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

FORM 6-K

**REPORT OF FOREIGN ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
OF THE SECURITIES EXCHANGE ACT OF 1934**

For the month of November 2018

(Commission File No. 001-38217)

Nightstar Therapeutics plc
(Translation of registrant's name into English)

**10 Midford Place, 2nd Floor
London W1T 5BJ United Kingdom**
(Address of registrant's principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.
Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101 (b)(1): ___

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101 (b)(7): ___

EXHIBIT INDEX

Exhibit	Description
99.1	<u>Unaudited Condensed Consolidated Financial Statements as of September 30, 2018 and December 31, 2017 and for the Three Months and Nine Months Ended September 30, 2018 and 2017</u>
99.2	<u>Management's Discussion and Analysis for the Three and Nine Months Ended September 30, 2018 and 2017</u>
101	The following materials formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets at September 30, 2018 (unaudited) and December 31, 2017 (unaudited), (ii) Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and nine month periods ended September 30, 2018 and 2017 (unaudited), (iii) Condensed Consolidated Statements of Cash Flows for the nine month periods ended September 30, 2018 and 2017 (unaudited) and (iv) Notes to Condensed Consolidated Financial Statements (unaudited)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereto duly authorized.

NIGHTSTAR THERAPEUTICS PLC

By: /s/ David Fellows

Name: **David Fellows**

Title: **Chief Executive Officer**

Date: November 20, 2018

NIGHTSTAR THERAPEUTICS PLC

Condensed Consolidated Balance Sheets
(In thousands, except per share amounts)
(unaudited)

	<u>September 30,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 45,974	\$ 129,404
Marketable securities	54,800	—
Prepaid expenses and other assets	6,219	3,685
Research and development tax credit	6,284	1,753
Total current assets	<u>113,277</u>	<u>134,842</u>
Property and equipment, net	534	355
Other assets	632	—
Total assets	<u>\$ 114,443</u>	<u>\$ 135,197</u>
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	\$ 4,424	\$ 3,196
Accrued expenses and other liabilities	10,339	6,189
Total current liabilities	<u>14,763</u>	<u>9,385</u>
Total liabilities	<u>14,763</u>	<u>9,385</u>
Commitments and contingencies (see Note 11)		
Shareholders' equity:		
Ordinary shares, £0.01 nominal value	1	1
Additional paid-in capital	188,949	185,943
Accumulated other comprehensive income	1,226	1,890
Accumulated deficit	(90,496)	(62,022)
Total shareholders' equity	<u>99,680</u>	<u>125,812</u>
Total liabilities and shareholders' equity	<u>\$ 114,443</u>	<u>\$ 135,197</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

NIGHTSTAR THERAPEUTICS PLC

Condensed Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except per share amounts)

(unaudited)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
Operating expenses:				
Research and development	\$ 7,845	\$ 3,983	\$ 21,961	\$ 10,275
General and administrative	3,019	2,025	9,119	3,432
Total operating expenses	<u>10,864</u>	<u>6,008</u>	<u>31,080</u>	<u>13,707</u>
Other income (expense):				
Interest and other income	798	55	1,887	61
Other income (expense), net	4,127	(2,258)	466	(2,258)
Total other income (expense), net	<u>4,925</u>	<u>(2,203)</u>	<u>2,353</u>	<u>(2,197)</u>
Loss before benefit from income taxes	(5,939)	(8,211)	(28,727)	(15,904)
Provision for (benefit from) income taxes	83	—	(251)	—
Net loss	<u>(6,022)</u>	<u>(8,211)</u>	<u>(28,476)</u>	<u>(15,904)</u>
Other comprehensive income (loss):				
Foreign exchange translation adjustment	(2,711)	1,848	(2,980)	3,570
Unrealized holding gains on marketable securities, net of tax provision of \$0.3 million and tax benefit of \$0.5 million for the three and nine months ended September 30, 2018, respectively	(1,618)	—	2,316	—
Total comprehensive loss	<u>\$ (10,351)</u>	<u>\$ (6,363)</u>	<u>\$ (29,140)</u>	<u>\$ (12,334)</u>
Weighted-average ordinary shares outstanding - basic and diluted	<u>28,139</u>	<u>21,514</u>	<u>27,975</u>	<u>18,858</u>
Basic and diluted net loss per ordinary share	<u>\$ (0.21)</u>	<u>\$ (0.38)</u>	<u>\$ (1.02)</u>	<u>\$ (0.84)</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

NIGHTSTAR THERAPEUTICS PLC

Condensed Consolidated Statements of Cash Flows

(In thousands)

(unaudited)

	Nine Months Ended September 30,	
	2018	2017
Cash flows from operating activities:		
Net loss	\$ (28,476)	\$ (15,904)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	195	146
Accretion on marketable securities	(470)	—
Non-cash share-based compensation	3,006	663
Unrealized foreign exchange losses	157	—
Deferred taxes	(251)	—
Changes in operating assets and liabilities:		
Deferred research and development tax credit receivable	(4,752)	(2,392)
Prepaid expenses and other current assets	(3,176)	(1,958)
Accounts payable	1,376	3,662
Accrued expenses and other liabilities	3,733	374
Net cash used in operating activities	<u>(28,658)</u>	<u>(15,409)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(387)	(107)
Purchases of marketable securities	(94,374)	—
Proceeds from maturities of marketable securities	40,000	—
Net cash used in investing activities	<u>(54,761)</u>	<u>(107)</u>
Cash flows from financing activities:		
Proceeds of issuance of ordinary shares, net of issuance costs	—	63,418
Deferred issuance costs	—	(1,604)
Net cash provided by financing activities	<u>—</u>	<u>61,814</u>
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	47	3,472
Net decrease in cash, cash equivalents, and restricted cash	(83,372)	49,770
Cash, cash equivalents, and restricted cash beginning of period	129,404	10,122
Cash, cash equivalents, and restricted cash, end of period	<u>\$ 46,032</u>	<u>\$ 59,892</u>
Supplemental non-cash financing activities disclosures:		
Deferred issuance costs included in accrued expenses	<u>\$ 431</u>	<u>\$ 1,604</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

NIGHTSTAR THERAPEUTICS PLC

Notes to the Condensed Consolidated Financial Statements (unaudited)

1. Nature of the Business

Nightstar Therapeutics plc (the “Company”) is a clinical-stage gene therapy company focused on developing and commercializing novel one-time treatments for patients suffering from rare inherited retinal diseases that would otherwise progress to blindness. The Company is developing a pipeline of proprietary product candidates that are designed to substantially modify or halt the progression of inherited retinal diseases for which there are no currently approved treatments. The Company’s lead product candidate, NSR-REP1, for the treatment of choroideremia (“CHM”) is in Phase 3 clinical development. The Company’s second product candidate, NSR-RPGR, is expected to begin Phase 2/3 clinical development for the treatment of X-linked retinitis pigmentosa by the end of 2018. The Company also has product candidates in preclinical development for a number of inherited retinal diseases for which there are no approved treatments such as Stargardt disease and Best vitelliform macular dystrophy.

The Company is a public limited company incorporated in England and Wales. On October 2, 2017 the Company completed its initial public offering (“IPO”) of American Depositary Shares (“ADSs”). In the IPO, the Company sold an aggregate of 6,164,000 ADSs representing the same number of ordinary shares at a public offering price of \$14.00 per ADS. Net proceeds were approximately \$77.4 million, after deducting underwriting discounts and commissions and offering expenses paid by the Company. As described in Note 16, in October 2018, the Company completed a follow-on public offering of 4,600,000 ADSs resulting in estimated net proceeds of approximately \$77.1 million.

Prior to its IPO in October 2017, the Company historically conducted its business through NightstaRx Limited (“NSL”) and its U.S. subsidiary, Nightstar, Inc. (“NSI”) and therefore the historical consolidated financial statements previously presented the consolidated results of operations of NSL. Following the completion of the Company’s IPO in October 2017, the consolidated financial statements present the consolidated results of operations of Nightstar Therapeutics plc.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, the timelines for clinical development and the results of our clinical trials, compliance with government regulations, receipt of regulatory approval for the Company’s product candidates, uncertainty of market acceptance of the Company’s products, securing reimbursement from government or third-party payors, procuring adequate supplies of the Company’s products and product candidates that comply with current good manufacturing practices and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of capital, adequate personnel and infrastructure, and extensive compliance-reporting capabilities. Even if the Company’s product development efforts are successful, it is uncertain when, if ever, the Company will realize revenue from its product sales.

The Company has funded its operations primarily from the sale of its ADSs and ordinary shares. The Company has incurred recurring losses since its inception, including net losses of \$6.0 million and \$8.2 million for the three months ended September 30, 2018 and 2017, respectively, and \$28.5 million and \$15.9 million for the nine months ended September 30, 2018 and 2017, respectively. In addition, as of September 30, 2018 and December 31, 2017, the Company had an accumulated deficit of \$90.5 million and \$62.0 million, respectively. The Company expects to continue to generate operating losses for the foreseeable future. As of September 30, 2018, the Company had cash, cash equivalents and marketable securities on hand of \$100.8 million. As further described in Note 16, in October 2018 the Company completed a follow-on offering of 4.6 million ADSs, resulting in estimated net proceeds of approximately \$77.1 million. The Company believes the cash, cash equivalents and marketable securities on hand at September 30, 2018 of \$100.8 million and the proceeds received from the follow-on offering of its ADSs in October 2018 will be sufficient to fund the Company’s operations for at least 12 months from the issuance date of these financial statements. The future viability of the Company beyond that point is dependent on its ability to raise additional capital to finance its operations. The Company’s inability to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies. There can be no assurances, however, that the current operating plan will be achieved or that additional funding will be available on terms acceptable to the Company, or at all.

