none at September 30, 2015 and December 31, 2014		
Ordinary shares, $0.01 par value:	315	274
Authorized shares — 100,000,000 at September 30, 2015 and December 31, 2014		
Issued and outstanding shares — 31,521,550 and 27,388,005 at September 30, 2015 and December 31, 2014, respectively		
Additional paid-in capital	482,584	338,106
Accumulated deficit	(104,946)	(48,491)
Total shareholders' equity	377,953	289,889
Total liabilities and shareholders' equity	$398,930	$304,116

See accompanying Notes to Condensed Consolidated Financial Statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Collaboration revenue	$429	$1,349	$1,300	$48,429
Revenue—related party	—	137	—	412
Total revenue	429	1,486	1,300	48,841
Operating expenses:				
Research and development	17,185	10,388	40,549	28,345
General and administrative	5,905	4,230	16,476	14,040
Total operating expenses	23,090	14,618	57,025	42,385
Income (loss) from operations	(22,661)	(13,132)	(55,725)	6,456
Other income (expense):				
Interest income	50	19	116	54
Other income (expense), net	(127)	172	(147)	138
Total other income (expense)	(77)	191	(31)	192
Income (loss) before income taxes	(22,738)	(12,941)	(55,756)	6,648
Provision for income taxes	238	241	699	688
Net income (loss)	$(22,976)	$(13,182)	$(56,455)	$5,960
Net income (loss) per share attributable to holders of ordinary shares				
Basic	$(0.73)	$(0.48)	$(1.89)	$0.25
Diluted	$(0.73)	$(0.48)	$(1.89)	$0.24
Shares used to compute net income (loss) per share attributable to holders of ordinary shares				
Basic	31,441	27,370	29,893	23,758
Diluted	31,441	27,370	29,893	24,722

See accompanying Notes to Condensed Consolidated Financial Statements.

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

	Nine Months Ended September 30, 2015	2014
Operating activities		
Net income (loss)	$(56,455)	$5,960
Adjustments to reconcile net income (loss) to cash provided by (used in) operating activities:		
Depreciation and amortization	588	549
Share-based compensation	7,136	4,199
Excess tax benefit from share-based award exercises	(2,351)	(262)
Deferred income taxes	(704)	(688)
Loss on sublease	261	—
Changes in operating assets and liabilities:		
Receivable from Roche	915	(967)
Receivable from related party	30	(34)
Other assets	304	(112)
Accounts payable, accruals and other liabilities	7,502	3,195
Net cash provided by (used in) operating activities	(42,774)	11,840
Investing activities		
Purchases of property and equipment	(397)	(459)
Net cash used in investing activities	(397)	(459)
Financing activities		
Proceeds from issuance of ordinary shares in public offering, net	131,481	117,391
Proceeds from issuance of ordinary shares upon exercise of stock options	3,562	442
Excess tax benefit from share-based award exercises	2,351	262
Net cash provided by financing activities	137,394	118,095
Net increase in cash and cash equivalents	94,223	129,476
Cash and cash equivalents, beginning of the year	293,579	176,677
Cash and cash equivalents, end of the period	$387,802	$306,153
Supplemental disclosures of cash flow information		
Cash paid for income taxes, net of refunds	$442	$988
Supplemental disclosures of non-cash investing and financing activities		
Offering costs in accounts payable and accrued liabilities	$12	$45

See accompanying Notes to Condensed Consolidated Financial Statements.

Notes to the Condensed Consolidated Financial Statements
(unaudited)

1. Organization

Description of Business

Prothena Corporation plc and its subsidiaries ("Prothena" or the "Company") is a late-stage clinical biotechnology company focused on the discovery, development and commercialization of novel protein immunotherapies for the potential treatment of diseases that involve amyloid or cell adhesion. The Company is developing antibody-based product candidates that target a number of potential indications including AL amyloidosis (NEOD001), Parkinson's disease and other related synucleinopathies (PRX002) and psoriasis and other inflammatory diseases (PRX003).

The Company is a public limited company formed under the laws of Ireland. The Company separated from Elan Corporation Limited, formerly Elan Corporation, plc ("Elan"), on December 20, 2012. After the separation from Elan, and the related distribution of the Company's ordinary shares to Elan's shareholders (the "Separation and Distribution"), the Company's ordinary shares commenced trading on The Nasdaq Global Market under the symbol "PRTA" on December 21, 2012 and currently trade on The Nasdaq Global Select Market.

