Prothena Corp plc
Form 10-Q
November 06, 2018

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

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FORM 10-Q

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(Mark One)

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

For the quarterly period ended September 30, 2018

Or

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

Commission file number: 001-35676

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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)

Adelphi Plaza
Upper George's Street
Dún Laoghaire
Co. Dublin, A96 T927, Ireland
(Address of principal executive offices including Zip Code)
Registrant’s telephone number, including area code: 011-353-1-236-2500

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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 o

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes x No o

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,” “smaller reporting company” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer	x	Accelerated filer	o
Non-accelerated filer	o	Smaller reporting company	x
		Emerging growth company	o

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP,

indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

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

The number of ordinary shares outstanding as of October 26, 2018 was 39,863,711.

PROTHENA CORPORATION plc
Form 10-Q – QUARTERLY REPORT
For the Quarter Ended September 30, 2018
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(in thousands, except share and per share data)

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 451,512	$ 417,620
Receivable from Roche	—	240
Prepaid expenses and other current assets	5,396	8,467
Total current assets	456,908	426,327
Non-current assets:		
Property and equipment, net	52,951	54,990
Deferred tax assets	10,209	8,113
Restricted cash	4,056	4,056
Other non-current assets	502	2,843
Total non-current assets	67,718	70,002
Total assets	$ 524,626	$ 496,329
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 4,485	$ 13,633
Accrued research and development	5,950	13,509
Income taxes payable, current	285	311
Build-to-suit lease obligation, current	1,575	733
Restructuring liability	5,908	—
Other current liabilities	5,424	9,185
Total current liabilities	23,627	37,371
Non-current liabilities:		
Deferred revenue	110,242	—
Deferred rent	216	254
Build-to-suit lease obligation, non-current	50,338	51,515
Other liabilities	553	—
Total non-current liabilities	161,349	51,769
Total liabilities	184,976	89,140
Commitments and contingencies (Note 7)		
Shareholders' equity:		
Euro deferred shares, €22 nominal value:	—	—
Authorized shares — 10,000 at September 30, 2018 and December 31, 2017		
Issued and outstanding shares — none at September 30, 2018 and December 31, 2017		
Ordinary shares, $0.01 par value:	398	385
Authorized shares — 100,000,000 at September 30, 2018 and December 31, 2017		
Issued and outstanding shares — 39,863,711 and 38,482,764 at September 30, 2018 and December 31, 2017, respectively		
Additional paid-in capital	914,786	849,154
Accumulated deficit	(575,534)	(442,350)
Total shareholders' equity	339,650	407,189
Total liabilities and shareholders' equity	$ 524,626	$ 496,329

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,	
	2018	2017	2018	2017
Collaboration revenue	$255	$219	$761	$27,290
Total revenue	255	219	761	27,290
Operating expenses:				
Research and development	18,515	41,315	84,673	101,045
General and administrative	9,235	12,438	34,456	34,182
Restructuring costs	(3,172)	—	17,732	—
Total operating expenses	24,578	53,753	136,861	135,227
Loss from operations	(24,323)	(53,534)	(136,100)	(107,937)
Other income (expense):				
Interest income (expense), net	791	118	1,822	(228)
Other income (expense), net	(65)	(683)	73	(1,967)
Total other income (expense), net	726	(565)	1,895	(2,195)
Loss before income taxes	(23,597)	(54,099)	(134,205)	(110,132)
Provision for (benefit from) income taxes	962	(1,705)	(1,021)	(4,653)
Net loss	$(24,559)	$(52,394)	$(133,184)	$(105,479)
Basic and diluted net loss per share	$(0.62)	$(1.37)	$(3.38)	$(2.82)
Shares used to compute basic and diluted net loss per share	39,850	38,292	39,457	37,384

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,	
	2018	2017
Operating activities		
Net loss	$(133,184)	$(105,479)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	2,390	2,285
Share-based compensation	20,253	19,357
Restructuring share-based compensation	2,512	—
Deferred income taxes	1,250	(479)
Interest expense under build-to-suit lease obligation	2,761	2,759
Gain from early lease retirement	—	(2,096)
Loss (gain) from disposal of fixed assets	101	(5)
Changes in operating assets and liabilities:		
Accounts receivable	240	(42)
Prepaid and other assets	5,412	(11,183)
Deferred revenue	110,242	—
Accounts payable, accruals and other liabilities	(23,345)	3,224
Restructuring liability	4,344	—
Net cash used in operating activities	(7,024)	(91,659)
Investing activities		
Purchases of property and equipment	(432)	(3,250)
Proceeds from disposal of fixed assets	—	105
Net cash used in investing activities	(432)	(3,145)
Financing activities		
Proceeds from issuance of ordinary shares in public offering, net	—	150,323
Proceeds from subscription of ordinary shares	39,758	—
Proceeds from issuance of ordinary shares upon exercise of stock options	4,686	15,424
Reduction of build-to-suit lease obligation	(3,096)	(1,805)
Net cash provided by financing activities	41,348	163,942
Net increase in cash, cash equivalents and restricted cash	33,892	69,138
Cash, cash equivalents and restricted cash, beginning of the year	421,676	390,979
Cash, cash equivalents and restricted cash, end of the period	$455,568	$460,117
Supplemental disclosures of cash flow information		
Cash paid for income taxes, net of refunds	$1,101	$294
Supplemental disclosures of non-cash investing and financing activities		
Acquisition of property and equipment included in accounts payable and accrued liabilities	$195	$163
Receivable from option exercises	$—	$1,128

See accompanying Notes to Condensed Consolidated Financial Statements.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the statement of financial position that sum to the total of the same such amounts shown in the Condensed Consolidated Statements of Cash Flows.

	Nine Months Ended September 30,	
	2018	2017
Cash and cash equivalents	$451,512	$456,061
Restricted cash	4,056	4,056
Total Cash, cash equivalents and restricted cash, end of the period	$455,568	$460,117

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 clinical-stage neuroscience company focused on the discovery and development of novel therapies with the potential to fundamentally change the course of progressive, life-threatening diseases. Fueled by a deep scientific understanding built over decades of neuroscience research, the Company is advancing a pipeline of therapeutic candidates for a number of indications and novel targets including Parkinson's disease and other related synucleinopathies (prasinezumab, or PRX002/RG7935) and ATTR amyloidosis (PRX004), as well as tau and A (Beta amyloid) for the potential treatment of Alzheimer's disease and other neurodegenerative disorders, and TDP-43 for the potential treatment of ALS (amyotrophic lateral sclerosis) and FTD (frontotemporal dementia).

The Company was formed on September 26, 2012 under the laws of Ireland and re-registered as an Irish public limited company on October 25, 2012. The Company's ordinary shares began trading on The Nasdaq Global Market under the symbol "PRTA" on December 21, 2012 and currently trade on The Nasdaq Global Select Market.

Liquidity and Business Risks

As of September 30, 2018, the Company had an accumulated deficit of $575.5 million and cash and cash equivalents of $451.5 million.

Based on the Company's business plans, management believes that the Company's cash and cash equivalents at September 30, 2018 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 research and 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 collaborations with Roche and Celgene, 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.

2. Summary of Significant Accounting Policies

Basis of Preparation and Presentation of Financial Information

These accompanying Unaudited 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 Regulation 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 U.S. Securities and Exchange Commission (the "SEC") on February 26, 2018 (the "2017 Form 10-K"). These Unaudited Interim Condensed Consolidated Financial Statements are presented in U.S. dollars, which is the functional currency of the Company and its consolidated subsidiaries. These Unaudited Interim 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 Unaudited 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 consolidated 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, 2018, from the significant accounting policies described in Note 2 of the Notes to Consolidated Financial Statements in the 2017 Form 10-K, with the exception of those noted below.

Restructuring Charges, Net

The Company recognizes restructuring charges related to its reorganization plan. In connection with these activities, the Company records restructuring charges for contractual employee termination benefits, one-time employee termination benefits and contract termination costs. The Company accounts for its restructuring charges as a liability when the obligations are incurred and records such charges at fair value.

The recognition of restructuring charges requires the Company to make certain judgments and estimates regarding the nature, timing and amount of costs associated with the planned reorganization plan. To the extent the Company's actual results differ from its estimates and assumptions, the Company may be required to revise the estimates of future liabilities, requiring the recognition of additional restructuring charges or the reduction of liabilities already recognized. Such changes to previously estimated amounts may be material to the consolidated financial statements. Changes in the estimates of the restructuring charges are recorded in the period the change is determined.

At the end of each reporting period, the Company evaluates the remaining accrued balances to ensure that no excess accruals are retained and the utilization of the provisions are for their intended purpose in accordance with developed restructuring plans. See Note 11, "Restructuring" for additional information regarding restructuring charges.

Recently Adopted Accounting Pronouncement

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers, which is largely codified in Accounting Standards Codification Topic 606 (ASC 606). ASC 606 supersedes the revenue recognition requirement in ASC 605, Revenue Recognition, and supersedes nearly all existing revenue recognition guidance under GAAP. To date, the Company has derived its revenue from a license and collaboration agreement and a service agreement. The consideration the Company is eligible to receive under these agreements includes upfront payments, research and development funding, milestone payments and royalties. The core principle of ASC 606 is to recognize revenue when promised goods or services are transferred to customers in an amount that reflects the consideration that is expected to be received for those goods and services. The Company adopted ASC 606 as of January 1, 2018 using the modified retrospective transition method. As of January 1, 2018, the Company did not record any changes to the opening balance of the accumulated deficit since the cumulative effect of applying the new revenue standard was the same as applying ASC 605. Prior period amounts are not adjusted and continue to be reported in accordance with the Company's historical accounting under ASC 605. Upon adoption of the new revenue standard, the Company has provided additional revenue-related disclosures in its notes to the Consolidated Financial Statements which commenced in the three months ended March 31, 2018.

Revenue Recognition

Revenue is recognized only when the Company satisfies an identified performance obligation by transferring a promised good or service to a customer.

Contracts with Multiple Performance Obligations

The Company's License Agreement with Roche contains multiple performance obligations. The Company accounts for the individual performance obligations separately if they are distinct. Factors considered in the determination of whether the license performance obligations are distinct included, among other things, the research and development capabilities of Roche and Roche's sublicense rights, and for the remaining performance obligations the fact that they are not proprietary and can be and have been provided by other vendors. The transaction price is allocated to the separate performance obligation on a relative standalone selling price basis.
The Company does not disclose the value of unsatisfied performance obligations for (i) contracts with an original expected length of one year or less and (ii) contracts for which the Company recognize revenue at the amount to which we have the right to invoice for services performed.

Collaboration Revenue

Upon adoption of ASC 606, the Company recognizes research and development reimbursements as collaboration revenue earned over time as services are performed. Prior to adoption of ASC 606, the Company recorded research reimbursement as collaboration revenue and development reimbursement as an offset to R&D expense once the license revenue cap was met.

Milestone Revenue

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

In general, the Company considers such milestone payments as variable consideration with constraint and therefore recognizes the revenue from such milestone payments as collaboration revenue at point in time when the Company can conclude it is probable that a significant revenue reversal will not occur in future periods.

Profit Share Revenue

For agreements, with profit sharing arrangements, the Company will record its share of the pre-tax commercial profit as collaboration revenue when the profit sharing can be reasonably estimated and that a significant revenue reversal will not occur in future periods.

Royalty Revenue

The Company will recognize revenue from royalties based on licensees' sales of the Company's products or products using the Company's technologies. Royalties are recognized as earned in accordance with the contract terms when royalties from licensees can be reasonably estimated and that a significant revenue reversal will not occur in future periods. There were no royalties earned during the nine months ended September 30, 2018 and 2017, respectively.

Taxes, Shipping and Handling

The Company excludes from the measurement of the transaction price all taxes assessed by a governmental authority that are both imposed on and concurrent with a specific revenue-producing transaction and collected by the Company from a customer (e.g., sales, use, value added, some excise taxes). In addition, we account for shipping and handling as activities that are performed after our customers obtain control of the goods as activities to fulfill our performance obligation to transfer the goods.

Incremental Costs to Obtain or Fulfill a Contract

For costs to obtain a contract, the Company will capitalize such amounts if they are incremental and expected to be recovered. Sales commissions directly related to obtaining new contracts will be capitalized unless the amortization period is one year or

less, at which these costs will be recorded within selling and general administrative expenses. As of September 30, 2018, the Company does not have such costs capitalized in its unaudited condensed consolidated balance sheet.

Share-based Compensation

To determine the fair value of share-based payment awards, the Company uses the Black-Scholes option-pricing model. The determination of fair value using the Black-Scholes option-pricing model is affected by the Company's share price as well as assumptions regarding a number of complex and subjective variables. Share-based compensation expense is recognized on a straight-line basis over the requisite service period for each award. Further, share-based compensation expense recognized in the Consolidated Statements of Operations is based on awards expected to vest and therefore the amount of expense has been reduced for estimated forfeitures. If actual forfeitures differ from estimates at the time of grant they will be revised in subsequent periods. Beginning in 2018, the Company uses its historical volatility for the Company's stock to estimate expected volatility. Through December 31, 2017, 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. 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 10 for further information).

The Company records any excess tax benefits or tax shortfalls from its equity awards in its Consolidated Statements of Operations in the reporting periods in which stock options are exercised.

Segment and Concentration of Risks

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

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

The receivable from Roche are amounts due from Roche entities located in the U.S. and Switzerland under the License Agreement that became effective January 22, 2014. Revenue recorded in the Statements of Operations consists of reimbursement from Roche for research and development services. The Company's credit risk exposure is up to the extent recorded on the Company's Condensed Consolidated Balance Sheet.