2. Summary of Significant Accounting Policies

Basis of Presentation

The condensed consolidated interim financial statements of Nightstar Therapeutics plc and its subsidiaries are unaudited, have been prepared in accordance with generally accepted accounting principles in the United States of America (“U.S. GAAP”) and are

presented in U.S. dollars. All significant intercompany accounts and transactions between the Company and its subsidiaries have been eliminated upon consolidation.

The accompanying unaudited interim financial statements should be read in conjunction with the audited consolidated financial statements and accompanying notes included in the Company's Annual Report on Form 20-F filed with the SEC on April 3, 2018 (the "Annual Report"). The balance sheet as of December 31, 2017 was derived from audited consolidated financial statements included in the Company's Annual Report but does not include all disclosures required by U.S. GAAP. There have been no significant changes in the Company's accounting policies from those disclosed in the Annual Report.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted from these interim financial statements. However, these interim financial statements include all adjustments, consisting only of normal recurring adjustments, which are, in the opinion of management, necessary to fairly state the results of the interim period. The interim results are not necessarily indicative of results to be expected for the full year or any future periods.

Research and development tax credit receivable as of December 31, 2017 previously included in prepaid and other assets has been presented as a separate line item on the Condensed Consolidated Balance Sheet to conform to current period presentation.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of income and expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the accrual for research and development expenses, the determination of the fair value of share-based awards issued, share-based compensation expense and the recoverability of the Company's net deferred tax assets and related valuation allowance. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ materially from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments that have maturities of three months or less when acquired to be cash equivalents. Cash equivalents as of September 30, 2018 and December 31, 2017 consisted of investments in money market funds and U.S. Treasury securities with an original maturity of less than three months.

Restricted Cash

The Company has entered into a certain lease transaction (refer to Note 13) that requires a security deposit of \$58,000 for the duration of the lease contract, which is reported in the other assets balance line on the condensed consolidated balance sheet. The Company includes the restricted cash balance in cash and cash equivalents when reconciling beginning-of-period and end-of-period total amounts shown on the condensed consolidated statements of cash flows.

Marketable securities

The Company invests available funds in high-quality Treasury securities that are classified as available-for-sale and carried at fair value. Changes in fair value of available-for-sale securities are recorded in other comprehensive income (loss) as net unrealized gains (losses) on available-for-sale securities. The Company recognized \$1.6 million in net unrealized holding losses and \$2.3 million in net unrealized holding gains for the three and nine months ended September 30, 2018, respectively. The Company did not recognize any net unrealized gains or losses on marketable securities in any prior period.

Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.

- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

For marketable securities, management utilizes values provided by the Company's investment advisor and compares them to the values published by a third-party source. Management believes that the carrying amounts of the Company's consolidated financial instruments, including cash equivalents, prepaid expenses, accounts payable and accrued expenses approximate fair value due to the short-term nature of those instruments.

Concentration of Credit Risk

Financial instruments that subject the Company to credit risk consist primarily of cash, cash equivalents and marketable securities. The Company places cash and cash equivalents in established financial institutions. Marketable securities held by the Company consist exclusively of U.S. Treasury securities. The Company has no significant off-balance-sheet risk or concentration of credit risk, such as foreign exchange contracts, options contracts or other foreign hedging arrangements.

Property and Equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the respective assets. As of September 30, 2018 and December 31, 2017, the Company's property and equipment consisted of lab equipment, computer equipment and office equipment, which has an estimated useful life of three years. The Company capitalizes the cost of leasehold improvements and amortizes them over the shorter of the useful life of the asset and the non-cancellable lease term. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in the condensed consolidated statements of operations and comprehensive loss. Expenditures for repairs and maintenance are charged to expense as incurred.

The Company evaluates assets for potential impairment when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparing the book values of the assets to the expected future net undiscounted cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book values of the assets exceed their fair value. The Company has not recognized any impairment losses from inception through September 30, 2018.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker in deciding how to allocate resources and assess performance. The Company's Chief Executive Officer, who is the Company's chief operating decision maker, views the Company's operations and manages its business as a single operating segment, which is the business of developing and commercializing gene therapies; however, the Company operates in two geographic regions: the United Kingdom and the United States.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including salaries, share-based compensation and benefits, depreciation expense, travel, third-party license fees, and external costs of outside vendors engaged to conduct clinical development activities, clinical trials, cost to manufacture clinical trial materials and tax credits associated with research and development activities. Research and development tax credits received from Her Majesty's Revenue & Customs ("HMRC") are recognized as offsets to research and development expenses.

Research Contract Costs and Accruals

The Company has entered into various research and development-related contracts with research institutions and other companies. These agreements are generally cancelable, and related payments are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes the progress of the studies or clinical trials, including the phase or completion of events, invoices received and contracted costs. Estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Patent Costs

The Company expenses patent application and related legal costs as incurred and classifies such costs as general and administrative expenses in the accompanying condensed consolidated statements of operations and comprehensive loss.

Share-Based Compensation

The Company recognizes compensation expense for equity awards based on the grant date fair value of the award on a straight-line basis over the requisite service period. The Company uses the fair value of its ordinary shares to determine the fair value of restricted share awards ("RSAs") and restricted share units ("RSUs"). The fair value of options is determined using the Black-Scholes option pricing model. The Company accounts for forfeitures as they occur.

Foreign Currency Translation

The Company maintains its financial statements in the functional currency pounds sterling. Monetary assets and liabilities denominated in currencies other than the functional currency are remeasured into the functional currency at rates of exchange prevailing at the balance sheet dates. Non-monetary assets and liabilities denominated in foreign currencies are remeasured into the functional currency at the exchange rates prevailing at the date of the transaction. Exchange gains or losses arising from foreign currency transactions are included in the determination of net income (loss) for the respective periods. The Company recorded foreign exchange gains of \$4.1 million and losses of \$2.3 million for the three months ended September 30, 2018 and 2017, respectively, and foreign exchange gains of \$0.5 million and losses of \$2.3 million for the nine months ended September 30, 2018 and 2017, respectively. Foreign exchange gains and losses are included in other expense, net in the condensed consolidated statement of operations and comprehensive loss.

For financial reporting purposes, the financial statements of the Company, which are prepared using the functional currency of pounds sterling, have been translated into the U.S. dollar. Assets and liabilities are translated at the exchange rates at the balance sheet dates, revenue and expenses are translated at the average exchange rates and shareholders' equity is translated based on historical exchange rates.

Translation adjustments are not included in the determination of net income (loss) but are included as foreign exchange adjustments in other comprehensive income (loss), a component of shareholders' equity. The Company recorded a loss of \$2.7 million and a gain of \$1.8 million on foreign currency translations for the three months ended September 30, 2018 and 2017, respectively, and a loss of \$3.0 million and a gain of \$3.6 million on foreign currency translations for the nine months ended September 30, 2018 and 2017, respectively.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the condensed consolidated financial statements or in its tax returns. Deferred tax assets and liabilities are determined on the basis of the differences between the condensed consolidated financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that deferred tax assets will be recovered in the future based upon the weight of available evidence, and to the extent management believes that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed as the amount of benefit to recognize in the consolidated financial statements. The amount of benefits that may be used is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate, as well as the related net interest and penalties.

The Company recognizes interest and penalties related to unrecognized tax benefits on the provision for income tax line in the accompanying condensed consolidated statement of operations and comprehensive loss. As of September 30, 2018 and December 31, 2017, no accrued interest or penalties are included on the related tax liability line in the condensed consolidated balance sheets.

The Company recognized income tax provision of \$0.1 million and income tax benefit of \$0.3 million for the three and nine months ended September 30, 2018, respectively, and an income tax provision in other comprehensive loss of \$0.3 million and income tax benefit of \$0.5 million related to the unrealized gain on available-for-sale securities for the three and nine months ended September 30, 2018, respectively. As of September 30, 2018, the Company recorded an accrued income tax provision of \$0.2 million related to this tax benefit included within accrued expenses and other liabilities in the condensed consolidated balance sheet, which is expected to be generated from continuing operations. There was no income tax provision for the three or nine months ended September 30, 2017.

Research and development tax credits received from HMRC are recognized as offsets to research and development expenses.

Comprehensive Loss

The Company follows the provisions of the Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) Topic 220, *Comprehensive Income*, which establishes standards for the reporting and display of comprehensive income (loss) and its components. Comprehensive income (loss) is defined to include all changes in equity during a period except those resulting from investments by owners and distributions to owners. The Company reports cumulative translation adjustments and unrealized gains (losses) on marketable securities as part of comprehensive income (loss).