Prothena's business consists of a substantial portion of Elan's former drug discovery business platform, including Neotope Biosciences Limited (now named Prothena Biosciences Limited) and its wholly owned subsidiaries Onclave Therapeutics Limited (now named Prothena Therapeutics Limited) and Prothena Biosciences Inc (which for the period prior to the Separation and Distribution are collectively referred to herein as the "Prothena Business"). Prior to December 21, 2012, the Prothena Business operated as part of Elan and not as a separate stand-alone entity.

Liquidity and Business Risks

As of September 30, 2015, the Company had an accumulated deficit of $104.9 million and cash and cash equivalents of $387.8 million.

Based on the Company's business plans, management believes that the Company's cash and cash equivalents at September 30, 2015 are sufficient to meet its obligations for at least the next twelve months. To operate beyond such period, or if the Company elects to increase its spending on development programs significantly above current long-term plans or enters into potential licenses and or other acquisitions of complementary technologies, products or companies, the Company may need additional capital. The Company expects to continue to finance future cash needs that exceed its cash from operating activities primarily through its current cash and cash equivalents, its collaboration with Roche, and to the extent necessary, through proceeds from public or private equity or debt financings, loans and other collaborative agreements with corporate partners or other arrangements.

The Company is subject to a number of risks, including but not limited to: the uncertainty of the Company's research and development ("R&D") efforts resulting in future successful commercial products; obtaining regulatory approval for its product candidates; its ability to successfully commercialize its product candidates, if approved; significant competition from larger organizations; reliance on the proprietary technology of others; dependence on key personnel; uncertain patent protection; dependence on corporate partners and collaborators; and possible restrictions on reimbursement from governmental agencies and healthcare organizations, as well as other changes in the healthcare industry.

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

2. Summary of Significant Accounting Policies

Basis of Preparation and Presentation of Financial Information

The accompanying interim Condensed Consolidated Financial Statements have been prepared in accordance with the accounting principles generally accepted in the U.S. ("GAAP") and with the instructions for Form 10-Q and Regulations S-X statements. Accordingly, they do not include all of the information and notes required for complete financial statements. These interim Condensed Consolidated Financial Statements should be read in conjunction with the Consolidated Financial Statements and Notes thereto contained in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on March 13, 2015 (the "2014 Form 10-K"). The Condensed Consolidated Financial Statements of Prothena Corporation plc are presented in U.S. dollars, which is the functional currency of the Company. The unaudited condensed consolidated financial statements include the accounts of the Company and its consolidated subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Unaudited Interim Financial Information

The accompanying interim Condensed Consolidated Financial Statements and related disclosures are unaudited, have been prepared on the same basis as the annual consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair presentation of the results of operations for the periods presented. The year-end condensed balance sheet data was derived from audited financial statements, however certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted. The condensed consolidated results of operations for any interim period are not necessarily indicative of the results to be expected for the full year or for any other future year or interim period.

Use of Estimates

The preparation of the Condensed Consolidated Financial Statements in conformity with GAAP requires management to make judgments, estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures. On an ongoing basis, management evaluates its estimates, including critical accounting policies or estimates related to revenue recognition, share-based compensation and research and development expenses. The Company bases its estimates on historical experience and on various other market specific and other relevant assumptions that management believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Because of the uncertainties inherent in such estimates, actual results may differ materially from these estimates.

Significant Accounting Policies

There were no significant changes to the accounting policies during the nine months ended September 30, 2015, from the significant accounting policies described in Note 2 of the "Notes to Consolidated Financial Statement" in the 2014 Form 10-K.

Recent Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update 2014-09 (ASU 2014-09), Revenue from Contracts with Customers. ASU 2014-09 supersedes the revenue recognition requirements in Revenue Recognition (Topic 605), and requires entities to recognize revenue in a way that depicts the transfer of promised goods and services to customers in an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. ASU 2014-09 is effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period, which for the Company is January 1, 2018. Early adoption is permitted after January 1, 2017. The standard permits the use of either retrospective or cumulative effect transition method. The Company is currently evaluating the potential impact the adoption of ASU 2014-09 will have on its consolidated financial statements. The Company has not yet selected a transition method nor has it determined the effect of the standard on its ongoing financial reporting.

3. Fair Value Measurements

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

Level 1 —	Observable inputs such as quoted prices (unadjusted) for identical assets or liabilities in active markets.
Level 2 —	Include other inputs that are based upon quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, and model-based valuation techniques for which all significant inputs are observable in the market or can be derived from observable market data. Where applicable, these models project future cash flows and discount the future amounts to a present value using market-based observable inputs including interest rate curves, foreign exchange rates, and credit ratings.
Level 3 —	Unobservable inputs that are supported by little or no market activities, which would require the Company to develop its own assumptions.