As of September 30, 2018, $52.4 million of the Company's long-lived assets were held in the U.S. and $0.5 million were in Ireland. As of December 31, 2017, $54.4 million of the Company's long-lived assets were held in the U.S. and $0.6 million were in Ireland.

The Company does not own or operate facilities for the manufacture, packaging, labeling, storage, testing or distribution of nonclinical or clinical supplies of any of its drug candidates, including for commercial supplies if the Company obtains regulatory approval to market any of its drug candidates. The Company instead contracts with and relies on third-parties to manufacture, package, label, store, test and distribute all pre-clinical development and clinical supplies of our drug candidates, and it plans to continue to do so for the foreseeable future, including for commercial supplies if the Company obtains regulatory approval to market any of its drug candidates. The Company also relies on third-party consultants to assist in managing these third-parties and assist with its manufacturing strategy.

Recent Accounting Pronouncements

In February 2016, the FASB issued Accounting Standards Update 2016-02 Topic 842, Leases (ASC 842), which will require lessees to recognize assets and liabilities for leases with lease terms of more than 12 months. Consistent with current GAAP, the recognition, measurement, and presentation of expenses and cash flows arising from a lease by a lessee primarily will depend on its classification as a finance or operating lease. However, unlike current GAAP,

which requires only capital leases to be recognized on the balance sheet, the new guidance will require both types of leases to be recognized on the balance sheet. ASC 842 is effective for annual periods beginning after December 15, 2018, and interim periods within those years. Early adoption is permitted for all entities. The standard requires that entities use a modified retrospective approach for leases that exist or are entered into after the beginning of the earliest comparative period in the financial statements. Entities have the option to use certain relief. Full retrospective application is prohibited. The FASB approved an amendment to ASC 842 in March 2018 permitting a company to use the effective date as the date of initial application on transition. Note 7, “Commitments and Contingencies” provides details

on the Company's current lease arrangements. The Company continues to evaluate the provisions of ASC 842 to determine the impact the adoption will have on its consolidated financial statements; however, the Company expects to use the new transition method which will result in the effective date being the date of initial application, which is expected to be January 1, 2019. The company anticipates recognition of additional assets and corresponding liabilities related to leases on its consolidated balance sheets. Additionally, the Company expects to derecognize its build-to-suit asset and liabilities upon adoption pending its final evaluation.

In December 2017, the SEC staff issued Staff Accounting Bulletin ("SAB") 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act (the "TCJA"), to provide guidance for companies that are not able to complete their accounting for the income tax effects of the Act in the period of enactment. In doing so, the SEC staff acknowledged the challenges companies may face in accounting for the effects of the Act by their financial reporting deadlines and said the guidance is intended to help companies provide investors with timely, decision-useful information. The TCJA was effective in the first quarter of 2018 and, among other things, lowered the Company's U.S. federal income tax rate from 34% to 21%. Accordingly, the Company recorded a provisional tax benefit of $0.4 million as of December 31, 2017 related to the remeasurement of its U.S. deferred tax assets to reflect the lower statutory tax rate. As of September 30, 2018, no adjustments have been made to the provisional net tax benefit reported as of the year ended December 31, 2017. As of September 30, 2018, the Company has not completed its accounting for the tax effects of the TCJA, and recorded a provisional net tax benefit based on the Company's best estimates. The provisional amounts incorporate assumptions made based upon the Company's current interpretation of the TCJA and are subject to revision as the Company receives and interprets any additional clarification and implementation guidance issued by the U.S. Treasury Department, Internal Revenue Service (the "IRS"), and other standard-setting bodies. Any adjustments to the provisional amounts recorded will be included as an adjustment to the provision for income taxes. Adjustments may materially impact the Company's provision for income taxes and effective tax rate in the period in which the adjustments are made. The Company anticipates its accounting for the tax effects of the TCJA will be completed in 2018.

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 consisted of $338.9 million and $319.7 million in money market funds included in cash and cash equivalents at September 30, 2018 and December 31, 2017, respectively.

4. Composition of Certain Balance Sheet Items

Property and Equipment, net

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

	September 30, 2018	December 31, 2017
Machinery and equipment	$9,137	$9,078
Leasehold improvements	822	579
Purchased computer software	1,350	1,316
Build-to-suit property	51,760	51,760
	63,069	62,733
Less: accumulated depreciation and amortization	(10,118)	(7,743)
Property and equipment, net	$52,951	$54,990

Depreciation expense was $0.8 million and $2.4 million for the three and nine months ended September 30, 2018, respectively, compared to $0.8 million and $2.3 million for the three and nine months ended September 30, 2017, respectively.

Other Current Liabilities

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

	September 30, 2018	December 31, 2017
Payroll and related expenses	$ 4,016	$ 7,342
Professional services	833	438
Deferred rent	49	49
Other	526	1,356
Other current liabilities	$ 5,424	$ 9,185

5. Net 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 and nine months ended September 30, 2018 and 2017, and therefore diluted net loss per share is equal to basic net loss per share.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Numerator:				
Net loss	$(24,559)	$(52,394)	$(133,184)	$(105,479)
Denominator:				
Weighted-average ordinary shares outstanding	39,850	38,292	39,457	37,384
Net loss per share:				
Basic and diluted net loss per share	$(0.62)	$(1.37)	$(3.38)	$(2.82)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Stock options to purchase ordinary shares	7,253	4,387	7,253	4,387

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6. Build-to-Suit Lease

In March 2016, the Company entered into a noncancelable operating sublease (the “Lease”) to lease 128,751 square feet of office and laboratory space in South San Francisco, California (the “Current SSF Facility”). Subsequently, in April 2016, the Company took possession of the Current SSF Facility. The Lease includes a free rent period and escalating rent payments and has a term that expires on December 31, 2023, unless terminated earlier. The Company's obligation to pay rent commenced on August 1, 2016. The Company is obligated to make lease payments totaling approximately $39.2 million over the lease term. The Lease further provides that the Company is obligated to pay to the sublandlord and master landlord certain costs, including taxes and operating expenses. Expected future lease payments under the build-to-suit lease as of September 30, 2018 are included in Note 7, “Commitments and Contingencies.”

In connection with this Lease, the Company received a tenant improvement allowance of $14.2 million from the sublandlord and the master landlord, for the costs associated with the design, development and construction of tenant improvements for the Current SSF Facility. The Company is obligated to fund all costs incurred in excess of the tenant improvement allowance. The scope of the tenant improvements did not qualify as “normal tenant improvements” under the lease accounting guidance. Accordingly, for accounting purposes, the Company is the deemed owner of the building during the construction period and the Company capitalized $36.5 million within property and equipment, net, including $1.2 million for capitalized interest and recognized a corresponding build-to-suit obligation in other non-current liabilities in the Condensed Consolidated Balance Sheets as of September 30, 2018. The Company has also recognized structural and non-structural tenant improvements totaling $15.5 million as of September 30, 2018 as an addition to the build-to-suit lease property for amounts incurred by the Company during the construction period, of which $14.2 million were reimbursed by the landlord during the year ended December 31, 2016 through the tenant improvement allowance. The Company increased its financing obligation for the additional building costs reimbursements received from the landlord during the construction period. In addition, for the three and nine months ended September 30, 2018 the Company recorded rent expense associated with the ground lease of $0.1 million and $0.4 million, respectively, in its Condensed Consolidated Statements of Operations. Total interest, which represents the cost of financing obligation under the Lease agreement, was $0.9 million and $2.8 million for the three and nine months ended September 30, 2018 , respectively, which was recognized within the Condensed Consolidated Statement of Operations.

During the fourth quarter of 2016, construction on the build-to-suit lease property was substantially completed and the build-to-suit lease property was placed in service. As such, the Company evaluated the Lease to determine whether it had met the requirements for sale-leaseback accounting, including evaluating whether all risks of ownership have been transferred back to the landlord, as evidenced by a lack of continuing involvement in the build-to-suit lease property. The Company determined that the construction project did not qualify for sale-leaseback accounting and will instead be accounted for as a financing lease, given the Company’s expected continuing involvement after the conclusion of the construction period. The build-to-suit lease property remains on the Company’s Consolidated Balance Sheets as of September 30, 2018 at its historical cost of $52.0 million and is being depreciated over its estimated useful life. As of September 30, 2018, the total amount of the build-to-suit lease obligation was $51.9 million, of which $1.6 million and $50.3 million were classified as current and non-current liability, respectively, on the Company's Condensed Consolidated Balance Sheets. The Company expects to derecognize the build-to-suit lease property and financing lease obligation at the end of the lease term.

The Company obtained a standby letter of credit in April 2016 in the initial amount of $4.1 million, which may be drawn down by the sublandlord in the event the Company fails to fully and faithfully perform all of its obligations under the Lease and to compensate the sublandlord for all losses and damages the sublandlord may suffer as a result of the occurrence of any default on the part of Company not cured within the applicable cure period. This standby letter of credit is collateralized by a certificate of deposit of the same amount which is classified as restricted cash. As of September 30, 2018, none of the standby letter of credit amount has been used.

7. Commitments and Contingencies

Lease Commitments

The Company recognizes rent expense for its operating leases on a straight-line basis over the noncancelable lease term and records the difference between cash rent payments and the recognition of rent expense as a deferred rent liability. Where leases contain escalation clauses, rent abatements and/or concessions, such as rent holidays and landlord or tenant incentives or allowances, the Company applies them in the determination of straight-line rent expense over the lease term. The Company records the tenant improvement allowance for operating leases as deferred rent and associated expenditures as leasehold improvements that are being amortized over the shorter of their estimated useful life or the term of the lease. Rent expense was $0.2 million and $0.6 million

for the three and nine months ended September 30, 2018, respectively, and $0.2 million and $0.7 million for the three and nine months ended September 30, 2017, respectively.

Dublin

In August 2015, the Company entered into an agreement to lease 6,258 square feet of office space in Dún Laoghaire, Ireland. 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, the Company is obligated to make lease payments totaling approximately €2.0 million, or $2.3 million as converted using an exchange rate as of September 30, 2018, over the term of the lease, assuming current lease payments. Of this obligation, approximately $1.7 million remains outstanding as of September 30, 2018.

In September 2018, the Company entered into an agreement to lease an office space in Dublin, Ireland. The lease term expires on November 30, 2019. As of September 30, 2018, the Company is obligated to make lease payments over the term of the lease of approximately €22,000, or $26,000 as converted using an exchange rate as of September 30, 2018.

Future minimum payments under the above-described noncancelable operating leases as of September 30, 2018 are as follows (in thousands):

Year Ended December 31,	Operating Lease
2018 (3 months)	$ 62
2019	264
2020	240
2021	240
2022	240
Thereafter	640
Total	$ 1,686

Current SSF Facility

In March 2016, the Company entered into a noncancelable operating sublease (the "Lease") of the Current SSF Facility which expires in December 31, 2023. The Company is considered the “accounting owner” of the Current SSF Facility as a build-to-suit property and has recorded a build-to-suit lease obligation on its consolidated balance sheet. Additional information regarding the build-to-suit lease is included in Note 6, “Build-To-Suit Lease.”

Sub-Sublease of Current SSF Facility

On July 18, 2018, the Company, through its wholly owned subsidiary Prothena Biosciences Inc, entered into a Sub-Sublease Agreement (the “Sub-Sublease”) with Assembly Biosciences, Inc. (the “Sub-Subtenant”) for Sub-Subtenant to sub-sublease from the Company approximately 46,641 square feet of office and laboratory space of the Company's Current SSF Facility.

The Sub-Sublease provides for initial annual base rent for the complete Sub-Subleased Premises of approximately $2.7 million, with increases of approximately 3.5% in annual base rent on September 1, 2019 and each anniversary thereof.

The Sub-Sublease became effective on September 24, 2018 and has a term of 5.2 years which terminates on December 15, 2023. The Sub-Sublease will terminate if the Master Lease or the Sublease terminates. The Company or the Sub-Subtenant may elect, subject to limitations set forth in the Sub-Sublease, to terminate the Sub-Sublease following a material casualty or condemnation affecting the Subleased Premises. The Company may terminate the Sub-Sublease following an event of default, which is defined in the Sub-Sublease to include, among other things,

non-payment of amounts owing by the Sub-Subtenant under the Sub-Sublease.

The Company is required under the Lease to pay to the sublandlord 50% of that portion of the cash sums and other economic consideration received from the Sub-Subtenant that exceeds the base rent paid by the Company to the sublandlord after deducting certain of the Company's costs.

Future minimum payments under build-to-suit lease obligation and future minimum rentals to be received under the Sub-Sublease as of September 30, 2018 are as follows (in thousands):

Year Ended December 31,	Expected Cash Payments Under Build-To-Suit Lease Obligation	Sub-Sublease Rental
2018 (3 months)	$ 1,433	$ 647
2019	5,803	2,746
2020	5,979	2,843
2021	6,165	2,944
2022	6,350	3,047
Thereafter	6,535	3,014
Total	$ 32,265	$ 15,241

Indemnity Obligations

The Company has entered into indemnification agreements with its current and former directors and officers and certain key employees. These agreements contain provisions that may require the Company, among other things, to indemnify such persons against certain liabilities that may arise because of their status or service and advance their expenses incurred as a result of any indemnifiable proceedings brought against them. The obligations of the Company pursuant to the indemnification agreements continue during such time as the indemnified person serves the Company and continues thereafter until such time as a claim can be brought. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited; however, the Company has a director and officer liability insurance policy that limits its exposure and enables the Company to recover a portion of any future amounts paid. As a result of its insurance policy coverage, the Company believes the estimated fair value of these indemnification agreements is minimal. Accordingly, the Company had no liabilities recorded for these agreements as of September 30, 2018 and December 31, 2017.