Net Loss per Share

Basic and diluted net loss per ordinary share is determined by dividing net loss by the weighted-average number of ordinary shares outstanding during the period. For all periods presented, issued and outstanding but unvested RSAs have been excluded from the calculation because their effect would be anti-dilutive. Therefore, the weighted-average shares outstanding used to calculate both basic and diluted loss per share are the same.

The following potentially dilutive securities have been excluded from the calculation of diluted net loss per share due to their anti-dilutive effect at September 30, 2018 and 2017, respectively:

	For the Three and Nine Months Ended	
	September 30,	
	2018	2017
Unvested restricted share and restricted share unit awards	737,065	1,200,507
Unvested share options	1,072,526	—

Emerging Growth Company Status

As of September 30, 2018, the Company maintained its status as an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act.

Recent Accounting Pronouncements

Recently issued accounting pronouncements not yet adopted

In August 2018, the FASB issued Accounting Standards Update (“ASU”) 2018-15 (“ASU 2018-15”), *Intangibles – Goodwill and Other – Internal Use Software (Subtopic 350-40), Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement that is a Service Contract* requiring a customer in a cloud computing arrangement that is a service contract to follow the internal use software guidance in ASC 350-402 to determine which implementation costs to capitalize as assets.

The guidance is effective for the Company in annual periods beginning after December 15, 2019, and interim periods within those annual periods. The Company has the option to apply the guidance prospectively to all implementation costs incurred after the date of adoption or retrospectively.

The new guidance requires certain disclosures in the interim and annual period of adoption. The Company does not expect the adoption of this guidance to have a material impact on the consolidated financial statements due to limited use in its operations of cloud computing arrangements that are service contracts.

In August 2018, the FASB issued ASU 2018-13 (“ASU 2018-13”), *Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*, removing the requirements to disclose:

- The amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy;

- The policy for timing of transfers between levels; and
- The valuation processes for Level 3 fair value measurements;

and clarifying certain aspects of disclosures regarding uncertainty in measurement of the reporting date. The guidance is effective for the Company in annual periods beginning after December 15, 2019, and interim periods within those annual periods. The Company does not expect the adoption of this guidance to have a material impact on the consolidated financial statements as the Company does not currently have and does not anticipate, based on its conservative investment policy and nature of operations, to have assets or liabilities falling within Level 3 of the fair value hierarchy.

In July 2018, the FASB issued ASU 2018-11 (“ASU 2018-11”), *Leases (Topic 842) – Targeted Improvements*. The FASB decided to provide another transition method in addition to the existing transition method by allowing entities to initially apply the new leases standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. If the Company chooses to adopt ASC 842 using the additional transition method provided by ASU 2018-11, that guidance will be effective for the Company on January 1, 2019. The Company is currently evaluating whether to adopt the guidance in ASU 2018-11 or follow other acceptable method on transitioning to the guidance of ASC 842.

In July 2018, the FASB issued ASU 2018-10 (“ASU 2018-10”) *Codification Improvements to Topic 842, Leases*. ASU 2018-10 provides a number of improvements and clarifications to the guidance of ASC 842. The guidance of ASC 842, and ASU 2018-10, will be effective for the Company on January 1, 2019. The Company is currently assessing the impact of ASU 2018-10 will have on its consolidated financial statements.

In July 2018, the FASB issued ASU 2018-09 (“ASU 2018-09”), *Codification Improvements*. The ASU 2018-09 provides updates and clarifications to a number of previously issued accountings standards and such updates and clarifications are effective concurrently with the related standards. The Company does not expect the adoption of ASU 2018-09 to have a material impact on the consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07, *Compensation—Stock Compensation (Topic 718) - Improvements to Nonemployee Share-Based Payment Accounting* that largely aligns the accounting for share-based payment awards issued to employees and nonemployees, with certain exceptions. The new guidance expands the scope of ASC 718 to include share-based payments granted to nonemployees in exchange for goods or services used or consumed in an entity’s own operations and supersedes the guidance in ASC 505-30. Under the new guidance, the measurement of equity-classified nonemployee awards will be fixed at the grant date, which may lower their cost and reduce volatility in the income statement. The guidance is effective for the Company in annual periods beginning after December 15, 2018, and interim periods within those annual periods, but not before the Company adopts ASC 606, *Revenue from contracts with customers*. In the period of adoption, the Company will apply the new guidance to any equity-classified nonemployee awards for which a measurement date has not been established and liability-classified nonemployee awards that have not been settled as of the date of adoption by recognizing a cumulative-effect adjustment to retained earnings as of the beginning of the annual period of adoption. The Company does not expect the adoption of this guidance to have a material impact on the consolidated financial statements due to its limited use of share-based arrangements to compensate nonemployees for their services provided.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments Credit Losses (Topic 326)* (“ASU 2016-13”), which replaces the incurred loss impairment methodology for financial instruments in current U.S. GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The guidance is effective for the fiscal year beginning January 1, 2020, including interim periods within that fiscal year. Early application is permitted for the fiscal year beginning January 1, 2019, including interim periods within that fiscal year. The guidance must be adopted using a modified-retrospective approach and a prospective transition approach is required for debt securities for which an other-than-temporary impairment had been recognized before the effective date. The Company is currently evaluating the impact of ASU 2016-13 on the consolidated financial statements.

In February 2016, FASB issued ASU 2016-02, *Leases (Topic 842)* (“ASU 2016-02”), which requires a lessee to recognize most leases on the balance sheet but recognize expenses on the income statement in a manner similar to current practice. The update states that a lessee will recognize a lease liability for the obligation to make lease payments and a right-to-use asset for the right to use the underlying assets for the lease term. Leases will continue to be classified as either financing or operating, with classification affecting the recognition, measurement, and presentation of expenses and cash flows arising from a lease. The guidance must be adopted on a modified-retrospective transition approach for leases existing, or entered into after, the beginning of the earliest comparative period presented in the financial statements. For public entities, the new standard is effective for interim and annual periods beginning on or after January 1, 2019, with early adoption permitted. The Company is currently evaluating the impact that the adoption of ASU 2016-02 will have on its consolidated financial statements.

The Company has considered other recent accounting pronouncements and concluded that they are either not applicable to the business, or that the effect is not expected to be material to the unaudited condensed consolidated financial statements as a result of future adoption.

Recently adopted accounting pronouncements

In October 2016, the FASB issued ASU No. 2016-16, *Income Taxes (Topic 740): Intra-Entity Transfer of Assets Other than Inventory* (“ASU 2016-16”), which requires the recognition of the income tax consequences of an intra-entity transfer (sales) of an asset, other than inventory, when the transfer occurs. The standard is effective for the Company beginning January 1, 2018. The Company does not currently engage in sale transactions with its wholly owned subsidiaries. Adoption of this standard did not have a material impact on the Company’s consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting* (“ASU 2016-09”). The new standard involves several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. The new standard was effective for the Company on January 1, 2017 with early adoption permitted. The Company elected to early adopt ASU 2016-09 on January 1, 2015 and has reflected the adoption in its consolidated financial statements. The adoption of ASU 2016-09 did not have a material impact on the Company’s consolidated financial statements.

In November 2015, the FASB issued ASU No. 2015-17, *Balance Sheet Classification of Deferred Taxes* (“ASU 2015-17”), which requires deferred tax liabilities and assets to be classified as noncurrent in the consolidated balance sheet. ASU 2015-17 was required to be adopted for annual periods beginning after December 15, 2016, including interim periods within those fiscal years. The amendment may be applied either prospectively to all deferred tax liabilities and assets or retrospectively to all periods presented. The Company elected to early adopt this guidance on January 1, 2015 and classified all previously recognized deferred tax assets and liabilities as noncurrent. The adoption of ASU 2015-17 did not have a material impact on the Company’s consolidated financial statements as the Company recorded a full valuation allowance on deferred tax assets at January 1, 2015 and subsequent reporting period ends.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash* (“ASU 2016-18”), which requires companies to include amounts generally described as restricted cash and restricted cash equivalents in cash and cash equivalents when reconciling beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The Company complied with the requirement to adopt ASU 2016-18 for annual periods beginning after December 15, 2017, and interim periods within those fiscal years. The adoption of ASU 2016-18 did not have a material impact on the Company’s consolidated financial statements as the Company does not have material balances meeting the definition of restricted cash or restricted cash equivalents.

In January 2017, the FASB issued ASU 2017-01, *Clarifying the Definition of a Business* (“ASU 2017-01”). ASU 2017-01 clarified the definition of a business to assist entities with evaluating whether transactions should be accounted for as acquisitions of assets or businesses. The Company adopted ASU 2017-01 on January 31, 2018. The adoption did not have a material effect on the Company’s consolidated financial statements as the Company has not entered into transactions within the scope of ASU 2017-01.

On August 26, 2016, the FASB issued Accounting Standards Update No 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments* (“ASU 2016-15”) to clarify guidance on the classification of certain cash receipts and payments in the statement of cash flows. This guidance became effective for the Company for interim and annual periods beginning on January 1, 2018. The adoption of ASU 2016-15 did not have a material impact on the Company’s financial statements.