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The carrying amounts of certain financial instruments, such as cash equivalents, accounts receivable, accounts payable and accrued liabilities, approximate fair value due to their relatively short maturities, and low market interest rates, if applicable.

Based on the fair value hierarchy, the Company classifies its cash equivalents within Level 1. This is because the Company values its cash equivalents using quoted market prices. The Company's Level 1 securities consist of $348.1 million and $262.5 million in money market funds included in cash and cash equivalents at September 30, 2015 and December 31, 2014, respectively.

4. Composition of Certain Balance Sheet Items

Property and Equipment, net

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

	September 30, 2015	December 31, 2014
Machinery and equipment	$5,653	$5,481
Leasehold improvements	2,254	2,214
Purchased computer software	159	137
	8,066	7,832
Less: accumulated depreciation and amortization	(5,136)	(4,711)
Property and equipment, net	$2,930	$3,121

Depreciation expense was $0.2 million and $0.6 million for the three and nine months ended September 30, 2015 compared to $0.2 million and $0.5 million for the three and nine months ended September 30, 2014, respectively.

Other Current Liabilities

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

	September 30, 2015	December 31, 2014
Payroll and related expenses	$3,500	$3,138
Professional services	442	1,169
Deferred rent	268	172
Other	768	496
Other current liabilities	$4,978	$4,975

5. Net income (loss) Per Ordinary Share

Basic net income (loss) per ordinary share is calculated by dividing net income (loss) by the weighted-average number of ordinary shares outstanding during the period. Shares used in diluted net income per ordinary share would include the dilutive effect of ordinary shares potentially issuable upon the exercise of stock options outstanding. However, potentially issuable ordinary shares are not used in computing diluted net loss per ordinary share as their effect would be anti-dilutive due to the loss recorded during the three months ended September 30, 2015 and 2014 and the nine months ended September 30, 2015, and therefore diluted net loss per share is equal to basic net loss per share. During the nine months ended September 30, 2014, diluted net income per ordinary share is computed by giving effect to all dilutive potential ordinary shares including options.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Numerator:				
Net income (loss)	$(22,976)	$(13,182)	$(56,455)	$5,960
Denominator (basic):				
Weighted-average ordinary shares outstanding	31,441	27,370	29,893	23,758
Denominator (diluted):				
Weighted-average ordinary shares outstanding	31,441	27,370	29,893	23,758
Dilutive stock options outstanding	—	—	—	964
Net weighted average ordinary shares outstanding	31,441	27,370	29,893	24,722
Net income (loss) per share attributable to holders of ordinary shares:				
Basic net income (loss) per share	$(0.73)	$(0.48)	$(1.89)	$0.25
Diluted net income (loss) per share	$(0.73)	$(0.48)	$(1.89)	$0.24

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Stock options to purchase ordinary shares	3,306	2,621	3,306	632

6. Commitments and Contingencies

Operating Lease

In December 2014, the Company entered into a noncancelable operating sublease agreement with a third party to sublease a portion of its leased facility. This sublease agreement has a three-year term which commenced in January 2015 (with options to extend for another year). The Company recognized a loss of $0.4 million in the nine months ended September 30, 2015 for the cash difference between the total payments associated with the sublease, including executory costs, and the amount of sublease rental receipts over the sublease term.

In August 2015, the Company entered into an agreement to lease 6,258 square feet of office space in Dublin, Ireland. The Company expects to occupy this office space by the beginning of 2016. This lease has a term of 10 years from commencement and provides for an option to terminate the lease at the end of the fifth year of the term. It is also subject to a rent review every five years. As a result of this noncancelable operating lease agreement, the Company is obligated to make lease payments totaling approximately €2.0 million, or $2.3 million as converted using exchange rate as of September 30, 2015, over the term of the lease, assuming current lease payments.

Commitments

In the normal course of business, the Company enters into various firm purchase commitments primarily related to research and development activities. As of September 30, 2015, the Company had non-cancelable purchase commitments to suppliers for $3.0 million of which $2.7 million is included in accrued current liabilities, and contractual obligations under license agreements of $1.6 million of which $0.1 million is included in accrued current liabilities. The following is a summary of the Company's non-cancelable purchase commitments and contractual obligations as of September 30, 2015 (in thousands):

	Total	2015 (Remaining 3 months)	2016	2017	2018	2019	Thereafter
Purchase Obligations	$3,034	$ 3,007	$9	$9	$9	$—	$—
Contractual obligations under license agreements [(1)]	1,602	205	123	123	123	123	905
Total	$4,636	$ 3,212	$132	$132	$132	$123	$905