Other Commitments

In April 2018, the Company decided to discontinue all development of NEOD001. The commitments table below includes the obligations under the Company’s restructuring plan following the discontinuation of the NEOD001 program.

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, 2018, the Company had non-cancelable purchase commitments to suppliers for $1.6 million of which $0.6 million is included in accrued current liabilities, and contractual obligations under license agreements of $1.3 million of which $0.3 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, 2018 (in thousands):

	Total	2018	2019	2020	2021	2022	Thereafter
Purchase Obligations	$1,577	$1,577	$—	$ —	$ —	$ —	$ —
Contractual obligations under license agreements [1]	1,325	295	185	85	85	70	605
Obligations under restructuring plan	4,469	3,351	1,118	—	—	—	—
Total	$7,371	$5,223	$1,303	$ 85	$ 85	$ 70	$ 605

[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.

Legal Proceedings

On May 17, 2018, a purported class action lawsuit entitled Arkansas Teacher Retirement System v. Prothena Corporation plc, et al., Civil Action No. 18-cv-2865-WHA, was filed in the U.S. District Court for the Northern District of California against the Company and certain of its current and former officers; the plaintiff voluntarily dismissed that case on July 10, 2018. On July 5, 2018, another purported class action lawsuit, entitled Michael

Ramezani v. Prothena Corporation plc, et al., Civil Action No. 3:18-cv-04035-WHA, was filed in the same court against the same parties; the plaintiff voluntarily dismissed that case on July 13, 2018. On July 16, 2018, an additional purported class action lawsuit, entitled Simon James v. Prothena Corporation plc, et al., Civil Action No. 18-cv-04261-JST, was filed in the same court against the same parties; the plaintiff voluntarily dismissed that case on August 7, 2018. On July 16, 2018, another purported class action lawsuit, entitled Granite Point Capital v. Prothena Corporation plc, et al., Civil Action No. 18-cv-06425, was filed against the same parties, but in the U.S. District Court for the Southern District of New York. The plaintiff in this case, as in the previously-filed cases, seeks compensatory damages, costs and

expenses in an unspecified amount on behalf of a putative class of persons who purchased the Company's ordinary shares between October 15, 2015 and April 20, 2018, inclusive. The complaint alleges that the defendants violated federal securities laws by allegedly making false and misleading statements and omitting certain material facts in certain public statements and in the Company's filings with the U.S. Securities and Exchange Commission during the putative class period, regarding the clinical trial results and prospects for approval of the Company's NEOD001 drug development program. On September 17, 2018, the plaintiff in the Granite Point Capital lawsuit, together with the plaintiff in the previously-dismissed Simon James lawsuit, filed a motion with the court in the Granite Point Capital lawsuit seeking to be appointed as the lead plaintiffs in that purported class action. That motion was granted on October 31, 2018, and that proceeding is now entitled In re Prothena Corporation plc Securities Litigation. Because the Company is in the early stages of this proceeding, the Company is not able to estimate a reasonably possible loss or range of loss, if any, that could result from the proceeding.

8. Significant Agreements

Roche License Agreement

In December 2013, the Company through its wholly owned subsidiary Prothena Biosciences Limited and Prothena Biosciences Inc entered into a License, Development, and Commercialization Agreement (the "License Agreement") with F. Hoffmann-La Roche Ltd. and Hoffmann-La Roche Inc. (together, "Roche") to develop and commercialize certain antibodies that target -synuclein, including PRX002/RG7935, which are referred to collectively as "Licensed Products." Upon the effectiveness of the License Agreement in January 2014, the Company granted to Roche an exclusive, worldwide license to develop, make, have made, use, sell, offer to sell, import and export the Licensed Products. The Company retained certain rights to conduct development of the Licensed Products and an option to co-promote PRX002/RG7935 in the U.S. During the term of the License Agreement, the Company and Roche will work exclusively with each other to research and develop antibody products targeting alpha-synuclein (or -synuclein) potentially including incorporation of Roche's proprietary Brain Shuttle™ technology to potentially increase delivery of therapeutic antibodies to the brain. The License Agreement provided for Roche making an upfront payment to the Company of $30.0 million, which was received in February 2014; making a clinical milestone payment of $15.0 million upon initiation of the Phase 1 study for PRX002/RG7935, which was received in May 2014; and making a clinical milestone payment of $30.0 million upon dosing of the first patient in the Phase 2 study for PRX002/RG7935, which was achieved in June 2017.

For PRX002/RG7935, Roche is also obligated to pay:

- up to $350.0 million upon the achievement of development, regulatory and various first commercial sales milestones;
- up to an additional $175.0 million upon achievement of ex-U.S. commercial sales milestones; and
- tiered, high single-digit to high double-digit royalties in the teens on ex-U.S. annual net sales, subject to certain adjustments.

Roche bears 100% of the cost of conducting the research activities under the License Agreement. In the U.S., the parties share all development and commercialization costs, as well as profits, all of which will be allocated 70% to Roche and 30% to the Company, for PRX002/RG7935 in the Parkinson's disease indication, as well as any other Licensed Products and/or indications for which the Company opts in to participate in co-development and co-funding. After the completion of specific clinical trial activities, the Company may opt out of the co-development and cost and profit sharing on any co-developed Licensed Products and instead receive U.S. commercial sales milestones totaling up to $155.0 million and tiered, single-digit to high double-digit royalties in the teens based on U.S. annual net sales, subject to certain adjustments, with respect to the applicable Licensed Product.

The Company filed an Investigational New Drug Application ("IND") with the FDA for PRX002/RG7935 and subsequently initiated a Phase 1 study in 2014. Following the Phase 1 study, Roche became primarily responsible for developing, obtaining and maintaining regulatory approval for and commercializing Licensed Products. Roche also became responsible for the clinical and commercial manufacture and supply of Licensed Products.

In addition, the Company has an option under the License Agreement to co-promote PRX002/RG7935 in the U.S. in the Parkinson's disease indication. If the Company exercises such option, it may also elect to co-promote additional Licensed Products in the U.S. approved for Parkinson's disease. Outside the U.S., Roche will have responsibility for developing and commercializing the Licensed Products. Roche bears all costs that are specifically related to obtaining

or maintaining regulatory approval outside the U.S. and will pay the Company a variable royalty based on annual net sales of the Licensed Products outside the U.S.

While Roche will record product revenue from sales of the Licensed Products, the Company and Roche will share in the net profits and losses of sales of the PRX002/RG7935 for the Parkinson's disease indication in the U.S. on a 70%/30% basis with the Company receiving 30% of the profit and losses provided that the Company has not exercised its opt-out right.

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

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

Collaboration Accounting

The License Agreement was evaluated under ASC 808, Collaborative Agreements. At the outset of the License Agreement, the Company concluded that it did not qualify as collaboration under ASC 808 because the Company does not share significant risks due to the net profit and loss split (under which Roche incurs substantially more of the costs of the collaboration) and because of the Company's opt-out provision. The Company believes that Roche will be the principal in future sales transactions with third parties as Roche will be the primary obligor bearing inventory and credit risk. The Company will record its share of pre-tax commercial profit generated from the collaboration as collaboration revenue once the Company can conclude it is probable that a significant revenue reversal will not occur in future periods. Prior to commercialization of a Licensed Product, the Company's portion of the expenses related to the License Agreement reflected on its income statement will be limited to R&D expenses. After commercialization, if the Company opts-in to co-detail commercialization, expenses related to commercial capabilities, including expenses related to the establishment of a field sales force and other activities to support the Company's commercialization efforts, will be recorded as sales, general and administrative ("SG&A") expense and will be factored into the computation of the profit and loss share. The Company will record the receivable related to commercialization activities as collaboration revenue once the Company can conclude it is probable that a significant revenue reversal will not occur in future periods.

Adoption of ASC 606, Revenue from Contracts with Customers

The Company adopted ASC 606, Revenue from Contracts with Customers, as of January 1, 2018 using the modified retrospective transition method. The Company recognized the cumulative effect of applying the new revenue standard as an adjustment to the opening balance of the accumulated deficit as of January 1, 2018. Prior period amounts are not adjusted and continue to be reported in accordance with the Company's historical accounting under ASC 605, Revenue Recognition.

As of January 1, 2018, the Company did not record any changes to the opening balance of the accumulated deficit since the cumulative effect of applying the new revenue standard was the same as applying ASC 605. The impact of the adoption of ASC 606 to revenues for the three and nine months ended September 30, 2018 was an increase of $0.3 million and $0.8 million, respectively, both of which represent the revenue recognized for the development services provided by the Company during the period that is reimbursable by Roche. Historically, the Company recorded such reimbursement as an offset against its R&D expenses under ASC 605. Upon the adoption of ASC 606, the reimbursement for development services is now included as part of the Company's collaboration revenue.

Performance Obligations

The License Agreement was evaluated under ASC 606. The License Agreement includes the following distinct performance obligations: (1) the Company's grant of an exclusive royalty bearing license, with the right to sublicense to develop and commercialize certain antibodies that target -synuclein, including PRX002/RG7935, and the initial know how transfer which was delivered at the effective date (the "Royalty Bearing License"); (2) the Company's obligation to supply clinical material as

requested by Roche for a period up to twelve months (the "Clinical Product Supply Obligation"); (3) the Company's obligation to provide manufacturing related services to Roche for a period up to twelve months (the "Supply Services Obligation"); (4) the Company's obligation to prepare and file the IND (the "IND Obligation"); and (5) the Company's obligation to provide development activities under the development plan during Phase 1 clinical trials (the "Development Services Obligation"). Revenue allocated to the above performance obligations under the License Agreement are recognized when the Company has satisfied its obligations either at a point in time or over a period of time.

The Company concluded that the Royalty Bearing License and the Clinical Product Supply Obligation were satisfied at a point in time. The Royalty Bearing License is considered to be a functional intellectual property, in which the revenue would be recognized at the point in time since (a) the Company concluded that the license to Roche has a significant stand-alone functionality, (b) the Company does not expect the functionality of the intellectual property to be substantially changed during the license period as a result of activities of Prothena, and (c) Prothena's activities transfer a good or service to Roche. The Clinical Product Supply Obligation does not meet criteria for over time recognition; as such, the revenue related to such performance obligation was recognized the point in time at which Roche obtained control of manufactured supplies, which occurred during the first quarter of 2014.

The Company concluded that the Supply Services Obligation, the IND Obligation and the Development Services Obligation were satisfied over time. The Company utilized an input method measure of progress by basing the recognition period on the efforts or inputs towards satisfying the performance obligation (i.e. costs incurred and the time elapsed to complete the related performance obligations). The Company determined that such input method provides an appropriate measure of progress toward compete satisfaction of such performance obligations.

As of September 30, 2018 and December 31, 2017, there were no remaining performance obligations under License Agreement since the obligations related to research and development activities were only for the Phase 1 clinical trial and the remaining obligations were delivered or performed.

Transaction Price

According to ASC 606-10-32-2, the transaction price is the amount of consideration to which an entity expects to be entitled in exchange for transferring promised goods or services to a customer, excluding amounts collected on behalf of third parties (for example, some sales taxes). The consideration promised in a contract with a customer may include fixed amounts, variable amounts, or both. Factors considered in the determination of the transaction price include, among other things, estimated selling price of the license and costs for clinical supply and development costs.

The initial transaction price under the License Agreement, pursuant to ASC 606, was $55.1 million, including $45.0 million for the Royalty Bearing License, $9.1 million for the IND and Development Services Obligations, and $1.1 million for the Supply Services Obligation. The $45.0 million for the Royalty Bearing License included the upfront payment of $30.0 million and the clinical milestone payment of $15.0 million upon initiation of the Phase 1 clinical trial of PRX002/RG7935, both of which were made in 2014. The remaining transaction price amounts the Company expected to receive as reimbursements were based on costs expected to be paid to third parties and other costs to be incurred by the Company in order to satisfy its performance obligations. They are considered to be variable considerations not subject to constraint. The Company did not incur any incremental costs, such as commissions, to obtain or fulfill the License Agreement.
Under ASC 606, the transaction price was allocated to the performance obligations as follows: $48.9 million to the Royalty Bearing License; $4.6 million to the IND and Development Services Obligations; $1.1 million to the Clinical Product Supply Obligation; and $0.6 million to the Supply Services Obligation. As of September 30, 2018, the aggregate amount of the transaction price allocated to the performance obligations that are unsatisfied is $nil. Prior to the adoption of ASC 606, the transaction price was allocated to the deliverables as follows: $35.6 million to the

Royalty Bearing License; $3.3 million to the IND and Development Services Obligations; $0.8 million to the Clinical Product Supply Obligation; and $0.4 million to the Supply Services Obligation.

The Company allocated the initial transaction price to the Royalty Bearing License and other performance obligations using the relative selling price method based on its best estimate of selling price for the Royalty Bearing License and third party evidence for the remaining performance obligations. The best estimate of selling price for the Royalty Bearing License was based on a discounted cash flow model. The key assumptions used in the discounted cash flow model used to determine the best estimate of selling price for the Royalty Bearing License included the market opportunity for commercialization of PRX002/RG7935 in the U.S. and the royalty territory (for licensed products that are jointly funded the royalty territory is worldwide except for the U.S., and for all licensed products that are not jointly funded the Royalty Territory is worldwide), the probability of successfully developing and commercializing PRX002/RG7935, the estimated remaining development costs for PRX002/RG7935, and the estimated time to commercialization of PRX002/RG7935. The Company concluded that a change in the assumptions used to

determine the best estimate of selling price ("BESP") of the license deliverable would not have a significant effect on the allocation of arrangement consideration.