In January 2016, the FASB issued ASU 2016-01, *Financial Instruments – Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities* (“ASU 2016-01”), which amended the guidance on the recognition and measurement of financial assets and financial liabilities. The new guidance requires that equity investments (except those accounted for under the equity method of accounting, or those that result in consolidation of the investee) are measured at fair value with changes in fair value recognized in net income. The guidance also requires the use of an exit price when measuring the fair value of financial instruments for disclosure purposes, eliminates the requirement to disclose the methods and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost and requires separate presentation of financial assets and financial liabilities by measurement category and form of financial asset. The guidance became effective for the fiscal year beginning January 1, 2018, including interim periods within that fiscal year. Adoption of ASU 2016-01 did not have a material impact on the Company’s consolidated financial statements due to the Company’s highly conservative investment policy, which specifically restricts investment choices to high-quality, short term securities.

3. Fair value measurements

Assets measured at fair value on a recurring basis based on Level 1, Level 2 and Level 3 fair value measurement criteria as of September 30, 2018 are as follows (in thousands):

	Fair Value Measurements Using			
	Total	Level 1	Level 2	Level 3
Money market funds and U.S. Treasury Securities, included in cash and cash equivalents	\$ 38,858	\$ 38,858	\$ —	\$ —
U.S. Treasury Securities	54,800	14,963	39,837	—
	<u>\$ 93,658</u>	<u>\$ 53,821</u>	<u>\$ 39,837</u>	<u>\$ —</u>

The Company had no liabilities measured at fair value on a recurring basis as of September 30, 2018. The Company had no assets or liabilities measured at fair value on a recurring basis as of December 31, 2017.

4. Marketable securities

As of September 30, 2018, the Company has the following investments in marketable debt securities classified as available-for-sale (in thousands):

	Maturity	Amortized cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Impact of Foreign Currency Exchange Rate Fluctuations	Aggregate Estimated Fair Value
U.S. Treasury securities	3 - 9 months	\$ 52,508	\$ —	\$ (24)	\$ 2,316	\$ 54,800

As of September 30, 2018, the aggregate fair value of 11 securities held by the Company in an unrealized loss position was \$54.8 million and the aggregate unrealized holding losses was \$24,000. The Company recognized in other comprehensive income a \$2.3 million gain related to the translation of U.S. dollar investments held by NSL into its functional currency of pound sterling. No securities have been in an unrealized loss position for more than one year. As of September 30, 2018, these securities are not considered to be other than temporarily impaired because the impairments are not severe, have been for a short duration, and are due to normal market and interest rate fluctuations. Furthermore, the Company does not intend to sell the investment securities in an unrealized loss position and it is unlikely that the Company will be required to sell these securities before the recovery of the amortized cost. The Company did not have any investments in marketable securities at December 31, 2017.

During the three months ended September 30, 2018, the Company realized \$3.0 million in foreign currency gains on the settlement of maturing marketable securities as a result of favorable foreign currency exchange rate fluctuations. Realized gains and losses are determined using the specific identification method, reclassified from accumulated other comprehensive income and included in other income, net on the statement of comprehensive income.

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	September 30, 2018	December 31, 2017
Prepayments	\$ 3,634	\$ 2,586
Value-added tax receivable	2,408	905
Interest receivable	137	98
Other	40	96
Total prepaid expenses and other current assets	<u>\$ 6,219</u>	<u>\$ 3,685</u>

6. Property and Equipment, Net

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

	<u>September 30,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
Lab equipment	\$ 366	\$ 363
Leasehold improvements	126	—
Computer and office equipment	546	382
Construction in progress	61	—
	<u>1,099</u>	<u>745</u>
Less: accumulated depreciation	(565)	(390)
Total property and equipment, net	<u>\$ 534</u>	<u>\$ 355</u>

Depreciation expense was \$66,000 and \$57,000 for the three months ended September 30, 2018 and 2017, respectively, and \$195,000 and \$146,000 for the nine months ended September 30, 2018 and 2017, respectively.

7. Accrued Expenses and Other Liabilities

Accrued expenses and other liabilities consisted of the following (in thousands):

	<u>September 30,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
Research and development activities	\$ 5,834	\$ 3,779
Compensation and benefits	1,573	1,093
Professional fees	930	410
Taxes payable	193	—
Other	1,809	907
Total accrued expenses and other liabilities	<u>\$ 10,339</u>	<u>\$ 6,189</u>

8. Shareholders' Equity

Initial Public Offering

On October 2, 2017, the Company closed its IPO of ADSs. In the IPO, the Company sold an aggregate of 6,164,000 ADSs representing the same number of ordinary shares at a public offering price of \$14.00 per ADS, including the full exercise by the underwriters of their option to purchase additional ADSs. Net proceeds were approximately \$77.4 million, after deducting underwriting discounts and commissions and offering expenses paid by the Company of \$2.9 million.

Corporate Reorganization

On September 11, 2017, all shareholders of NSL exchanged each of the ordinary shares of different classes held by them for the same number and class of newly issued ordinary shares of Nightstar Therapeutics Limited and, as a result, NSL became a wholly-owned subsidiary of Nightstar Therapeutics Limited on that date. On September 15, 2017, Nightstar Therapeutics re-registered as a public limited company and was renamed Nightstar Therapeutics plc.

Ordinary Shares

Each holder of ordinary shares is entitled to one vote per ordinary share and to receive dividends when and if such dividends are recommended by the board of directors and declared by the shareholders. The Company has not declared any dividends since its inception.

9. Share-Based Compensation

The Company grants equity awards under its share-based compensation programs, which may include share options, RSAs, RSUs and other share-based awards. To date, the share-based awards granted to employees and directors have been in the form of RSAs, RSUs and share options.

2017 Equity Incentive Plan

Under the Company's 2017 Equity Incentive Plan (the "2017 Plan") approved in September 2017, the Company was authorized to issue a total of 1,500,000 ordinary shares as incentives to the Company's employees and directors, which includes shares underlying options that may be granted from time to time under the 2017 Plan. In addition, the number of ordinary shares reserved for issuance under the 2017 Plan will automatically increase on January 1 of each year, ending on (and including) January 1, 2027, in an amount equal to 4% of the total number of shares outstanding on December 31 of the preceding calendar year. Pursuant to this provision, 1,156,188 ordinary shares were added to the number of available shares pursuant to the 2017 Plan effective January 1, 2018.

Restricted Share Awards and Restricted Share Units

The Company typically grants employees restricted share awards which vest over a four-year service period with 25% of the award vesting on the first anniversary of the vesting commencement date, with the balance vesting ratably on a quarterly basis or monthly basis, over the remaining three years, with vesting commencing as of the first day of the quarter in which the award is granted. As of September 30, 2018, all granted awards contained only service-based vesting conditions. The Company recognizes share-based compensation expense for equity awards based on the grant date fair value of the award on a straight-line basis over the requisite service period.

The unvested RSAs are considered legally outstanding shares; however, they are subject to forfeiture in cases where the holders fail to complete the requisite service period with the Company. Unvested RSAs that are forfeited are considered deferred shares and, subject to certain conditions, all deferred shares can be repurchased by the Company for payment of £0.01 to the holder of the deferred shares. The unvested RSUs are not considered outstanding shares until the holders perform the requisite services as defined in the applicable award agreement.

A summary of the changes in the Company's RSAs and RSUs during the nine months ended September 30, 2018 were as follows:

	Number of Restricted Shares	Weighted Average Grant Date Fair Value
Unvested and outstanding at December 31, 2017	1,191,344	\$ 4.92
Granted	10,000	14.31
Vested	(414,668)	4.63
Forfeited	(49,611)	11.42
Unvested and outstanding at September 30, 2018	<u>737,065</u>	<u>\$ 4.76</u>

As of September 30, 2018, total compensation costs related to the unvested RSAs and RSUs amounted to \$3.2 million, which the Company expects to recognize over the weighted-average period of 2.57 years.

Share Options

The Company typically grants employees share option awards which vest over a four-year service period with 25% of the award vesting on the first anniversary of the vesting commencement date, with the balance vesting ratably on a monthly basis over the remaining three years. As of September 30, 2018, all granted awards contained only service-based vesting conditions. The Company recognizes share-based compensation expense for share option awards based on the grant date fair value of the award on a straight-line basis over the requisite service period.

No share options were granted during the nine months ended September 30, 2017 or in periods prior to such date. The following table summarizes the share options-related activity during the nine months ended September 30, 2018:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2017	191,275	\$ 21.00	—	—
Granted	912,151	14.55	—	—
Exercised	—	—	—	—
Forfeited	(30,900)	13.08	—	—
Outstanding at September 30, 2018	<u>1,072,526</u>	<u>\$ 15.83</u>	<u>9.39</u>	<u>\$ 5,485,833</u>
Exercisable as of September 30, 2018	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>
Vested and expected to vest as of September 30, 2018	<u>1,072,526</u>	<u>\$ 15.83</u>	<u>9.39</u>	<u>\$ 5,485,833</u>

The aggregate intrinsic value of share options is calculated as the difference between the exercise price of the share options and the fair value of the Company's ordinary shares for those share options that had exercise prices lower than the fair value of the Company's ordinary shares at the reporting date.

The weighted-average grant date fair value of options granted during the nine months ended September 30, 2018 was \$8.38. As of September 30, 2018, there was \$7.9 million of total unrecognized compensation cost related to unvested stock options; that cost is expected to be recognized over a weighted-average period of 3.19 years. All options granted have a term of 10 years.