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

7. Roche License Agreement

In December 2013, the Company entered into the License Agreement with Roche to develop and commercialize certain antibodies that target alpha-synuclein, including PRX002. The License Agreement was evaluated under ASC 605-25, "Multiple Element Arrangements". Under this agreement, the Company recognizes research reimbursement as collaboration revenue as earned. The Company recognized $0.4 million and $1.1 million as collaboration revenue for research reimbursement from Roche for the three and nine months ended September 30, 2015, respectively, as compared to $0.4 million and $1.1 million for the three and nine months ended September 30, 2014, respectively. Cost sharing payments to Roche are recorded as R&D expenses. The Company recognized $0.8 million and $2.2 million in R&D expenses for payments made to Roche during the three and nine months ended September 30, 2015, respectively, as compared to $0.5 million and $1.0 million for the three and nine months ended September 30, 2014, respectively. Reimbursement for development costs from Roche under the cost-sharing arrangement were allocated between license revenue and an offset to R&D expenses based on the relative selling price method until the full allocated consideration of $35.6 million was recognized as license revenue, after which the full reimbursement is recorded as an offset to R&D expenses. In the nine months ended September 30, 2015, the Company reached the full allocated consideration of $35.6 million recognized as license revenue; accordingly, future development revenue will be recorded as an offset to R&D expenses. Reimbursement for development costs from Roche during the three and nine months ended September 30, 2015 were $1.2 million and $4.2 million, respectively, of which $nil and $0.2 million, respectively, were recognized as collaboration license revenue and $1.2 million and $4.0 million, respectively, were recognized as an offset to R&D expenses. Reimbursement for development costs from Roche during the three and nine months ended September 30, 2014 were $1.0 million and $4.5 million, respectively, of which $0.9 million and $4.0 million respectively, were recognized as collaboration license revenue and $0.1 million and $0.5 million, respectively were recognized as an offset to R&D expenses.

The Company recognized the $30.0 million upfront payment from Roche as collaboration license revenue in the first quarter of 2014. Furthermore, in April 2014, the Company together with Roche initiated a Phase 1 clinical trial of PRX002. As a result of this initiation, the Company received a $15.0 million milestone payment from Roche under the License Agreement. The Company concluded that the $15.0 million clinical milestone triggered upon the initiation of the Phase 1 study from PRX002 in the clinic is consistent with the definition of a substantive milestone included in ASU No. 2010-17, "Milestone Method of Revenue Recognition". Factors considered in this determination included scientific and regulatory risk that must be overcome to achieve each milestone, the level of effort and investment required to achieve the milestone, and the monetary value attributed to the milestone.

Accordingly, the Company recognized payments related to the achievement of this milestone when the milestone was achieved. The milestone payment was allocated to the units of accounting based on the relative selling price method for income statement classification purposes. In the nine months ended September 30, 2014, the Company recognized $13.3 million of the $15.0 million milestone payment as collaboration revenue and $1.7 million as an offset to R&D expenses. The Company did not achieve any of the clinical and regulatory milestones under the License Agreement during the three and nine months ended September 30, 2015.

8. Shareholders' Equity

Ordinary Shares

As of September 30, 2015, the Company had 100,000,000 ordinary shares authorized for issuance with a par value of $0.01 per ordinary share and 31,521,550 ordinary shares issued and outstanding. Each ordinary share is entitled to one vote and, on a pro rata basis, to dividends when declared and the remaining assets of the Company in the event of a winding up.

Euro Deferred Shares

As of September 30, 2015, the Company had 10,000 Euro Deferred Shares authorized for issuance with a nominal value of €22 per share. No Euro Deferred Shares are outstanding at September 30, 2015. The rights and restrictions attaching to the Euro Deferred Shares rank pari passu with the ordinary shares and are treated as a single class in all respects.

February 2014 Offering

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

June 2014 Offering

In July 2014, the Company completed an underwritten public offering of an aggregate of 5,462,500 of its ordinary shares at a public offering price of $22.50 per ordinary share. The Company received aggregate net proceeds of approximately $117.4 million (of which $102.5 million and $14.9 million was received in June 2014 and July 2014, respectively), after deducting the underwriting discount and estimated offering costs.

April 2015 Offering

In April 2015, the Company completed an underwritten public offering of an aggregate of 3,795,000 of its ordinary shares at a public offering price of $37.00 per ordinary share. The Company received aggregate net proceeds of approximately $131.5 million, after deducting the underwriting discount and estimated offering costs.