The Company's discounted cash flow model included several market conditions and entity-specific inputs, including the likelihood that clinical trials for PRX002/RG7935 will be successful, the likelihood that regulatory approval will be obtained and the product commercialized, the appropriate discount rate, the market locations, size and potential market share of the product, the expected life of the product, and the competitive environment for the product. The market assumptions were generated using a patient-based forecasting approach, with key epidemiological, market penetration, dosing, compliance, length of treatment and pricing assumptions derived from primary and secondary market research, referenced from third-party sources.

Significant Payment Terms

Payments for development services are due within 45 days after receiving an invoice from the Company. Variable considerations related to clinical and regulatory milestone payments are constrained due to high likelihood of a revenue reversal. The payment term for all milestone payments are due within 45 days after the achievement of the relevant milestone and receipt by Roche of an invoice for such an amount from the Company.

According to ASC 606-10-32-17, a significant financing component does not exist if a substantial amount of the consideration promised by the customer is variable, and the amount or timing of that consideration varies on the basis of the occurrence or nonoccurrence of a future event that is not substantially within the control of the customer or the entity. Since a "substantial amount of the consideration" promised by Roche to the Company is variable (i.e., is in the form of either milestone payments or sales-based royalties) and the amount of such variable consideration varies based upon the occurrence or nonoccurrence of future events that are not within the control of either Roche or the Company (i.e., are largely subject to regulatory approval), the License Agreement does not have a significant financing component.

Optional Goods and Services

An option for additional goods or services exists when a customer has a present contractual right that allows it to choose the amount of additional distinct goods or services that are purchased. Prior to the customer's exercise of that right, the vendor is not presently obligated to provide those goods or services. ASC 606-10-25-18(j) requires recognition of an option as a distinct performance obligation when the option provides a customer with a material right.

In addition to the distinct performance obligations noted above, the Company was obligated to provide indeterminate research services for up to three years ending in 2017 at rates that were not significantly discounted and fully reimbursable by Roche (the "Research Services"). The amount for any such Research Services was not fixed and determinable and was not at a significant incremental discount. There were no refund rights, concessions or performance bonuses to consider.

The Company evaluated the obligation to perform Research Services under ASC 606-10-55-42 and 55-43 to determine whether it gave Roche a "material right". According to ASC 606-10-55-43, if a customer has the option to acquire an additional good or services at a price that would reflect the standalone selling price for that good or service, that option does not provide the customer with a material right even if the option can be exercised only by entering into a previous contract.

The Company concluded that Roche's option to have the Company perform Research Services did not represent a "material right" to Roche that it would not have received without entering into the License Agreement. As a result, Roche's option to acquire additional Research Services was not considered a performance obligation at the outset of the License Agreement under ASC 606. Accordingly, this deliverable will become new performance obligation for Prothena when Roche asks Prothena to conduct such Research Services. As of September 30, 2018, there were no remaining Research Services performance obligations. Prior to the adoption of ASC 606, the Company recognized Research Services as collaboration revenue as earned.

Post Contract Deliverables

Any development services provided by the Company after performance of the Development Service Obligation are not considered a contractual performance obligation under the License Agreement, since the License Agreement does not require the Company to provide any development services after completion of the Development Service Obligation. However, the collaboration's Joint Steering Committee approved continued funding for additional development services to be provided by the Company (the "Additional Development Services"). Under the License Agreement and upon the adoption of ASC 606, the Company recognizes the reimbursements for Additional Development Services as collaboration revenue as earned.

Revenue and Expense Recognition

The Company recognized $0.3 million and $0.8 million as collaboration revenue for the three and nine months ended September 30, 2018 for Additional Development Services and $nil for Research Services, as compared to $0.2 million and $0.7 million of Research Services as collaboration revenue for the three and nine months ended September 30, 2017, respectively. The Company recorded $0.3 million and $1.4 million of reimbursement for Additional Development Services from Roche for the three and nine months ended September 30, 2017, respectively, as offset to R&D expenses. Cost sharing payments to Roche are recorded as R&D expenses. The Company recognized $3.1 million and $9.5 million in R&D expenses for payments made to Roche during the three and nine months ended September 30, 2018, as compared to $1.6 million and $5.7 million for the three and nine months ended September 30, 2017, respectively.

Milestone Accounting

Under the License Agreement, only if the U.S. and or global options are exercised, the Company is eligible to receive milestone payments upon the achievement of development, regulatory and various first commercial sales milestones. Milestone payments are evaluated under ASC Topic 606. 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 estimates payments in the transaction price based on the most likely approach, which considers the single most likely amount in a range of possible amounts related to the achievement of these milestones. Additionally, milestone payments are included in the transaction price only when the Company can conclude it is probable that a significant revenue reversal will not occur in future periods when the milestone is achieved.

The Company excludes the milestone payments and royalties in the initial transaction price calculation because such payments are considered to be variable considerations with constraint. Such milestone payments and royalties will be recognized as revenue once the Company can conclude it is probable that a significant revenue reversal will not occur in future periods.

The clinical and regulatory milestones under the License Agreement after the point at which the Company could opt-out are considered to be variable considerations with constraint due to the fact that active participation in the development activities that generate the milestones is not required under the License Agreement, and the Company can opt-out of these activities. There are no refunds or claw-back provisions and the milestones are uncertain of occurrence even after the Company has opted out. Based on this determination, these milestones will be recognized when the Company can conclude it is probable that a significant revenue reversal will not occur in future periods.

In June 2017, the Company achieved a $30.0 million clinical milestone under the License Agreement as a result of dosing of first patient in Phase 2 study for PRX002. The milestone was accounted for under ASC 605 and was allocated to the units of accounting based on the relative selling price method for income statement classification purposes. As such, the Company recognized $26.6 million of the $30.0 million milestone as collaboration revenue and $3.4 million as an offset to R&D expenses during the nine months ended September 30, 2017. The Company did not achieve any clinical and regulatory milestones under the License Agreement during the three and nine months ended September 30, 2018.

Celgene Collaboration Agreement

Overview

On March 20, 2018, the Company, through its wholly owned subsidiary, Prothena Biosciences Limited, entered into a Master Collaboration Agreement (the “Collaboration Agreement”) with Celgene Switzerland LLC (“Celgene”), a subsidiary of Celgene Corporation, pursuant to which Prothena granted to Celgene a right to elect in its sole discretion to exclusively license rights both in the U.S. (the “US Rights”) and on a global basis (the “Global Rights”), with respect to the Company’s programs to develop and commercialize antibodies targeting Tau, TDP-43 and an undisclosed target (the “Collaboration Targets”). For each such program, Celgene has an exclusive right to license clinical candidates in the U.S. at the IND filing and if exercised, would also have a right to expand the license to global rights at the completion of Phase 1. Following the exercise for global rights, Celgene would have decision making authority over all further global clinical development and commercialization. The Company is responsible for all research and development

activity through completion of Phase 1 clinical studies of products in each such program, unless Celgene elects otherwise at its cost.

The Collaboration Agreement provided for Celgene making an upfront payment to the Company of $100.0 million, which was received in April 2018, plus future potential license exercise payments and regulatory and commercial milestones for each program under the Collaboration Agreement, as well as royalties on net sales of any resulting marketed products. In connection with the Collaboration Agreement, the Company and Celgene entered into a Share Subscription Agreement on March 20, 2018, under which Celgene subscribed to 1,174,536 of the Company's ordinary shares for a price of $42.57 per share, for a total of approximately $50.0 million.

Celgene U.S. and Global Rights and Licenses

On a program-by-program basis, following the Company's filing of an IND application for any of the Company's three collaboration programs to Celgene, Celgene may elect in its sole discretion to exercise its US Rights to receive an exclusive license to develop and commercialize antibodies targeting the applicable Collaboration Target in the U.S. If Celgene exercises its US Rights for a collaboration program, it is obligated to pay the Company an exercise fee of approximately $80.0 million per program. Thereafter, following Phase 1, Celgene would have decision making authority over development activities, and all regulatory, manufacturing and commercialization activities, for antibody products targeting the relevant Collaboration Target (the "Collaboration Products") in the U.S.

On a program-by-program basis, following completion of a Phase 1 clinical trial for a collaboration program for which Celgene has previously exercised its US Rights, Celgene may elect in its sole discretion to exercise its Global Rights with respect to such collaboration program to receive a worldwide, exclusive license to develop and commercialize antibodies targeting the applicable Collaboration Target. If Celgene exercises its Global Rights, Celgene would be obligated to pay the Company an additional exercise fee of $55.0 million for such collaboration program. The Global Rights would then replace the US Rights for that collaboration program, and Celgene would have decision making authority over developing, obtaining and maintaining regulatory approval for, manufacturing and commercializing the Collaboration Products worldwide.

After Celgene's exercise of Global Rights for a collaboration program, the Company is eligible to receive up to $562.5 million in regulatory and commercial milestones per program. For obtaining either US Rights or Global Rights for such collaboration program by Celgene, the Company will also be eligible to receive tiered royalties on net sales of Collaboration Products ranging from high single digit to high teen percentages, on a weighted average basis depending on the achieving of certain net sales thresholds. Such exercise fees, milestones and royalty payments are subject to certain reductions as specified in the Collaboration Agreement, the agreement for US Rights and the agreement for Global Rights.

Celgene will continue to pay royalties on a Collaboration Product-by-Collaboration Product and country-by-country basis, until the latest of (i) expiration of certain patents covering the Collaboration Product, (ii) expiration of all regulatory exclusivity for the Collaboration Product, and (iii) an agreed period of time after the first commercial sale of the Collaboration Product in the applicable country (the "Royalty Term").

Term and Termination

The research term under the Collaboration Agreement continues for a period of six years, which Celgene may extend for up to two additional 12-month periods by paying an extension fee of $10.0 million per extension period. The term of the Collaboration Agreement continues until the last to occur of the following: (i) expiration of the research term; (ii) expiration of all US Rights terms; and (iii) expiration of all Global Rights terms.

The term of any US License or Global License would continue on a Licensed Product-by-Licensed Product and country-by-country basis until the expiration of all Royalty Terms under such agreement.

The Collaboration Agreement may be terminated (i) by either party on a program-by-program basis if the other party remains in material breach of the Collaboration Agreement following a cure period to remedy the material breach, (ii) by Celgene at will on a program-by-program basis or in its entirety, (iii) by either party, in its entirety, upon insolvency of the other party, or (iv) by Prothena, in its entirety, if Celgene challenges a patent licensed by Prothena to Celgene under the Collaboration Agreement.

Share Subscription Agreement

Pursuant to the terms of the Collaboration Agreement, the Company entered into a Share Subscription Agreement (the "SSA") with Celgene, pursuant to which the Company issued, and Celgene subscribed for, 1,174,536 of the Company's ordinary shares (the "Shares") for an aggregate subscription price of approximately $50.0 million, pursuant to the terms and conditions thereof.

Under the SSA, Celgene is subject to certain transfer and standstill restrictions, including a restriction on acquiring more than 9.9% of the Company's share capital for a specified period of time following the closing of the subscription

of the Shares, or earlier upon announcement of the intent to consummate a change of control of the Company by the Company or a third party, or expiration or termination of the Collaboration Agreement. In addition, Celgene will be entitled to request the registration of the Shares with the U.S. Securities and Exchange Commission on Form S-3ASR or Form S-3 following termination of the transfer restrictions if the Shares cannot be resold without restriction pursuant to Rule 144 promulgated under the U.S. Securities Act of 1933, as amended (the “Securities Act”).

Collaboration Accounting

The Collaboration Agreement was evaluated under ASC 808, Collaborative Agreements. At the outset of the Collaboration Agreement, the Company concluded that it does not qualify as collaboration under ASC 808 because the Company does not share significant risks due to economics of the collaboration.

Performance Obligations

The Collaboration Agreement was evaluated under ASC 606. Per ASC 606, a performance obligation is defined as a promise to transfer a good or service or a series of distinct goods or services. At inception of the Collaboration Agreement, the Company concluded that it does not have material distinct performance obligation as the Company is not obligated to transfer the US or Global license to Celgene unless Celgene exercises its US Right or Global Right, respectively, and the Company is not obligated to perform development activities under the development plan during preclinical and Phase 1 clinical trials including the regulatory filing of the IND. The discovery, preclinical and clinical development activities performed by the Company are to be performed at the Company's discretion and therefore are not considered distinct performance obligations under ASC 606. Per the terms of the Collaboration Agreement, the Company may conduct discovery activities to characterize, identify and generate antibodies to become collaboration candidates that target such Collaboration Target, and thereafter may pre-clinically develop collaboration candidates to identify lead candidates that target such Collaboration Target and file an IND with the U.S. Food and Drug Administration (the "FDA") for a Phase 1 clinical trial for such lead candidates. The Company is solely responsible for any and all costs and expenses in connection with the performance, in its discretion, of any program prior to the exercise of the Global Right for such program. The Company is not obligated to perform manufacturing activities. Per the terms of the Collaboration Agreement, to the extent that the Company, at its discretion, conducts a program, the Company shall be responsible for the manufacture of collaboration candidates and collaboration products for use in such program, as well as the associated costs. Delivery of manufactured compound (clinical product supply) is not deemed a performance obligation under ASC 606 as the Company is not obligated to transfer supply of collaboration product to Celgene unless Celgene exercises its right to participate in the Phase 1 development.

Transaction Price

According to ASC 606-10-32-2, the transaction price is the amount of consideration to which an entity expects to be entitled in exchange for transferring promised goods or services to a customer, excluding amounts collected on behalf of third parties (for example, some sales taxes). The consideration promised in a contract with a customer may include fixed amounts, variable amounts, or both. Factors considered in the determination of the transaction price included, among other things, estimated selling price of the license and costs for clinical supply and development costs.