Share option valuation

The assumptions used in the Black-Scholes option pricing model to determine the fair value of the share options granted to employees and directors during the nine months ended September 30, 2018 were as follows:

	September 30, 2018
Expected option life	6 years
Risk-free interest rate	2.63% - 2.92%
Expected volatility	65.50 - 66.69%
Expected dividend yield	0.00%

Share-based compensation expense

The Company recorded share-based compensation expense of \$959,000 and \$428,000 during the three months ended September 30, 2018 and 2017, respectively, and \$3.0 million and \$663,000 for the nine months ended September 30, 2018 and 2017, respectively.

Share-based compensation expense recorded as research and development and general and administrative expenses is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Research and development	\$ 337	\$ 131	\$ 1,230	\$ 273
General and administrative	622	297	1,776	390
Total share-based compensation	<u>\$ 959</u>	<u>\$ 428</u>	<u>\$ 3,006</u>	<u>\$ 663</u>

10. License Agreements

Oxford University Innovation Limited Licenses

In November 2013, the Company entered into an exclusive license agreement (the "2013 Oxford Agreement") with Oxford University Innovation ("Oxford"), formerly Isis Innovation Limited, to obtain a license to certain patent rights for the commercial development,

manufacture, distribution, use and sale of products and processes resulting from the development of those patent rights. The Company is using the licensed patent rights to develop NSR-REP1 for CHM.

As part of the consideration for this license, the Company paid upfront fees of \$78,000 and past patent costs of \$68,000. The 2013 Oxford Agreement requires the Company to remit fees upon the Company or any sub-licensee meeting certain milestones, as well as up to an aggregate of £375,000 (\$507,000) upon the achievement of specified milestones and a low single-digit percentage of net sales upon the Company achieving regulatory approval, subject to quarterly minimums. In addition, the Company agreed to pay a mid-single-digit percentage of all upfront fees, milestone and other one-off payments received by the Company.

The Company incurred £25,000 (\$34,000) and £0 (\$0) for maintenance fees under the 2013 Oxford Agreement during the nine months ended September 30, 2018 and 2017, respectively. No fees were incurred or paid during the three months ended September 30, 2018 or 2017.

In November 2015, the Company entered into five separate exclusive license agreements (the “2015 Oxford Agreements”) to obtain a license to certain patent rights for the commercial development, manufacture, distribution, use and sale of gene therapy product candidates targeting five different types of inherited retinal diseases, including NSR-RPGR and NSR-BEST1, and processes resulting from the development of those patent rights.

As part of the consideration for these licenses, the Company paid upfront fees of £378,000 (\$575,000) in the aggregate. The Company also paid past patent costs of £1,300 (\$2,000) related to the licenses for NSR-RPGR. In addition, the Company agreed to pay Oxford annual maintenance fees for all five licenses until the formal application for regulatory approval of the product is filed, as well as a royalty upon the achievement of specified development and commercial milestones, which is calculated as a single-digit percentage of all upfront fees, milestone and other one-off payments received by the Company. The Company is also required to pay royalty payments, subject to quarterly minimums, based on a single-digit percentage of net sales. In connection with the licenses, Oxford was required to transfer certain manufactured license products as well as all manufacturing documentation. The annual maintenance fee for all five licenses was £50,000 (\$68,000) and £60,000 (\$78,000) for the years ending December 31, 2017 and 2018, respectively, and will increase annually until the year ending December 31, 2025, at and after which time such maintenance fee shall be £100,000 (\$135,000).

During the nine months ended September 30, 2018 and 2017, the Company has not recorded any fees due to Oxford under the 2015 Oxford Agreements.

In October 2017, the Company entered into a separate exclusive license agreement (the “2017 Oxford Agreement”) to obtain a license to certain patent rights for the commercial development, manufacture, distribution, use and sale of gene therapy products, including NSR-ABCA4, for the treatment of Stargardt disease.

As part of the consideration for the 2017 Oxford Agreement, the Company paid Oxford an upfront signing fee of £100,000 (\$135,000). In addition, the Company agreed to pay Oxford annual maintenance fees and payments upon the achievement of specified development and commercial milestones, sales milestones based on the first achievement of predefined sales thresholds, a royalty on annual net sales, and a royalty, which is calculated as a high single-digit percentage of all upfront fees, milestone and other one-off payments received by the Company. In connection with the licenses, Oxford was required to transfer all manufacturing documentation. No annual maintenance fee was due for the year ending December 31, 2017. Such fee is £10,000 for the year ending December 31, 2018 and will increase annually until the year ending December 31, 2025, at and after which time such maintenance fee shall be £20,000.

During the nine months ended September 30, 2018 and 2017, the Company has not recorded any fees due to Oxford under the 2017 Oxford Agreement.

In the event that the Company commits a material breach, has a petition presented for winding up of the business or passes a resolution for voluntary winding up or challenges the licensed patent rights of Oxford, Oxford can terminate the applicable agreement. The Company has the right to terminate the 2013 Oxford Agreement and the 2015 Oxford Agreements if Oxford commits a material breach and at any time after the second anniversary of the applicable agreement. The Company has the right to terminate the 2017 Oxford Agreement if Oxford commits a material breach and at any time after the third anniversary of its execution date upon two months’ written notice. The 2013 Oxford Agreement, 2015 Oxford Agreements and 2017 Oxford Agreement expire on the twentieth anniversary of the applicable effective date or each license will expire upon the Company’s written election when for twelve consecutive months none of these items exist: the licensed patents continue to be in force or subsisting in another country, the Company has market exclusivity as specified in the agreement throughout the world, the Company has market exclusivity throughout any region or the Company has market exclusivity in any country. The Company can sublicense its rights under the 2013 Oxford Agreement, 2015 Oxford Agreements and 2017 Oxford Agreement.

Oxford BioMedica License

In December 2013, the Company entered into a non-exclusive license agreement (the “BioMedica License Agreement”) with Oxford BioMedica (UK) Limited (“Oxford BioMedica”) to obtain a license to certain patent rights for the commercial development, manufacture, distribution, use and sale of products and processes resulting from the development of those patent rights.

As part of the consideration for this license, the Company paid upfront fees of \$100,000. In addition, the Company is also required to pay quarterly royalty payments based on net sales at a low-single digit percentage. The BioMedica License Agreement also requires the Company to make a \$100,000 milestone payment upon the grant by the U.S. Food and Drug Administration of marketing approval for an AAV product for the treatment of CHM. The Company is allowed to sublicense its rights under the agreement. If this occurs, the Company is required to pay an upfront sublicense fee and royalty payments equal to a low-to-mid single-digit amount quarterly as a percentage of sublicense revenue.

In the event that the Company commits a material breach, challenges the validity of the licensed patent rights, becomes insolvent or if an order is passed or resolution is passed for the winding up of the Company or if an administrator, administrative receiver or receiver is appointed over the Company’s assets, Oxford BioMedica can terminate the BioMedica License Agreement. The Company can terminate the BioMedica License Agreement at any time and if Oxford BioMedica commits a material breach or becomes insolvent or if an order is passed or resolution is passed for the winding up of Oxford BioMedica or if an administrator, administrative receiver or receiver is appointed over Oxford BioMedica’s assets. The BioMedica License Agreement will expire on the expiration date of the related patent.

The Company has not recorded any research and development expense for the nine months ended September 30, 2018 and 2017 in connection with the BioMedica License Agreement as the Company has not met any milestones or achieved net sales, which would require the Company to remit payments.

11. Research and Development Tax Credit

As a company that carries out extensive research and development activities, the Company seeks to benefit from one of two U.K. research and development tax credit cash rebate regimes, the Small and Medium-sized Enterprises R&D Tax Credit Scheme (“SME Scheme”) and the Research and Development Expenditure scheme (“RDEC Scheme”). Under the SME Scheme, the Company’s principal research subsidiary company, NSL, may be eligible to surrender the trading losses that arise from its research and development activities for a payable tax credit of up to approximately 33.4% of eligible research and development expenditures. Qualifying expenditures largely comprise employment costs for research staff, consumables and certain internal overhead costs incurred as part of research projects for which the Company does not receive income. Subcontracted research expenditures are eligible for a cash rebate of up to approximately 21.7%.

For certain periods where NSL is not eligible for the SME Scheme, NSL may be eligible for the RDEC Scheme, whereby tax relief was given at 11% of allowable research and development costs, and increased to 12% on January 1, 2018. The RDEC plan is more restrictive with qualifying expenditures mainly comprising of employment costs for research staff.

Based on criteria established by HMRC, management of NSL expects a proportion of expenditures being carried out by NSL in relation to its pipeline research, clinical trials management and manufacturing development activities is likely to be eligible for inclusion within one of these two tax credit cash rebate regimes.

The Company has recorded U.K. research and development tax credit as an offset to research and development expense in the consolidated statements of operations and comprehensive loss of \$2.1 million and \$1.0 million for the three months ended September 30, 2018 and 2017, respectively, and \$5.1 million and \$2.4 million for the nine months ended September 30, 2018 and 2017, respectively.