9. Share-Based Compensation

Amended and Restated 2012 Long Term Incentive Plan (“LTIP”)

Employees and consultants of the Company, its subsidiaries and affiliates, as well as members of the Board, are eligible to receive equity awards under the LTIP. The LTIP provides for the grant of stock options, including incentive stock options and nonqualified stock options, stock appreciation rights (“SARS”), restricted shares, restricted share units ("RSUs"), cash or stock-based performance awards and other share-based awards to eligible individuals. Options under the LTIP may be granted for periods up to ten years. All options issued to date have had a ten year life.

The Company granted 157,500 and 1,083,050 share options during the three and nine months ended September 30, 2015, respectively and 47,500 and 710,500 share options during the three and nine months ended September 30, 2014, respectively, under the LTIP. The Company's option awards generally vest over four years. The aggregate number of ordinary shares authorized for issuance under the LTIP is 5,550,000 ordinary shares and as of September 30, 2015, 1,835,992 ordinary shares remain available for grant and options to purchase 3,306,219 ordinary shares granted from the LTIP were outstanding with a weighted-average exercise price of approximately $20.05 per share.

Share-based Compensation Expense

The Company estimates the fair value of share-based compensation on the date of grant using an option-pricing model. The Company uses the Black-Scholes model to value share-based compensation, excluding RSUs, which the Company values using the fair market value of its ordinary shares on the date of grant. The Black-Scholes option-pricing model determines the fair value of share-based payment awards based on the share price on the date of grant and is affected by assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to, the Company’s share price, volatility over the expected life of the awards and actual and projected employee stock option exercise behaviors. Since the Company does not have sufficient historical employee share option exercise data, the simplified method has been used to estimate the expected life of all options. Prior to 2015, the expected volatility was based on historical stock volatilities of several of the Company's publicly traded comparable companies over a period equal to the expected life of the options, as the Company did not have a long enough trading history to use the volatility of its own ordinary shares. Starting in 2015, the expected volatility was based on a combination of historical volatility for the Company's stock and the historical volatilities of several of the Company's publicly traded comparable companies. Although the fair value of share options granted by the Company is estimated by the Black-Scholes model, the estimated fair value may not be indicative of the fair value observed in a willing buyer and seller market transaction.

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

Share-based compensation expense will continue to have an adverse impact on the Company’s results of operations, although it will have no impact on its overall financial position. The amount of unearned share-based compensation currently estimated to be expensed from now through the year 2018 related to unvested share-based payment awards at September 30, 2015 is $32.6 million. The weighted-average period over which the unearned share-based compensation is expected to be recognized is 2.6 years. If there are any modifications or cancellations of the underlying unvested securities, the Company may be required to

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accelerate, increase or decrease any remaining unearned share-based compensation expense. Future share-based compensation expense and unearned share-based compensation will increase to the extent that the Company grants additional equity awards.

Share-based compensation expense recorded in these Condensed Consolidated Financial Statements for the three and nine months ended September 30, 2015 and 2014 was based on awards granted under the LTIP. The following table summarizes share-based compensation expense for the periods presented (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Research and development[(1)]	$ 1,220	$ 601	$ 2,953	$ 1,650
General and administrative	1,797	817	4,183	2,549
Total share-based compensation expense	$ 3,017	$ 1,418	$ 7,136	$ 4,199

(1) Includes zero and $20,000 for the three months ended September 30, 2015 and 2014, respectively, and $42,000 and $92,000 for the nine months ended September 30, 2015 and 2014, respectively, of share-based compensation expense related to options granted to a consultant.

The fair value of the options granted to employees and non-employee directors during the three and nine months ended September 30, 2015 and 2014 was estimated as of the grant date using the Black-Scholes option-pricing model assuming the weighted-average assumptions listed in the following table:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Expected volatility	77.0%	86.3%	76.2%	84.5%
Risk-free interest rate	1.8%	1.9%	1.8%	1.8%
Expected dividend yield	—%	—%	—%	—%
Expected life (in years)	6.0	6.0	6.0	6.0
Weighted average grant date fair value	$40.05	$15.01	$22.52	$20.03

The fair value of employee stock options is being amortized on a straight-line basis over the requisite service period for each award. Each of the inputs discussed above is subjective and generally requires significant management judgment to determine.

The following table summarizes the Company’s share option activity during the nine months ended September 30, 2015:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2014	2,612,080	$13.13	8.45	$25,298
Granted	1,083,050	33.72		
Exercised	(338,545)	10.51		
Canceled	(50,366)	18.89		
Outstanding at September 30, 2015	3,306,219	$20.05	8.31	$85,969
Vested and expected to vest at September 30, 2015				