The initial transaction price under the Collaboration Agreement, pursuant to ASC 606, was $110.2 million, including the $100.0 million upfront payment and $10.2 million premium on the ordinary shares purchased under the SSA.

The Company evaluated the potential obligations to transfer the U.S. and global licenses to Celgene under ASC 606-10-55-42 and 55-43 to determine whether it gave Celgene a "material right". According to ASC 606-10-55-43, if a customer has the option to acquire an additional good or services at a price that would reflect the standalone selling price for that good or service, that option does not provide the customer with a material right even if the option can be exercised only by entering into a previous contract. The Company concluded that Celgene's options to exercise its US Rights or Global Rights did not represent a "material right" to Celgene that it would not have received without entering into the Collaboration Agreement. As a result, the obligations to transfer the U.S. and Global licenses to Celgene were not considered performance obligations at the outset of the Collaboration Agreement under ASC 606.

In addition, the Company did not include the option fees in the initial transaction price because such fees are variable consideration that are contingent on the options to the US Rights and the Global Rights being exercised. Upon the exercise of the US Rights and the Global Rights, the Company will have the obligation to deliver the U.S. and global licenses, respectively. The Company will include the option fees in the transaction price at a point in time when the Company can conclude that it is probable that a significant revenue reversal will not occur. In addition, the Company did not include in the initial transaction price certain clinical and regulatory milestone payments since these variable considerations are constrained due to high likelihood of a revenue reversal.

At the inception of the Collaboration Agreement, the Company did not transfer any goods or services to Celgene. Accordingly, the Company has concluded that the initial transaction price will be recognized as contract liability and will be deferred until the Company transfers control of goods or services to Celgene (which would be when Celgene exercises the US Right and receives control of the US license for at least one of the programs) or at the termination of the Collaboration Agreement, whichever occurs

first. The total transaction price will be allocated to each of the Company's performance obligations on a relative standalone selling price basis at the point that Celgene receives the license for each program.

Significant Payment Terms

The upfront payment of $100.0 million was due within ten business days after the effective date of the Collaboration Agreement and was received in April 2018, while all option fees and milestone payments are due within 30 days after the achievement of the relevant milestone by Celgene or receipt by Celgene of an invoice for such an amount from the Company.

The Collaboration Agreement does not have a significant financing component since a substantial amount of consideration promised by Celgene to the Company is variable and the amount of such variable consideration varies based upon the occurrence or nonoccurrence of future events that are not within the control of either Celgene or the Company. Variable considerations related to clinical and regulatory milestone payments and option fees are constrained due to high likelihood of a revenue reversal.

Milestone and Royalties Accounting

Under the Collaboration Agreement, the Company is eligible to receive milestone payments upon the achievement of development, regulatory and various first commercial sales milestones. Milestone payments are evaluated under ASC Topic 606. 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 estimates payments in the transaction price based on the most likely approach, which considers the single most likely amount in a range of possible amounts related to the achievement of these milestones. Additionally, milestone payments are included in the transaction price only when the Company can conclude it is probable that a significant revenue reversal will not occur in future periods.

The Company excluded the milestone payments and royalties in the initial transaction price because such payments are considered to be variable considerations with constraint. Such milestone payments and royalties will be recognized as revenue at a point in time when the Company can conclude it is probable that a significant revenue reversal will not occur in future periods.

The Company did not achieve any clinical and regulatory milestones under the Collaboration Agreement during the three and nine months ended September 30, 2018.

9. Shareholders' Equity

Ordinary Shares

As of September 30, 2018, the Company had 100,000,000 ordinary shares authorized for issuance with a par value of $0.01 per ordinary share and 39,863,711 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, 2018, 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, 2018. 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.

March 2017 Offering

In March 2017, the Company completed an underwritten public offering of an aggregate of 2,700,000 of its ordinary shares at a public offering price of $57.50 per ordinary share. The Company received aggregate net proceeds of approximately $150.3 million, after deducting the underwriting discount and offering costs.

Celgene Share Subscription Agreement

In connection with the Celgene Collaboration Agreement, the Company entered into a Share Subscription Agreement (the "SSA") with Celgene, pursuant to which the Company issued, and Celgene subscribed for, 1,174,536 of the

Company’s ordinary shares (the “Shares”) for an aggregate subscription price of approximately $50.0 million, of which the fair value of $39.8 million was recorded in shareholders' equity and the premium of $10.2 million was recorded as deferred revenue from Celgene.

Under the SSA, Celgene is subject to certain transfer and standstill restrictions, including a restriction on acquiring more than 9.9% of the Company’s share capital for a specified period of time following the closing of the subscription of the Shares,

or earlier upon announcement of the intent to consummate a change of control of the Company by the Company or a third party, or expiration or termination of the Collaboration Agreement. In addition, Celgene will be entitled to request the registration of the Shares with the SEC on Form S-3ASR or Form S-3 following termination of the transfer restrictions if the Shares cannot be resold without restriction pursuant to Rule 144 promulgated under the Securities Act.

10. Share-Based Compensation

2018 Long Term Incentive Plan ("2018 LTIP")

In May 2018, the Company's shareholders approved the 2018 Long Term Incentive Plan (the "2018 LTIP"), which provides for the grant of ISOs, NQSOs, SARs, restricted shares, RSUs, performance bonus awards, performance share units awards, dividend equivalents and other share or cash-based awards to eligible individuals. Options under the 2018 LTIP may be granted for periods up to ten years. All options issued to date have had a ten year life. Under the 2018 LTIP, the number of ordinary shares authorized for issuance under the 2018 LTIP is equal to the sum of (a) 1,800,000 shares, (b) 1,177,933 shares that were available for issuance under the 2012 LTIP as of the May 15, 2018 effective date of the 2018 LTIP, and (c) any shares subject to issued and outstanding awards under the Amended and Restated Long Term Incentive Plan (the "2012 LTIP") that expire, are cancelled or otherwise terminate following the effective date of the 2018 LTIP; provided, that no more than 2,500,000 shares may be issued pursuant to the exercise of ISOs.

Amended and Restated 2012 Long Term Incentive Plan

Prior to the effective date of the 2018 LTIP, employees and consultants of the Company, its subsidiaries and affiliates, as well as members of the Company's Board of Directors, received equity awards under the 2012 LTIP. Options under the 2012 LTIP were granted for periods up to ten years. All options issued to date have had a ten year life.

Shares Available for Grant

The Company granted nil and 162,500 share options during the three months ended September 30, 2018 and 2017, respectively, and 4,046,300 and 1,447,300 share options during the nine months ended September 30, 2018 and 2017, respectively, in aggregate under the 2012 LTIP and the 2018 LTIP. The Company's option awards generally vest over four years. As of September 30, 2018, 1,009,486 ordinary shares remained available for grant under the 2018 LTIP, and options to purchase 7,252,600 ordinary shares, in aggregate under the 2012 LTIP and the 2018 LTIP were outstanding with a weighted-average exercise price of approximately $27.87 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 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. The Company uses its historical volatility for the Company's stock to estimate expected volatility starting January 1, 2018. Through December 31, 2017, 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 due to insufficient historical employee share option exercise data. Although the fair value of share options granted by the Company is estimated by the Black-Scholes model, the estimated fair value may not be indicative of the fair value observed in a willing buyer and seller market transaction.

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

Share-based compensation expense will continue to have an adverse impact on the Company's 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 2022 related to unvested share-based payment awards at September 30, 2018 is $75.2 million. The weighted-average period over which the unearned share-based compensation is expected to be recognized is 3.27 years. If there are any modifications or cancellations of the underlying unvested securities, the Company may be required to

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

Share-based compensation expense recorded in these Consolidated Financial Statements for the three and nine months ended September 30, 2018 and 2017 was based on awards granted under the 2012 LTIP and the 2018 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,	
	2018	2017	2018	2017
Research and development	$2,888	$2,820	$7,699	$7,863
General and administrative	4,154	4,282	12,554	11,494
Restructuring costs [1]	—	—	2,512	—
Total share-based compensation expense	$7,042	$7,102	$22,765	$19,357

(1) Restructuring costs for the three and nine months ended September 30, 2018 includes $nil and $2.5 million, respectively, of share-based compensation expense related to the contractual acceleration of vesting of certain stock options granted to executive officers.

For the three months ended September 30, 2018 and 2017, the Company recognized tax benefits from share-based awards of $1.3 million and $1.1 million, respectively, and $3.4 million and $3.0 million for the nine months ended September 30, 2018 and 2017, respectively.

The fair value of the options granted to employees and non-employee directors during the three months ended September 30, 2018 and 2017 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,	
	2018	2017	2018	2017
Expected volatility	—%	71.2%	79.4%	72.6%
Risk-free interest rate	—%	2.0%	2.8%	2.0%
Expected dividend yield	—%	—%	—%	—%
Expected life (in years)	—	6.0	6.0	6.0
Weighted average grant date fair value	$—	$38.06	$13.82	$35.63

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 stock option activity during the nine months ended September 30, 2018:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2017	4,406,752	$ 38.93	7.60	$ 30,455
Granted	4,046,300	20.39		
Exercised	(206,411)	22.70		
Canceled	(994,041)	47.51		
Outstanding at September 30, 2018	7,252,600	$ 27.87	7.46	$ 3,764

Vested and expected to vest at September 30, 2018	6,742,150	$ 28.23	7.36	$ 3,763
Vested at September 30, 2018	2,494,497	$ 32.33	5.47	$ 3,759

The total intrinsic value of options exercised was $0.3 million and $13.6 million during the three months ended September 30, 2018 and 2017, respectively, and $2.4 million and $39.5 million during the nine months ended September 30, 2018 and 2017, respectively, determined as of the date of exercise.

11. Restructuring

In May 2018, the Company commenced a reorganization plan to reduce its operating costs and better align its workforce with the needs of its business following the Company's April 23, 2018 announcement of its decision to discontinue further development of NEOD001.

The Company incurred aggregate restructuring charges of approximately $17.7 million for the nine months ended September 30, 2018. Restructuring charges incurred under this plan primarily consisted of employee termination benefits and and contract termination costs primarily associated with exit fees relating to third-party manufacturers that we contracted with for NEOD001 clinical and commercial supplies. Employee termination benefits include severance costs, employee-related benefits, supplemental one-time termination payments and non-cash share-based compensation expense related to the acceleration of stock options. Charges and other costs related to the workforce reduction and structure realignment are presented as restructuring costs in the Condensed Consolidated Statements of Operations. Substantially all of the cash payments are expected to be paid out by the end of the first quarter of 2019. The Company may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the restructuring.

The following table summarizes the restructuring liability and utilization by cost type associated with the restructuring activities during the three and nine months ended September 30, 2018 (in thousands):

	Restructuring Liability			
	Termination Benefits	Contract Termination Costs	Other[2]	Total
Balance at March 31, 2018	$—	$ —	$ —	$—
Restructuring charges	8,507	9,875	—	18,382
Non cash charges	2,512	—	—	2,512
Reductions for cash payments	(2,119)	(96)	—	(2,215)
Foreign Exchange	(5)	(278)	—	(283)
Balance at June 30, 2018	$8,895	$ 9,501	$ —	$18,396
Restructuring charges	502	5	705	1,212
Adjustments[1]	(36)	(4,348)	—	(4,384)
Reduction in non cash charges	(948)	—	—	(948)
Reductions for cash payments	(3,157)	(5,167)	(65)	(8,389)
Foreign Exchange	12	9	—	21
Balance at September 30, 2018	$5,268	$ —	$ 640	$5,908

[1] Adjustments include a $4.3 million reduction in contract termination costs resulting from renegotiation of a commercial supply agreement. On July 20, 2018, the Company entered into a Termination and Release Agreement to the Commercial Supply Contract (the "CSC") with Rentschler Biopharma SE. Under the Termination and Release Agreement, the Company agreed to pay €4.1 million in full and final settlement of any and all remaining payments owed by the Company under the CSC, including without limitation, any and all exit fees. This amount is a reduction of €3.7 million from the €7.8 million included in the restructuring liability as of June 30, 2018.

[2] Includes $0.7 million of costs incurred related to the sub-sublease of the Current SSF Facility as discussed in Note 7, "Commitments and Contingencies".

The total amount expected to be incurred in connection with the restructuring plan is $17.9 million. The cumulative amount incurred to date is $17.7 million as of September 30, 2018. As of September 30, 2018, the restructuring liability is included in current liabilities on the consolidated balance sheets.

12. Income Taxes

The major taxing jurisdictions for the Company are Ireland and the U.S. The Company recorded an income tax provision of $1.0 million and an income tax benefit of $1.0 million for the three and nine months ended September 30, 2018, respectively, as compared to an income tax benefit of $1.7 million and $4.7 million for the three and nine months ended September 30, 2017, respectively. The provision for income taxes differs from the statutory tax rate of 12.5% applicable to Ireland primarily due to Irish net operating losses for which a tax provision benefit is not recognized and U.S. income taxed at different rates. The income tax provision reflects the estimate of the effective tax rate expected to be applicable for the full year and the Company re-evaluates this estimate each quarter based on its forecasted tax expense for the full year. Jurisdictions with a projected loss for the year where no tax benefit can be recognized are excluded from the estimated annual effective tax rate.