12. Income Taxes

The Company has evaluated the positive and negative evidence bearing on the Company’s ability to realize the deferred tax assets. Management has considered the Company’s history of cumulative net losses incurred since inception and its lack of commercialization of any products or generation of any revenue from product sales since inception and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the net deferred tax assets as of September 30, 2018 and December 31, 2017. Management reevaluates the positive and negative evidence at each reporting period.

The Company recognized an income tax provision of \$0.1 million and income tax benefit of \$0.3 million for the three and nine months ended September 30, 2018, respectively, and an income tax provision in other comprehensive loss of \$0.3 million and income tax benefit of \$0.5 million related to the unrealized gain on available-for-sale securities for the three and nine months ended September 30, 2018, respectively. As of September 30, 2018, the Company recorded an accrued income tax provision of \$0.2 million related to this tax benefit included within accrued expenses and other liabilities in the condensed consolidated balance sheet, which is expected to be generated from continuing operations. The Company recognized no income tax benefit or provision for three or nine months ended September 30, 2017.

The Company has not recorded any amounts for unrecognized tax benefits as of September 30, 2018 or December 31, 2017. The Company files income tax returns in the United Kingdom, United States and certain state and local jurisdictions. The income tax returns are generally subject to tax examinations for the tax years ended December 31, 2013 through December 31, 2017. There are currently no pending income tax return examinations.

13. Commitments and Contingencies

License Agreements

The Company has entered into several license agreements (see Note 10). In connection with these agreements, the Company is required to make a number of milestone payments and annual license maintenance payments. The Company evaluated all milestone payments within the arrangements to estimate the probability of the Company meeting the milestones in accordance with ASC 450, *Contingencies*. All milestones that have been achieved and unpaid at September 30, 2018 and December 31, 2017 have been accrued as of September 30, 2018 and December 31, 2017.

Legal Proceedings

From time to time, the Company may be a party to litigation or subject to claims incident to the ordinary course of business. Although the results of litigation and claims cannot be predicted with certainty, the Company currently believes that the final outcome of these ordinary course matters will not have a material adverse effect on its business. Regardless of the outcome, litigation can have an adverse impact on the Company because of defense and settlement costs, diversion of management resources and other factors. The Company was not a party to any litigation and did not have contingency reserves established for any liabilities as of September 30, 2018 and December 31, 2017.

Leases

NSL entered into a noncancelable sublease on January 10, 2017 for a facility in Lexington, Massachusetts for its U.S. operations. The lease related to the facility commenced on February 1, 2017 and is scheduled to terminate in June 2020. The initial rent for the office space is approximately \$76,000, increasing every year by approximately 4%.

On April 6, 2018, NSI entered into a sublease for its new corporate headquarters in Waltham, Massachusetts. The sublease provides NSI with approximately 12,000 rentable square feet for general office use. The sublease became effective on April 26, 2018 (the "Sublease Commencement Date") and will expire in March 2021. The initial rent for the office space is approximately \$209,000 per annum, increasing every year by approximately 6%. As part of the agreement, NSI arranged for a letter of credit for \$58,000 as security for the sublease.

On May 24, 2018, NSL entered into an agreement to receive the assignment of the lease for its new office on Midford Place in London, United Kingdom. This office also serves as the corporate headquarters of the Company. The assignment of the lease to NSL became effective on June 8, 2018 and the lease will expire on October 30, 2020. Annual rent is approximately £198,000 (\$261,000), payable quarterly. NSL provided the landlord with an upfront security deposit of approximately £119,000 (\$157,000), including value added tax. As part of this agreement, NSL also received a one-time rent concession payment from the landlord in the amount of £75,000 (\$99,000) plus value added taxes. NSL's performance under the lease is guaranteed by Nightstar Therapeutics plc.

As of September 30, 2018, the Company is committed to making the following future minimum lease payments:

	Premises Operating Leases	
	(In thousands)	
2018	\$	140
2019		567
2020		426
2021		58
Total contractual obligations	\$	1,191

The Company recorded rent expense totaling \$233,000 and \$58,000 for the three months ended September 30, 2018 and 2017, respectively, and \$423,000 and \$154,000 for the nine months ended September 30, 2018 and 2017, respectively. All leases are classified as operating leases.

Indemnification

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnification. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations.

In accordance with its Articles of Association, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving at the Company's request in such capacity. There have been no claims to date, and the Company has director and officer insurance that may enable it to recover a portion of any amounts paid for future potential claims.

Credit Arrangement

The Company has a line of credit arrangement with a bank that allows the Company to submit payments up to £300,000 per month through the Bankers Automated Clearing Services (BACS) system. The arrangement does not require the Company to pay any interest or fees and will remain effective until terminated by either party. At September 30, 2018 and December 31, 2017, there were no amounts outstanding under the arrangement.

14. Related Party Transactions

Syncona

In the normal course of business, the Company has entered into agreements with controlled or majority owned entities of Syncona Partner LLP, Syncona Limited and their affiliates (collectively "Syncona") under which the Company may obtain from or otherwise engage in certain limited research and development activities with these affiliated entities of Syncona in connection with the development of its product candidates. In addition, the Company may provide services to or otherwise engage in certain limited research and development activities with companies affiliated with Syncona, including the provision of clinical manuals and other support of documents to such affiliated entities. Syncona is a shareholder of the Company and the Chairman of the Board of Directors of the Company serves as the chief investment officer and managing partner of Syncona. The Company recorded research and development expenses totaling \$42,000 and \$2,000 for the three months ended September 30, 2018 and 2017, respectively, and \$74,000 and \$11,000 for the nine months ended September 30, 2018 and 2017, respectively. The Company also recorded \$36,000 as other income during the nine months ended September 30, 2018. As of September 30, 2018 and December 31, 2017, the Company had payments of \$1,000 and \$14,000, respectively, outstanding to affiliates of Syncona.

University of Oxford and Related Entities

The Company, under various service agreements, receives research and development services from the University of Oxford and its subsidiaries. The University of Oxford is a shareholder of the Company. The Company recorded research and development expenses totaling \$75,000 and \$208,000 for the three months ended September 30, 2018 and 2017, respectively, and \$426,000 and \$470,000 for the nine months ended September 30, 2018 and 2017, respectively. As of September 30, 2018 and December 31, 2017, there was \$34,000 and \$414,000, respectively, included in accrued expenses. See also Note 10 in relation to payments made to Oxford under certain license agreements between Oxford and the Company.

MacLaren Agreement

In November 2013 and as amended in 2016, the Company entered into a consulting agreement with Oxford University Innovation Ltd. (“Consulting Agreement”), for consulting services of Prof. Robert MacLaren, who was a member of the Company’s board of directors until April 15, 2018. Under the terms of the Consulting Agreement, Prof. MacLaren provides the Company with advice and expertise in relation to regulatory submissions, prepares for and attend meetings of the Company’s clinical advisory board, prepare for and attend regulatory meetings, provides scientific and medical advice in relation to the preparation of medical education materials and provide consulting services to the Company.

Under the terms of the Consulting Agreement, the Company agreed to pay consulting fees for Prof. MacLaren’s services subject to a minimum annual fee of £99,000 (\$134,000). In October 2017, the Company’s board of directors awarded Prof. MacLaren 58,000 RSUs which would have vested annually over a four-year period from the date of award. In connection with Prof. MacLaren’s resignation from the Board of Directors (the “Board”), the Board agreed to allow for immediate vesting of 29,000 of the RSUs awarded in October 2017, with the remainder being forfeited as of the same date. The Board also agreed that the Company would pay a bonus to Prof. MacLaren for services provided in 2017 in the amount of \$26,000.

Under the Consulting Agreement, the Company recorded consulting fees totaling \$0 and \$19,000 for the three months ended September 30, 2018 and 2017, respectively, and \$50,000 and \$77,000 for the nine months ended September 30, 2018 and 2017, respectively. In August 2018, the Company and Oxford mutually agreed to terminate the Consulting Agreement. Simultaneously, the Company entered into a consulting agreement directly with Prof. MacLaren. Under the agreement with Prof. MacLaren, consulting fees totaling \$76,000 were recorded for the three and nine months ended September 30, 2018. As of September 30, 2018 and December 31, 2017, there were payment obligations of \$103,000 and \$8,000, respectively, outstanding to Prof. MacLaren and Oxford.

15. Employee Benefit Plans

In the United Kingdom, the Company makes contributions to private defined contribution pension schemes on behalf of its employees. The Company paid \$45,000 and \$35,000 in contributions in the three months ended September 30, 2018 and 2017, respectively, and \$149,000 and 130,000 for the nine months ended September 30, 2018 and 2017, respectively.

In the United States, the Company established a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. This plan covers substantially all U.S. employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. The Company does not currently match employee contributions and accordingly, no matching contributions were recorded for the nine months ended September 30, 2018 and 2017.

16. Subsequent Events

On October 2, 2018, the Company completed an underwritten public offering of 4.6 million ADSs, representing 4.6 million ordinary shares, at a public offering price of \$18.00 per ADS, which included the exercise in full by the underwriters of their option to purchase up to an additional 600,000 ADSs. The estimated net proceeds to the Company from the offering were approximately \$77.1 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company.

Management's Discussion and Analysis of Financial Condition and Results of Operations

We maintain our books and records in pounds sterling, our results are subsequently translated to U.S. dollars, and we prepare our condensed consolidated financial statements in accordance with generally accepted accounting principles in the United States, or U.S. GAAP, as issued by the Financial Accounting Standards Board, or FASB. All references in the unaudited condensed consolidated financial statements to "\$" are to U.S. dollars and all references to "£" are to pounds sterling. Our condensed consolidated financial statements as at and for the three month and nine-month periods ended September 30, 2018 and 2017 have been translated from pounds sterling into U.S. dollars at the rate of £1.00 to \$1.3053 and £1.00 to \$1.3402, which were the noon buying rates of the Federal Reserve Bank of New York on the last business day of the three months ended September 30, 2018 and 2017, respectively. These translations should not be considered representations that any such amounts have been, could have been or could be converted into U.S. dollars at that or any other exchange rate as of that or any other date.

We have historically conducted our business through our subsidiary, NightstaRx Limited and Nightstar, Inc., our U.S. subsidiary of NightstaRx Limited, and therefore our historical consolidated financial statements previously presented the consolidated results of operations of NightstaRx Limited. Following the completion of our initial public offering in October 2017, our consolidated financial statements present the consolidated results of operations of Nightstar Therapeutics plc.

The statements in this discussion regarding industry outlook, our expectations regarding our future performance, liquidity and capital resources and other non-historical statements are forward-looking statements. These forward-looking statements are subject to numerous risks and uncertainties, including, but not limited to, the risks and uncertainties described in "Risk Factors" in our Report of Foreign Private Issuer on Form 6-K, furnished to the U.S. Securities and Exchange Commission, or SEC, on September 25, 2018 and "Forward-Looking Statements" in our Annual Report for the year ended December 31, 2017, previously filed with the SEC on April 3, 2018. Management reviewed the risks disclosed in the Annual Report and believe that all risks disclosed continue to be relevant to us as of the date of this Report on Form 6-K. Any references to this Report on Form 6-K shall be deemed to include any exhibits to the Form 6-K. Our actual results may differ materially from those contained in or implied by any forward-looking statements.

The following discussion should be read in conjunction with the unaudited condensed consolidated financial statements and accompanying notes included elsewhere in this Report on Form 6-K and the consolidated financial statements and accompanying notes included within our Annual Report for the year ended December 31, 2017.

A. Operating Results

Overview

We are a leading clinical-stage gene therapy company focused on developing and commercializing novel one-time treatments for patients suffering from rare inherited retinal diseases that would otherwise progress to blindness. Leveraging our expertise in ophthalmology, gene therapy and drug development, we are developing a pipeline of proprietary product candidates that are designed to substantially modify or halt the progression of inherited retinal diseases for which there are no currently approved treatments.

Our lead product candidate, NSR-REP1, is in Phase 3 clinical development for the treatment of choroideremia, or CHM, and represents the most clinically advanced product candidate for this indication worldwide. In data from 32 patients treated with NSR-REP1 across four open-label clinical trials, over 90% of treated patients maintained their visual acuity over a two-year follow-up period. In some cases, we also observed substantial improvements in visual acuity. In June 2018, the U.S. Food and Drug Administration, or FDA, granted Regenerative Medicine Advanced Therapy, or RMAT, designation for NSR-REP1 in CHM.

Our second product candidate, NSR-RPGR, is expected to begin Phase 2/3 clinical development for the treatment of X-linked retinitis pigmentosa, or XLRP, by the end of 2018. NSR-RPGR is being evaluated in an open-label, dose-ranging, single-eye clinical trial consisting of a dose escalation study and an expansion study, which we refer to as the XIRIUS trial. In September 2018, we announced positive preliminary safety and efficacy data from the first five cohorts (combined n=15) of the Phase 1 dose escalation study of the XIRIUS trial at the EURETINA medical meeting. The safety data and efficacy signals observed in the higher dose groups of the dose escalation study provided the basis for an early clinical proof of concept for the XIRIUS trial to progress to the expansion study. Sixth-month follow-up data on all 18 patients in the dose escalation study is expected to be available in the second quarter of 2019, with one-year follow-up data expected to be available in the fourth quarter of 2019. In November 2018, we announced modifications to the trial design of the expansion study in accordance with the FDA's draft guidance on the development of gene therapy products for retinal disorders, with the intention that it would qualify as a Phase 2/3 study. The Phase 2/3 expansion study is

expected to enroll approximately 45 patients randomized on a masked basis into one of three study arms: a high dose group, a low dose group and a no-sham control group. The Phase 2/3 expansion study is expected to begin by the end of 2018, with preliminary efficacy data expected to be available in mid-2019, which, if positive, would serve as the basis for discussions with regulatory agencies on potential Phase 3 trial requirements. One-year follow-up data from the Phase 2/3 expansion study is expected to be available in 2020.

We also have product candidates in preclinical development for a number of inherited retinal diseases for which there are no approved treatments such as Stargardt disease and Best vitelliform macular dystrophy, or Best disease.

Since our inception in May 2013, we have devoted substantially all our resources to research and development of our lead product candidates as well as to manufacturing our product candidates, organizing and staffing our company, raising capital and establishing our intellectual property portfolio. We do not have any products approved for sale and have not generated any revenue from product sales. We have funded our operations to date primarily with proceeds from the sale of our American Depositary Shares, or ADSs, and ordinary shares. Through September 30, 2018, we had received net cash proceeds of \$178.1 million from sales of our ADSs and ordinary shares. On October 2, 2018, we completed an underwritten public offering of 4,600,000 ADSs (representing the same number of ordinary shares), including the full exercise by the underwriters of their option to purchase additional ADSs, at a public offering price of \$18.00 per ADS, resulting in estimated net proceeds of approximately \$77.1 million, after deducting underwriting discounts, and commissions and estimated offering expenses.

Since our inception, we have incurred operating losses. Our net loss was \$6.0 million and \$8.2 million for the three months ended September 30, 2018 and 2017, respectively, and \$28.5 million and \$15.9 million for the nine-month periods ended September 30, 2018 and 2017, respectively. As of September 30, 2018 and December 31, 2017, we had an accumulated deficit of \$90.5 million and \$62.0 million, respectively. As of September 30, 2018, we had cash, cash equivalents and marketable securities of \$100.8 million.

We expect to continue to incur significant expenses for the foreseeable future as we advance our product candidates through preclinical and clinical development and seek regulatory approval and pursue commercialization of any approved product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution.

Recent Development – Phase 2/3 Expansion Study in XIRIUS Trial

In November 2018, we announced modifications to the trial design of the expansion study in the XIRIUS trial for NSR-RPGR in XLRP. These modifications were made to the expansion study in accordance with the FDA's draft guidance on the development of gene therapy products for retinal disorders, with the intention that it would qualify as a Phase 2/3 study.

The Phase 2/3 expansion study is expected to enroll approximately 45 patients across six surgical centers in both the United States and the United Kingdom. In order to be eligible to enter the expansion study, patients must exhibit functional impairment as measured by microperimetry and the presence of viable photoreceptors as indicated by ellipsoid zone measurements on optical coherence tomography. Patients will be randomized on a masked basis into one of three study arms: approximately 15 patients receiving a high-dose of NSR-RPGR in one-eye (2.5×10^{11} genome particles, or gp); approximately 15 patients receiving a low-dose of NSR-RPGR in one-eye (5×10^{10} gp); and approximately 15 patients receiving no treatment (no-sham, parallel control arm). The two treatment groups correspond to doses used in cohorts 5 and 3 of the dose escalation study, respectively. A standardized eight-week steroid regimen will be included to maximize any potential treatment benefit.

The Phase 2/3 expansion study is designed to evaluate the safety and efficacy of NSR-RPGR in patients with a diagnosis of XLRP due to RPGR mutations, as confirmed by genetic testing. The primary efficacy endpoint will evaluate changes in retinal sensitivity following treatment with NSR-RPGR. Secondary endpoints include both anatomical and functional endpoints of efficacy and safety similar to those evaluated in the dose escalation study, as well as exploratory efficacy endpoints such as mobility maze assessments.

The Phase 2/3 expansion study is expected to begin by the end of 2018, with preliminary efficacy data expected to be available in mid-2019, which, if positive, would serve as the basis for discussions with regulatory agencies on potential Phase 3 trial requirements. One-year follow-up data from the Phase 2/3 expansion study is expected to be available in 2020.

In September 2018, we announced positive preliminary safety and efficacy data for the first five cohorts of the Phase 1 dose escalation study of the XIRIUS trial at the EURETINA medical meeting. Preliminary efficacy signals were observed in 5 out of 9 patients (approximately 56%) in cohorts 3, 4 and 5 of the dose escalation study, including durable improvements in overall macula sensitivity, central 16 macula sensitivity and number of improved macula loci. NSR-RPGR was well-tolerated with no observed dose limiting toxicities or reported serious treatment-related adverse events. The safety data and efficacy signals observed in the higher dose groups of the dose escalation study provided the basis for an early clinical proof of concept for the XIRIUS trial to progress to the expansion study.