The Company adopted ASU 2016-09 on January 1, 2017. Pursuant to the adoption of ASU 2016-09, tax attributes previously tracked off balance sheet have been recorded as deferred tax assets, offset by a valuation allowance. Further, excess benefits of stock compensation have been recorded as a benefit to the tax provision for all periods presented. For the three and nine months ended September 30, 2018, the Company recorded a net tax shortfall of $1.0 million and $1.3 million, respectively as compared to excess tax benefits of $2.0 million and $5.4 million, respectively, for the three and nine months ended September 30, 2017 all of which were recorded as part of its income tax provision in the Condensed Consolidated Statements of Operations. The Company’s income tax expense will continue to be impacted by fluctuations in stock price between the grant dates and the exercise dates of its option awards.

On December 22, 2017, the U.S. Tax Cuts and Jobs Act (the “TCJA”) was signed into law. It contains many significant changes to the U.S. income tax laws. The TCJA is effective in the first quarter of 2018 and, among other things, lowers the Company’s U.S. federal income tax rate from 34% to 21%. Accordingly, for the year ended December 31, 2017, the Company recorded a provisional tax benefit of $0.4 million related to the remeasurement of its U.S. deferred tax assets to reflect the lower statutory tax rate. As of September 30, 2018, no adjustments have been made to the provisional net tax benefit reported as of the year ended December 31, 2017.

As of September 30, 2018, the Company has not completed its accounting for the tax effects of the TCJA, but recorded a provisional net tax benefit based on the Company’s best estimates. The provisional amounts incorporate assumptions made based upon the Company’s current interpretation of the TCJA and are subject to revision as the Company receives and interprets any additional clarification and implementation guidance issued by the U.S. Treasury Department, IRS and other standard-setting bodies. Any adjustments to the provisional amounts recorded will be included as an adjustment to the provision for income taxes. Adjustments may materially impact the Company's provision for income taxes and effective tax rate in the period in which the adjustments are made. The Company anticipates its accounting for the tax effects of the TCJA will be completed in 2018.

The Company’s deferred tax assets are composed primarily of its Irish subsidiaries’ net operating loss carryovers, state net operating loss carryforwards available to reduce future taxable income of the Company’s U.S. subsidiary, federal and California research and development credit carryforward, shared-based compensation and other temporary differences. The Company maintains a valuation allowance against its Irish and certain U.S. federal and state deferred tax assets. Each reporting period, the Company evaluates the need for a valuation allowance on its deferred tax assets by jurisdiction.

No provision for income tax in Ireland has been recognized on undistributed earnings of the Company’s U.S. and Swiss subsidiaries. The Company considers the U.S. earnings to be indefinitely reinvested and is evaluating the Swiss undistributed earnings. The Company considers any potential tax associated with the distribution of Swiss earnings to be insignificant.

ITEM 2. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Quarterly Report on Form 10-Q, including this Management’s Discussion and Analysis of Financial Condition and Results of Operations, contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. These statements relate to, among other things, our objective to fundamentally

change the course of progressive, life-threatening diseases; our goal of advancing a pipeline of therapeutic candidates for a number of potential indications and novel targets; when we expect to have made substantially all cash payments under our restructuring plan; our expectation of continued impacts on our income tax expense from fluctuations in our stock price; the sufficiency of our cash and cash equivalents to meet our obligations; our anticipated need for additional capital; and our estimates of certain future contractual obligations. Forward-looking statements may include words such as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “due,” “estimate,” “expect,” “goa “objective” “plan,” “predict,” “potential,” “positioned,” “seek,” “should,” “target,” “will,” “would” and other similar expressio predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. Forward-looking statements are subject to risks and uncertainties, and actual events or results may differ materially. Factors that could cause our actual results to differ materially include, but are not limited to, the risks and uncertainties listed below as well as those discussed under Part II Item 1A - Risk Factors of this Form 10-Q:

- our ability to obtain additional financing in future offerings and/or obtain funding from future collaborations;

- our operating losses;
- our ability to successfully complete research and development of our drug candidates;
- our ability to develop, manufacture and commercialize products;
- our collaborations with third parties, including Roche and Celgene;
- our ability to protect our patents and other intellectual property;
- our ability to hire and retain key employees;
- tax treatment of our separation from Elan and subsequent distribution of our ordinary shares;
- 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;
- potential disruptions in the U.S. and global capital and credit markets;
- government regulation of our industry;
- the volatility of our ordinary share price;
- business disruptions; and
- the other risks and uncertainties described in Item 1A - Risk Factors of this Form 10-K.

We undertake no obligation to revise or update any forward-looking statements to reflect any event or circumstance that arises after the date of this report.

This discussion should be read in conjunction with the Condensed Consolidated Financial Statements and Notes presented in this Quarterly Report on Form 10-Q and the Consolidated Financial Statements and Notes contained in our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (the "SEC") on February 26, 2018 (the "2017 Form 10-K").

Overview

Prothena Corporation plc is a clinical-stage neuroscience company focused on the discovery and development of novel therapies with the potential to fundamentally change the course of progressive, life-threatening diseases. Fueled by a deep scientific understanding built over decades of neuroscience research, we are advancing a pipeline of therapeutic candidates for a number of indications and novel targets including Parkinson's disease and other related synucleinopathies (prasinezumab, or PRX002/RG7935) and ATTR amyloidosis (PRX004), as well as tau and A (Amyloid beta) for the potential treatment of Alzheimer's disease and other neurodegenerative disorders, and TDP-43 for the potential treatment of ALS (amyotrophic lateral sclerosis) and FTD (frontotemporal dementia).

We were formed on September 26, 2012 under the laws of Ireland and re-registered as an Irish public limited company on October 25, 2012. Our ordinary shares began trading on The Nasdaq Global Market under the symbol "PRTA" on December 21, 2012 and currently trade on The Nasdaq Global Select Market.

Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with the accounting principles generally accepted in the U.S. ("GAAP"). The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, revenues, expenses and related disclosures.

Except for the accounting policies for revenue recognition that was updated as a result of adopting ASC 606, there were no significant changes to our critical accounting policies and estimates during the three months ended September 30, 2018 from the critical accounting policies and estimates disclosed in Management's Discussion and Analysis of Financial Condition and Results of Operations in our 2017 Form 10-K.

Recent Accounting Pronouncements

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

pronouncements during the three months ended September 30, 2018 , as compared to the recent accounting pronouncements described in our 2017 Form 10-K, that are of significance or potential significance to us.

Results of Operations

Comparison of Three and Nine Months Ended September 30, 2018 and 2017

Revenue

	Three Months Ended September 30,		Percentage Change
	2018	2017	
	(Dollars in thousands)		
Collaboration revenue	$255	$219	16 %
Total revenue	$255	$219	16 %

	Nine Months Ended September 30,		Percentage Change
	2018	2017	
	(Dollars in thousands)		
Collaboration revenue	$761	$27,290	(97)%
Total revenue	$761	$27,290	(97)%

Total revenue was $0.3 million and $0.2 million for the three months ended September 30, 2018 and 2017, respectively, and $0.8 million and $27.3 million for the nine months ended September 30, 2018 and 2017, respectively.

Collaboration revenue includes reimbursements under our License Agreement with Roche. For the nine months ended September 30, 2017, collaboration revenue recognized also includes $26.6 million of a $30.0 million clinical milestone from Roche. See Note 8, “Significant Agreements” to the Condensed Consolidated Financial Statements regarding the Roche License Agreement for more information.

Operating Expenses

	Three Months Ended September 30,		Percentage Change
	2018	2017	
	(Dollars in thousands)		
Research and development	$18,515	$41,315	(55)%
General and administrative	9,235	12,438	(26)%
Restructuring costs	(3,172)	—	nm
Total operating expenses	$24,578	$53,753	(54)%

	Nine Months Ended September 30,		Percentage Change
	2018	2017	
	(Dollars in thousands)		
Research and development	84,673	$101,045	(16)%
General and administrative	34,456	34,182	1 %
Restructuring costs	17,732	—	nm
Total operating expenses	$136,861	$135,227	1 %

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nm = not meaningful

Total operating expenses consist of research and development (“R&D”) expenses, general and administrative (“G&A”) expenses and restructuring costs. Our operating expenses for the three and nine months ended September 30, 2018 were $24.6 million and $136.9 million, respectively, and for the three and nine months ended September 30, 2017 were $53.8 million and $135.2 million, respectively.

Our R&D expenses primarily consist of personnel costs and related expenses, including share-based compensation and external costs associated with nonclinical activities and drug development related to our drug programs, including NEOD001, PRX002/RG7935, PRX004 and our discovery programs. Pursuant to our License Agreement with Roche, we make payments to Roche for our share of the development expenses incurred by Roche related to PRX002/RG7935 program, which is included in our R&D expense. Prior to January 1, 2018, we recorded reimbursements from Roche for development as an offset to R&D expense.

Our G&A expenses primarily consist of professional service expenses and personnel costs and related expenses, including share-based compensation.

Research and Development Expenses

Our R&D expenses decreased by $22.8 million, or 55%, for the three months ended September 30, 2018, and decreased by $16.4 million, or 16%, for the nine months ended September 30, 2018, as compared to the same periods in the prior year. The decrease for the three and nine months ended September 30, 2018, compared to the same periods in the prior year, was primarily due to a decrease in external expenses related to product manufacturing and to a lesser extent lower clinical trial costs associated

primarily with the NEOD001 program and lower personnel costs, offset in part by higher expense associated with PRX002/RG7935.

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 costs and related expenses, external expenses associated with nonclinical and drug development and materials, equipment and facilities costs that are allocated to clearly related R&D activities.

The following table sets forth the R&D expenses for our major programs (specifically, any program with successful first dosing in a Phase 1 clinical trial, which were NEOD001, PRX002/RG7935, PRX003 and PRX004) and other R&D expenses for the three and nine months ended September 30, 2018 and 2017, and the cumulative amounts to date (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,		Cumulative to Date
	2018	2017	2018	2017	
NEOD001[1]	$8,069	$31,514	$53,413	$75,960	$ 305,621
PRX002/RG7935[2]	3,570	2,193	10,702	4,389	61,450
PRX003[3]	—	3,205	362	8,375	59,036
PRX004[4]	3,745	3,271	12,125	9,923	42,290
Other R&D[5]	3,131	1,132	8,071	2,398	
	$18,515	$41,315	$84,673	$101,045	

(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 the early discovery stage are not tracked by program and accordingly have been excluded from this cumulative amount. In April 2018, we announced that we were discontinuing development of NEOD001. Since that date we have incurred costs associated with the close out of our Phase 2b PRONTO, Phase 3 VITAL as well as the open label extension studies of NEOD001.

(2) Cumulative R&D costs to date for PRX002/RG7935 and related antibodies include the costs incurred from the date when the program was separately tracked in nonclinical development. Expenditures in the early discovery stage are not tracked by program and accordingly have been excluded from this cumulative amount. PRX002/RG7935 costs include payments to Roche for our share of the development expenses incurred by Roche related to PRX002/RG7935 programs and, through December 31, 2017, is net of reimbursements from Roche for development and supply services recorded as an offset to R&D expense. For the three and nine months ended September 30, 2018, $0.3 million and $0.8 million, respectively, of reimbursements from Roche for development services were recorded as part of collaboration revenue as a result of the adoption of new revenue standard. For the three and nine months ended September 30, 2017, $0.3 million and $4.8 million, respectively, were recorded as an offset to R&D expenses including $3.4 million (for a portion of the $30.0 million milestone received from Roche in the nine months ended September 30, 2017), as well as reimbursements from Roche for development services.

(3) Cumulative R&D costs to date for PRX003 include the costs incurred from the date when the program was separately tracked in nonclinical development. Expenditures in the early discovery stage are not tracked by program and accordingly have been excluded from this cumulative amount. Based on the Phase 1b multiple ascending dose study results announced in September 2017, we announced that we will not advance PRX003 into mid-stage clinical development for psoriasis or psoriatic arthritis as previously planned.

(4) Cumulative R&D costs to date for PRX004 include the costs incurred from the date when the program was separately tracked in nonclinical development. Expenditures in the early discovery stage are not tracked by program and accordingly have been excluded from this cumulative amount.

(5) Other R&D is comprised of preclinical development and discovery programs that have not progressed to first patient dosing in a Phase 1 clinical trial.

General and Administrative Expenses

Our G&A expenses decreased by $3.2 million, or 26%, for the three months ended September 30, 2018, and increased by $0.3 million, or 1%, for the nine months ended September 30, 2018, as compared to the same periods in the prior year. The decrease for the three months ended September 30, 2018, compared to the same period the prior year, was primarily due to lower personnel

costs (including share based compensation expense) and lower consulting expenses. The increase for the nine months ended September 30, 2018, compared to the same period in the prior year, was primarily due to a gain recognized from the assignment of an operating lease in 2017 with no corresponding amount in 2018, higher legal fees and to a lesser extent higher personnel costs (including share-based compensation expenses), offset in part by lower consulting expenses.

Restructuring Costs

In May 2018, we commenced a reorganization plan to reduce our operating costs and better align our workforce with the needs of our business following our decision in April 2018 to discontinue further development of NEOD001. On July 20, 2018, we entered into a Termination and Release Agreement to the Commercial Supply Contract (the "CSC") with Rentschler Biopharma SE. Under the Termination and Release Agreement, we agreed to pay €4.1 million in full and final settlement of any and all remaining payments owed by us under the CSC, including without limitation, any and all exit fees. This amount is a reduction of €3.7 million from the €7.8 million included in the restructuring liability as of June 30, 2018. We have incurred aggregate restructuring charges of approximately $17.7 million for the nine months ended September 30, 2018. Restructuring charges incurred under this plan primarily consist of employee termination benefit and contract termination costs. Employee termination benefits include severance costs, employee-related benefits, supplemental one-time termination payments and non-cash share-based compensation expense related to the acceleration of stock options. Substantially all of the cash payments are expected to be paid out by the end of the first quarter of 2019. We may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the workforce reduction. See Note 11, "Restructuring" to the Condensed Consolidated Financial Statements for more information.

Other Income (Expense)

	Three Months Ended September 30,		Percentage Change
	2018	2017	
	(Dollars in thousands)		
Interest income	$1,727	$1,047	65 %
Interest expense	(936)	(929)	1 %
Interest income, net	791	118	570 %
Other income (expense)	(65)	(683)	(90)%
Total other income (expense), net	$726	$(565)	(228)%

	Nine Months Ended September 30,		Percentage Change
	2018	2017	
	(Dollars in thousands)		
Interest income	$4,583	$2,531	81 %
Interest expense	(2,761)	(2,759)	— %
Interest income (expense), net	1,822	(228)	(899)%
Other income (expense)	73	(1,967)	(104)%
Total other income (expense), net	$1,895	$(2,195)	(186)%

Interest income (expense), net increased by $0.7 million, or 570%, for the three months ended September 30, 2018, and increased by $2.1 million, or 899%, for the nine months ended September 30, 2018, as compared to the same periods in the prior year. The increases for the three and nine months ended September 30, 2018, compared to the same periods in the prior year, were primarily due to higher interest income associated with higher balances in our

cash and money market accounts.

Other income (expense), net for the three and nine months ended September 30, 2018 and 2017 were primarily due to foreign exchange gain (losses) from transactions with vendors denominated in Euros.

Provision for (benefit from) Income Taxes

	Three Months Ended September 30,		Percentage Change
	2018	2017	
	(Dollars in thousands)		
Provision for (benefit from) income taxes	$962	$(1,705)	(156)%

	Nine Months Ended September 30,		Percentage Change
	2018	2017	
	(Dollars in thousands)		
Benefit from income taxes	$(1,021)	$(4,653)	(78)%

The provision for income taxes for the three months ended September 30, 2018 was $1.0 million and the benefit from income taxes for three months ended September 30, 2017 was $1.7 million. The tax benefits from income taxes for the nine months ended September 30, 2018 and 2017 were $1.0 million and $4.7 million, respectively. The benefit from income taxes decreased by $2.7 million for the three months ended September 30, 2018, and decreased by $3.6 million for the nine months ended September 30, 2018, as compared to the same periods in the prior year, primarily due to lower excess tax benefits in the three and nine months ended September 30, 2018.

For the three and nine months ended September 30, 2018, we recorded a net tax shortfall of $1.0 million and $1.3 million, respectively, as compared to excess tax benefits of $2.0 million and $5.4 million, respectively, for the three and nine months ended September 30, 2017, as part of our income tax provision related to the adoption of ASU 2016-09, Improvements to Employee Share-Based Payment Accounting. Our income tax expense will continue to be impacted by fluctuations in stock price between the grant dates and the exercise dates of stock options.

The tax provisions for all periods presented reflect U.S. federal taxes associated with recurring profits attributable to intercompany services that our U.S. subsidiary performs for the Company and also include Swiss taxes associated with intercompany services that our Swiss subsidiary performed for the Company. No tax benefit has been recorded related to tax losses recognized in Ireland and any deferred tax assets for those losses are offset by a valuation allowance.

On December 22, 2017, the U.S. Tax Cuts and Jobs Act (the “TCJA”) was signed into law in the U.S. The TCJA significantly changed existing U.S. tax law and includes numerous provisions that will affect our business going forward, including changes to the U.S. federal statutory tax rate, the repeal of alternative minimum tax, and additional limits on the deductibility of executive compensation, among other things. The TCJA reduced the U.S. federal statutory tax rate from 34% to 21% effective January 1, 2018. Accordingly, for the year ended December 31, 2017, we recorded a provision tax benefit of $0.4 million related to the remeasurement of our U.S. deferred tax assets to reflect the lower statutory tax rate. As of September 30, 2018, no adjustments have been made to the provisional net tax benefit reported as of the year ended December 31, 2017.

As of September 30, 2018, we have not completed our accounting for the tax effects of the TCJA, but recorded provisional net tax benefit based on our best estimates. The provisional amounts incorporate assumptions made based upon our current interpretation of the TCJA and are subject to revision as we receive and interpret any additional clarification and implementation guidance issued by the U.S. Treasury Department, Internal Revenue Service (the “IRS”) and other standard-setting bodies. Any adjustments to the provisional amounts recorded will be included as an adjustment to the provision for income taxes. Adjustments may materially impact our provision for income taxes and effective tax rate in the period in which the adjustments are made. We anticipate our accounting for the tax effects of the TCJA will be completed in 2018.

Liquidity and Capital Resources

Overview

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	September 30, 2018	December 31, 2017
Working capital	$433,281	$388,956
Cash and cash equivalents	451,512	417,620
Total assets	524,626	496,329
Total liabilities	184,976	89,140
Total shareholders' equity	339,650	407,189

Working capital was $433.3 million as of September 30, 2018, an increase of $44.3 million from working capital of $389.0 million as of December 31, 2017. This increase in working capital during the nine months ended September 30, 2018 was primarily due to a higher net cash and cash equivalents balance resulting from a $100.0 million upfront payment from the Celgene Collaboration Agreement and to a lesser extent from the proceeds of $50.0 million from our share subscription agreement with Celgene, which were partially offset by use of $136.9 million for operating expenses (adjusted to exclude non-cash charges).

As of September 30, 2018, we had $451.5 million in cash and cash equivalents. Although we believe, based on our current business plans, that our existing cash and cash equivalents will be sufficient to meet our obligations for at least the next twelve months, we anticipate that we will require additional capital in the future in order to continue the research and development of our drug candidates. As of September 30, 2018, $94.2 million of our outstanding cash and cash equivalents related to U.S. operations are considered permanently reinvested. We do not intend to repatriate these funds. However, if these funds were repatriated back to Ireland we would incur a withholding tax from the dividend distribution.

We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development of our product candidates. Our future capital requirements will depend on numerous factors, including, without limitation, the timing of initiation, progress, results and costs of our clinical trials; the results of our research and nonclinical studies; the costs of clinical manufacturing and of establishing commercial manufacturing arrangements; the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims; the costs and timing of capital asset purchases; our ability to establish research collaborations, strategic collaborations, licensing or other arrangements; the costs to satisfy our obligations under current and potential future collaborations; and the timing, receipt, and amount of revenues or royalties, if any, from any approved drug candidates. Pursuant to the License Agreement with Roche, in the U.S., we and Roche share all development and commercialization costs, as well as profits, all of which will be allocated 70% to Roche and 30% to us, for PRX002/RG7935 in the Parkinson's disease indication, as well as any other Licensed Products and/or indications for which we opt in to co-develop and co-fund. Pursuant to the Collaboration Agreement with Celgene the Company is eligible to receive payments for commercial and regulatory milestones and royalties on net sales of Collaboration Products payments. In order to develop and obtain regulatory approval for our potential products we will need to raise substantial additional funds. We expect to raise any such additional funds through public or private equity or debt financings, collaborative agreements with corporate partners or other arrangements. We cannot assume that such additional financings will be available on acceptable terms, if at all, and such financings may only be available on terms dilutive to our shareholders.

Cash Flows for the Nine Months Ended September 30, 2018 and 2017

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

	Nine Months Ended September 30,	
	2018	2017
Net cash used in operating activities	$(7,024)	$(91,659)

Net cash used in investing activities	(432)	(3,145)
Net cash provided by financing activities	41,348	163,942
Net increase in cash and cash equivalents and restricted cash	$33,892	$69,138

Cash Used in Operating Activities

Net cash used in operating activities was $7.0 million for the nine months ended September 30, 2018, was primarily due to $136.9 million for operating expenses (adjusted to exclude non-cash charges) and a decrease in account payables and accrued liabilities, which were partially offset by $110.2 million in deferred revenue related largely to the upfront payment from the Celgene Collaboration Agreement, reduction in prepaid and other assets and increase in restructuring liabilities.

Net cash used in operating activities was $91.7 million for the nine months ended September 30, 2017, primarily due to use of $135.2 million for operating expenses (adjusted to exclude non-cash charges), an increase in prepaid expenses and other current assets, which were partially offset by an increase in accounts payable and accrued liabilities.

Cash Used in Investing Activities

Net cash used in investing activities was $0.4 million and $3.1 million for the nine months ended September 30, 2018 and 2017, respectively. Net cash used in investing activities for the nine months ended September 30, 2018 and 2017 were primarily related to purchases of property and equipment.

Cash Provided by Financing Activities

Net cash provided by financing activities was $41.3 million for the nine months ended September 30, 2018, primarily from the $39.8 million proceeds from Celgene's subscription of ordinary shares at market value and, to a lesser extent, from the $4.7 million proceeds from issuances of ordinary shares upon exercises of stock options.

Net cash provided by financing activities was $163.9 million for the nine months ended September 30, 2017, primarily from the $150.3 million net proceeds from our March 2017 public offering and $15.4 million from issuances of ordinary shares upon exercises of stock options.

Off-Balance Sheet Arrangements

At September 30, 2018, we were not a party to any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources.

Contractual Obligations

Our contractual obligations as of September 30, 2018 consisted of minimum cash payments under a build-to-suit lease obligation of $32.3 million, operating leases of $1.7 million, purchase obligations of $1.6 million (of which $0.6 million is included in accrued current liabilities), obligations under our restructuring plan of $4.5 million and contractual obligations under license agreements of $1.3 million (of which $0.3 million is included in accrued current liabilities). Purchase obligations consist of non-cancelable purchase commitments to suppliers. Operating leases represent our future minimum rental commitments under our non-cancelable operating leases.

In August 2015, we entered into an agreement to lease 6,258 square feet of office space in Dún Laoghaire, Ireland. 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, we are obligated to make lease payments totaling approximately €2.0 million, or $2.3 million as converted using an exchange rate as of September 30, 2018, over the term of the lease, assuming current lease payments. Of this obligation, approximately $1.7 million remains outstanding as of September 30, 2018.

In March 2016, we entered into a noncancelable operating sublease to lease 128,751 square feet of office and laboratory space in South San Francisco, California. We are obligated to make lease payments totaling approximately $39.2 million over the lease term. Of this obligation, approximately $32.3 million remains outstanding as of September 30, 2018.

In September 2018, we entered into an agreement to lease an office space in Dublin, Ireland. The lease term expires on November 30, 2019. As of September 30, 2018, we are obligated to make lease payments over the term of the lease of approximately €22,000, or $26,000 as converted using an exchange rate as of September 30, 2018.

The following is a summary of our contractual obligations as of September 30, 2018 (in thousands):

	Total	2018	2019	2020	2021	2022	Thereafter
Operating leases [1]	$1,686	$62	$264	$240	$240	$240	$ 640
Minimum cash payments under build-to-suit lease obligation [1]	32,265	1,433	5,803	5,979	6,165	6,350	6,535
Purchase obligations	1,577	1,577	—	—	—	—	—
Obligations under restructuring plan	4,469	3,351	1,118	—	—	—	—
Contractual obligations under license agreements [2]	1,325	295	185	85	85	70	605
Total	$41,322	$6,718	$7,370	$6,304	$6,490	$6,660	$ 7,780

[1] See Note 7, “Commitments and Contingencies” to our Condensed Consolidated Financial Statements.
[2] Excludes future obligations pursuant to the cost-sharing arrangement under our License Agreement with Roche. Amounts of such obligations, if any, cannot be determined at this time.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Foreign Currency Risk

Our business is primarily conducted in U.S. dollars except for our agreements with contract manufacturers for drug supplies which are denominated in Euros. We recorded a gain on foreign currency exchange rate differences of approximately $0.1 million during the nine months ended September 30, 2018 and a loss on foreign currency exchange rate differences of approximately $2.0 million during the nine months ended September 30, 2017. If we continue or increase our business activities that require the use of foreign currencies, we may incur further losses if the Euro and other such currencies continue to strengthen against the U.S. dollar.

Interest Rate Risk

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

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

Credit Risk

Our receivable from Roche are amounts due from Roche entities located in the U.S. and Switzerland under the License Agreement with Roche.

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer (“CEO”) and chief financial officer (“CFO”) evaluated the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15 under the U.S. Securities Exchange Act of 1934, as amended (the “Exchange Act”), as of the end of the period covered by this Form 10-Q. Based on this evaluation, our CEO and CFO concluded that, as of September 30, 2018, our disclosure controls and procedures are designed and are effective

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to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our CEO and CFO, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during our fiscal quarter ended September 30, 2018 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Effectiveness of Controls and Procedures

Internal control over financial reporting has inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements will not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management necessarily applies its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On May 17, 2018, a purported class action lawsuit entitled Arkansas Teacher Retirement System v. Prothena Corporation plc, et al., Civil Action No. 18-cv-2865-WHA, was filed in the U.S. District Court for the Northern District of California against the Company and certain of its current and former officers; the plaintiff voluntarily dismissed that case on July 10, 2018. On July 5, 2018, another purported class action lawsuit, entitled Michael Ramezani v. Prothena Corporation plc, et al., Civil Action No. 3:18-cv-04035-WHA, was filed in the same court against the same parties; the plaintiff voluntarily dismissed that case on July 13, 2018. On July 16, 2018, an additional purported class action lawsuit, entitled Simon James v. Prothena Corporation plc, et al., Civil Action No. 18-cv-04261-JST, was filed in the same court against the same parties; the plaintiff voluntarily dismissed that case on August 7, 2018. On July 16, 2018, another purported class action lawsuit, entitled Granite Point Capital v. Prothena Corporation plc, et al., Civil Action No. 18-cv-06425, was filed against the same parties, but in the U.S. District Court for the Southern District of New York. The plaintiff in this case, as in the previously-filed cases, seeks compensatory damages, costs and expenses in an unspecified amount on behalf of a putative class of persons who purchased the Company's ordinary shares between October 15, 2015 and April 20, 2018, inclusive. The complaint alleges that the defendants violated federal securities laws by allegedly making false and misleading statements and omitting certain material facts in certain public statements and in the Company's filings with the U.S. Securities and Exchange Commission during the putative class period, regarding the clinical trial results and prospects for approval of the Company's NEOD001 drug development program. On September 17, 2018, the plaintiff in the Granite Point Capital case, together with the plaintiff in the previously-dismissed Simon James lawsuit, filed a motion with the court in the Granite Point Capital case seeking to be appointed as the lead plaintiffs in that purported class action. That motion was granted on October 31, 2018, and that proceeding is now entitled In re Prothena Corporation plc Securities Litigation.

ITEM 1A. RISK FACTORS

Investing in our ordinary shares involves a high degree of risk. Our Annual Report on Form 10-K for 2017 (filed with the SEC on February 26, 2018) includes a detailed discussion of our business and the risks to our business. You should carefully read that Form 10-K. You should also read and carefully consider the risks described below and the other information in this Quarterly Report on Form 10-Q. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and/or growth prospects. In such an event, the market price of our ordinary shares could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

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

We anticipate that we will incur losses for the foreseeable future and we may never sustain profitability.

We may not generate the cash that is necessary to finance our operations in the foreseeable future. We incurred net losses of $153.2 million, $160.1 million and $80.6 million for the years ended December 31, 2017, 2016 and 2015, respectively. We expect to continue to incur substantial losses for the foreseeable future as we:

- support the Phase 2 PASADENA clinical trial for PRX002/RG7935 (prasinezumab) being conducted by Roche,
- conduct our Phase 1 clinical trial for PRX004 and possibly initiate additional clinical trials for these and other programs;
- develop and commercialize our product candidates, including PRX002/RG7935 and PRX004;
- undertake nonclinical development of other product candidates and initiate clinical trials, if supported by nonclinical data; and
- pursue our early stage research and seek to identify additional drug candidates and potentially acquire rights from third parties to drug candidates through licenses, acquisitions or other means.

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

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

As of September 30, 2018, we had cash and cash equivalents of $451.5 million. Although we believe, based on our current business plans, that our existing cash and cash equivalents will be sufficient to meet our obligations for at least the next twelve

months, we anticipate that we will require additional capital in the future in order to continue the research and development, and eventually commercialization, of our drug candidates. Our future capital requirements will depend on many factors that are currently unknown to us, including, without limitation:

- the timing of initiation, progress, results and costs of our clinical trials, including the Phase 2 clinical trial for PRX002/RG7935 and our Phase 1 clinical trial for PRX004;
- the timing, initiation, progress, results and costs of these and our other research, development and commercialization activities;
- the results of our research and nonclinical studies;
- the costs of manufacturing our drug candidates for clinical development as well as for future commercialization needs;
- the costs of preparing for commercialization of our drug candidates;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims;
- our ability to establish research collaborations, strategic collaborations, licensing or other arrangements;
- the timing, receipt and amount of any payments or royalties that we might receive under current or potential future collaborations;
- the costs to satisfy our obligations under current and potential future collaborations; and
- the timing, receipt and amount of revenues or royalties, if any, from any approved drug candidates.

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

In the pharmaceutical industry, the research and development process is lengthy and involves a high degree of risk and uncertainty. This process is conducted in various stages and, during each stage, there is a substantial risk that product candidates in our research and development pipeline will experience difficulties, delays or failures. This makes it difficult to estimate the total costs to complete our ongoing clinical trials and to estimate anticipated completion dates with any degree of accuracy, which raises concerns that attempts to quantify costs and provide estimates of timing may be misleading by implying a greater degree of certainty than actually exists.

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

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

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

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

The United Kingdom's announced withdrawal from the European Union could have a negative effect on global economic conditions and financial markets, EU regulatory procedures and our business.

In June 2016, a majority of voters in the United Kingdom (the "UK") elected in a national referendum to withdraw from the European Union (the "EU"). In March 2017, the UK government formally initiated the withdrawal process. That withdrawal has created significant uncertainty about the future relationship between the UK and the EU, including with respect to the laws and regulations that will apply as the UK determines which EU laws to replace or replicate upon withdrawal. The pending withdrawal has also given rise to calls for the governments of other EU member states to consider withdrawal. These developments, or the perception that any of them could occur, have had and may continue to have a material adverse effect on global economic conditions and the stability of global financial markets, and may significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. Any of these factors could depress economic activity and restrict access to capital, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

We are highly dependent on key personnel, including Dr. Gene G. Kinney, our President and Chief Executive Officer. There can be no assurance that we will be able to retain Dr. Kinney or any of our key personnel. The loss of the services of Dr. Kinney or any other person on whom we are highly dependent might impede the achievement of our research, development and commercial objectives.

Recruiting and retaining qualified scientific and other personnel are critical to our growth and future success. Competition for qualified personnel in our industry is intense. We may not be able to attract and retain these personnel on acceptable terms given that competition. Failure to recruit and retain qualified personnel could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

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

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

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

We may be adversely affected by earthquakes or other natural disasters.

We have a key facility and operations in the San Francisco Bay Area of Northern California, which in the past has experienced severe earthquakes. If an earthquake, other natural disaster or similar event were to occur and prevent us from using all or a significant portion of those operations or local critical infrastructure, or that otherwise disrupts our operations, it could be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. We have disaster recovery and business continuity plans, but they may prove to be inadequate in the event of

a natural disaster or similar event. We may incur substantial expenses if our disaster recovery and business continuity plans prove to be inadequate. We do not carry earthquake insurance. Furthermore, third parties upon which we are materially dependent upon may be vulnerable to natural disasters or similar events. Accordingly, such a natural disaster or similar event could have an adverse effect on our business, financial condition or results of operations.

We may experience breaches or similar disruptions of our information technology systems or data.

Our business is increasingly dependent on critical, complex and interdependent information technology systems to support business processes as well as internal and external communications. The size and complexity of those systems make them vulnerable to breakdown, malicious intrusion and computer viruses. We have developed systems and processes that are designed to protect our information technology systems and prevent data loss and other security breaches, including systems and processes designed to reduce the impact of a security breach. However, such measures cannot provide absolute security. Any breakdown, malicious intrusion or computer virus could result in the impairment of key business processes or breach of data security, which could cause us to lose trade secrets or other intellectual property or lead to unauthorized disclosure of personal data of our employees, third parties with which we do business, clinical trial participants or others. Such an event could have an adverse effect on our business, financial condition or results of operations.

We are subject to increasingly complex data protection laws and regulations.

We are subject to various data protection laws and regulations, which are expanding and becoming more complex. In April 2016, the EU General Data Protection Regulation (the "GDPR") was adopted in the EU and superseded the previous EU Data Protection Directive in May 2018. Under the GDPR, enhanced data protection requirements as well as substantial fines for breaches of personal data apply and increase our obligations and potential liabilities for the personal data that we process or control. We may be required to implement additional controls to facilitate compliance with the GDPR and other new or evolving data protection laws and regulations. Ensuring our compliance with these laws and regulations involves substantial costs, and it is possible that governmental authorities or third parties will assert that our business practices fail to comply with these laws and regulations. If our operations are found to be in violation of any of such laws and regulations, we may be subject to significant civil, criminal and administrative damages, penalties and fines, as well as reputational harm, which could have a material adverse effect on our business, financial condition or results of operations.

We could be adversely impacted by tax reform in the United States.

The U.S. Tax Cuts and Jobs Act (the "TCJA") was signed into law on December 22, 2017. The TCJA significantly changed U.S. tax law and includes numerous provisions that will impact our business going forward, including changes to the U.S. federal statutory tax rate, the repeal of alternative minimum tax and additional limits on the deductibility of executive compensation, among other things. Some of those effects are expected to be positive for us, such as the lower statutory tax rate and repeal of the alternative minimum taxes. However, other effects are expected to negative for us, such as the expanded limitations on the deductibility of compensation paid to certain of our executive officers. We have not yet completed an assessment of the impact on us of the TCJA. The actual net effect could be adverse.

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. Our drug candidates are in various stages of development and we may not be able to successfully discover, develop, obtain regulatory approval for or commercialize any drug candidates.

The success of our business depends substantially upon our ability to discover, develop, obtain regulatory approval for and commercialize our drug candidates successfully. Our research and development programs are prone to the significant and likely risks of failure inherent in drug development. We intend to continue to invest most of our time and financial resources in our research and development programs.

Although we have an ongoing Phase 2 clinical trial for PRX002/RG7935 and an ongoing Phase 1 clinical trial for PRX004, there is no assurance that this work will support further development of these drug candidates. In addition, we currently do not, and may never, have any other drug candidates in clinical trials and we have not identified drug candidates for many of our research programs.

Before obtaining regulatory approvals for the commercial sale of any drug candidate for a target indication, we must demonstrate with substantial evidence gathered in adequate and well-controlled clinical trials that the drug candidate is safe and effective for use for that target indication. In the U.S., this must be done to the satisfaction of the U.S. Food and Drug Administration (the "FDA"); in the EU this must be done to the satisfaction of the EMA; and in other countries this must be done to the satisfaction of comparable regulatory authorities.

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 treatment options;

- be proven safe and effective in clinical trials; or
- meet applicable regulatory standards.

Positive results in nonclinical 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 nonclinical 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 nonclinical studies or clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional nonclinical studies or clinical trials, or to discontinue clinical trials altogether.

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

- obtaining and maintaining commercial manufacturing arrangements with third-party manufacturers;
- developing the marketing and sales capabilities, internal and/or in collaboration 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 several years and some or all may never become commercially available. Accordingly, we may never generate revenues through the sale of products.

We have entered into collaborations and may enter into additional collaborations in the future, and we might not realize the anticipated benefits of such collaborations.

Research, development and/or commercialization collaborations, including those that we have with Roche and Celgene, are subject to numerous risks, which include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration, and might not commit sufficient efforts and resources or might misapply those efforts and resources;
- we may have limited influence or control over the approaches to development and commercialization of products candidates in the territories in which our collaboration partners lead development and commercialization;
- collaborators might not pursue research, development and commercialization of collaboration product candidates or might elect not to continue or renew research, development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competing products, availability of funding or other factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators might delay, provide insufficient resources to, or modify or stop clinical trials for collaboration product candidates or require a new formulation of a product candidate for clinical testing;
- collaborators could develop or acquire products outside of the collaboration that compete directly or indirectly with our product candidates or require a new formulation of a product candidate for clinical testing;
- collaborators with sales, marketing and distribution rights to one or more product candidates might not commit sufficient resources to sales, marketing and distribution or might otherwise fail to successfully commercialize those product candidates;
- collaborators might not properly maintain or defend our intellectual property rights or might use our intellectual property improperly or in a way that jeopardizes our intellectual property or exposes us to potential liability;
- collaboration activities might result in the collaborator having intellectual property covering our activities or product candidates, which could limit our rights or ability to research, develop or commercialize our product candidates;
- disputes might arise between us and a collaborator that could cause a delay or termination of the collaboration or result in costly litigation that diverts management attention and resources; and
- collaborations might be terminated, which could result in a need for additional capital to pursue further development or commercialization of our product candidates.

In addition, funding provided by a collaborator might not be sufficient to advance product candidates under the collaboration. For example, although Celgene made a $100 million upfront payment to us and made a $50 million equity investment in us upon entering into the Collaboration Agreement, we might need additional funding to advance product candidates prior to when Celgene decides whether to exercise its license rights to those product candidates.

If a collaborator terminates a collaboration or a development program under a collaboration, including by failing to exercise a license or other option under the collaboration, whether because we fail to meet a milestone or otherwise, any potential revenue from the collaboration would be significantly reduced or eliminated. In addition, we will likely need to either secure other funding to advance research, development and/or commercialization of the relevant product candidate or abandon that program, the development of the relevant product candidate could be significantly delayed, and our cash expenditures could increase significantly if we are to continue research, development and commercialization of the relevant product candidates.

Any one or more of these risks, if realized, could reduce or eliminate future revenue from product candidates under our collaborations, and could have a material adverse effect on our business, financial condition, results of operations and/or growth prospects.

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

We cannot predict whether we will encounter problems with the Phase 2 clinical trial for PRX002/RG7935, our Phase 1 clinical trial for PRX004 or any other future clinical trials that will cause us or any regulatory authority to delay or suspend those clinical trials or delay the analysis of data derived from them. A number of events, including any of the following, could delay the completion of our ongoing or 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, the EMA or other comparable regulatory authorities regarding the scope or design of our clinical trials;

- delays in obtaining, or our inability to obtain, required approvals from institutional review boards ("IRBs") or other reviewing entities at clinical sites selected for participation in our clinical trials;
- insufficient supply or deficient quality of our drug candidates or other materials necessary to conduct our clinical trials;
- delays in obtaining regulatory agency agreement for the conduct of our clinical trials;
- lower than anticipated enrollment and/or retention rate of subjects in our clinical trials, which can be impacted by a number of factors, including size of patient population, design of trial protocol, trial length, eligibility criteria, perceived risks and benefits of the study drug, patient proximity to trial sites, patient referral practices of physicians, availability of other treatments for the relevant disease and competition from other clinical trials;
- slower than expected rates of events in trials with a composite primary endpoint that is event-based;