Components of Our Results of Operations

Revenues

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the near future. If our development efforts for our product candidates are successful and result in regulatory approval, we may generate revenue in the future from product sales.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the research and development of our product candidates, which are partially offset by research and development tax credits provided by Her Majesty's Revenue and Customs, or HMRC. We expense research and development costs as incurred. These expenses consist of:

- expenses incurred under agreements with contract research organizations, or CROs, contract manufacturing organizations, or CMOs, as well as investigative sites and consultants that conduct our clinical trials, preclinical studies and other scientific development services;
- manufacturing validation, qualification and scale-up expenses and the cost of acquiring and manufacturing preclinical studies and clinical trial materials;
- employee-related expenses, including salaries, related benefits, travel and share-based compensation expense for employees engaged in research and development functions;
- costs related to compliance with regulatory requirements;
- facilities costs, depreciation and other expenses, which include rent and utilities; and
- fees for maintaining our third-party licensing agreements.

We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers.

Our direct research and development expenses are tracked on a program-by-program basis for our product candidates and consist primarily of external costs, such as fees paid to outside consultants, CROs and CMOs in connection with our preclinical development, manufacturing and clinical development activities. Our direct research and development expenses by program also include fees incurred under our license agreements. We do not allocate employee costs or facility expenses, including depreciation or other indirect costs, to specific programs because these costs are deployed across multiple programs and, as such, are not separately classified. We use internal resources primarily to oversee the research and discovery as well as for managing our preclinical development, process development, manufacturing and clinical development activities. These employees work across multiple programs and, therefore, we do not track their costs by program.

The table below summarizes our research and development expenses incurred by program:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2018	2017	2018	2017
	(in thousands)		(in thousands)	
Direct research and development expense by program:				
NSR-REP1	\$ 4,144	\$ 3,019	\$ 12,188	\$ 7,667
NSR-RPGR	2,277	551	5,553	1,331
Total direct research and development expense	6,421	3,570	17,741	8,998
Personnel-related expense (including share-based compensation)	2,312	1,291	\$ 6,797	3,075
Research and development tax credit	(2,057)	(1,045)	\$ (5,058)	(2,422)
Indirect and other research and development expense	1,169	167	\$ 2,481	624
Total research and development expense	\$ 7,845	\$ 3,983	\$ 21,961	\$ 10,275

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials and related product manufacturing expenses. As a result, we expect that our research and development expenses will increase substantially over the next several years as we increase personnel costs and prepare for regulatory filings related to our product candidates. We also expect to incur additional expenses related to milestone, royalty payments and maintenance fees payable to third parties with whom we have entered into license agreements to acquire the rights related to our product candidates.

The successful development and commercialization of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our product candidates or when, if ever, material net cash inflows may commence from any of our product candidates. This uncertainty is due to the numerous risks and uncertainties associated with development and commercialization, including the uncertainty of:

- the scope, progress, outcome and costs of our preclinical development activities, clinical trials and other research and development activities;
- establishing an appropriate safety profile with investigational new drug enabling and clinical trial application enabling studies;
- successful patient enrollment in, and the initiation and completion of, clinical trials;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities and reimbursement and market access from third-party payors;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- development and timely delivery of commercial-grade drug formulations that can be used in our clinical trials and for commercial launch;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- significant and changing government regulation;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- the efficacy and potential advantages of our product candidates compared to alternative treatments, if any;
- market acceptance of our product candidates; and
- maintaining a continued acceptable safety profile of the product candidates following approval.

We may never succeed in achieving regulatory approval for any of our product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. Any changes in the outcome of any of these variables with respect to the development of our product candidates in preclinical and clinical development could mean a significant change in the costs and timing associated with the development of these product candidates. For example, if the FDA, European Medicines Agency or another regulatory authority were to delay our planned start of clinical trials or require us to conduct clinical trials or other testing beyond those that we currently expect, or if we experience significant delays in enrollment in any of our planned clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development of that product candidate. Even if we receive regulatory approval for any of our product candidates, we may experience issues or be subject to requirements that may cause significant expenditures, such as regulatory post-marketing requirements and studies, safety events that occur in connection with the commercial use of our products, the implementation of a risk evaluation and mitigation strategy, or REMS, or similar requirements, restrictions in the label for our products or the inability to procure adequate supplies of our products that comply with current good manufacturing practices.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, related benefits and share-based compensation expense for personnel in executive, finance and administrative functions. General and administrative expenses also include professional fees for legal, consulting, accounting and audit services.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our product candidates. We also anticipate that we will incur increased accounting, audit, legal, compliance and insurance costs, as well as investor and public relations expenses associated with being a public company.

Other Income (Expense)

Interest and Other Income

Interest income consists of interest on cash, cash equivalents and marketable securities.

Foreign Currency Translation

We currently maintain our financial statements in the functional currency pounds sterling. Monetary assets and liabilities denominated in currencies other than the functional currency are remeasured into the functional currency at rates of exchange prevailing at the balance sheet dates. Non-monetary assets and liabilities denominated in foreign currencies are remeasured into the functional currency at the exchange rates prevailing at the date of the transaction. Exchange gains or losses arising from foreign currency transactions are included in the determination of net loss for the respective periods.

For financial reporting purposes, our financial statements, which are currently prepared using the functional currency of pounds sterling, have been translated into the U.S. dollar. Assets and liabilities are translated at the exchange rates at the balance sheet dates, revenue and expenses are translated at the average exchange rates for the corresponding period and shareholders' equity is translated based on historical exchange rates at the time of the transaction. The resulting currency translation adjustments are not included in determining net loss but are included as foreign exchange translation adjustments in total comprehensive income (loss), a component of shareholders' equity.

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

The following table summarizes our results of operations for the three months ended September 30, 2018 and 2017:

	For the Three Months Ended September 30,		Change
	2018	2017	
	(in thousands)		
Operating expenses:			
Research and development	\$ 7,845	\$ 3,983	\$ 3,862
General and administrative	3,019	2,025	994
Total operating expenses	10,864	6,008	4,856
Other income (expense):			
Interest and other income	798	55	743
Other income (expense), net	4,127	(2,258)	6,385
Total other income (expense), net	4,925	(2,203)	7,128
Loss before benefit from income taxes	(5,939)	(8,211)	2,272
Provision for income taxes	83	—	83
Net loss	\$ (6,022)	\$ (8,211)	\$ 2,189

Research and Development Expenses

Research and development expenses were \$7.8 million for the three months ended September 30, 2018, compared to \$4.0 million for the three months ended September 30, 2017. The increase of \$3.8 million resulted primarily from increases in program-related expenses of \$1.1 million for NSR-REP1 and \$1.7 million for NSR-RPGR, as well as a \$1.0 million increase in personnel-related costs, and a \$1.0 million increase in the indirect research and development and preclinical expenses. These increased expenses were partially offset by an increase of \$1.0 million of research and development tax credits from HMRC. Research and development personnel-related costs increased due to an increase in headcount during 2018 to support our growth and to assist in the further development of our product candidates and pipeline. The increase in research and development personnel-related costs includes \$0.2 million of additional non-cash share-based compensation compared to the three months ended September 30, 2017.

General and Administrative Expenses

General and administrative expenses were \$3.0 million for the three months ended September 30, 2018, compared to \$2.0 million for the three months ended September 30, 2017. The increase of \$1.0 million is mainly due to an increase in personnel-related costs. General and administrative personnel-related costs increased due to an increase in headcount to support our increased research and development activities, growth of our company and our status as a public company. The increase in general and administrative personnel-related costs includes \$0.3 million of additional non-cash share-based compensation compared to the three months ended September 30, 2017.

Total Other (Expense) Income, Net

Total other income, net was \$4.9 million for the three months ended September 30, 2018, compared to total other expense, net of \$2.2 million for the three months ended September 30, 2017. The change between periods of \$7.1 million mainly resulted from decrease in non-cash loss on foreign currency exchange of \$3.3 million due to exchange rate fluctuations between the pound sterling, our functional currency, and the U.S. dollar, our reporting currency, an increase of \$0.7 million in interest income due to investments in marketable securities of the proceeds from our initial public offering, or IPO, and a \$3.0 million increase in realized foreign currency exchange rate fluctuations on securities maturing during the three months ended September 30, 2018.

Provision for income taxes

During the three months ended September 30, 2018, we recognized a total of \$83,000 in provision for income taxes. Provision for income taxes recognized during the three months ended September 30, 2018 resulted from the realization of foreign currency gains on maturing marketable securities and changes in unrealized gains on those securities. We did not recognize any provision for or benefit from income taxes in the three months ended September 30, 2017.

Comparison of the Nine-month Periods Ended September 30, 2018 and 2017

The following table summarizes our results of operations for the nine months ended September 30, 2018 and 2017:

	For the Nine Months Ended September 30,		Change
	2018	2017	
	(in thousands)		
Operating expenses:			
Research and development	\$ 21,961	\$ 10,275	\$ 11,686
General and administrative	9,119	3,432	5,687
Total operating expenses	31,080	13,707	17,373
Other income (expense):			
Interest and other income	1,887	61	1,826
Other income (expense), net	466	(2,258)	2,724
Total other income (expense), net	2,353	(2,197)	4,550
Loss before benefit from income taxes	(28,727)	(15,904)	(12,823)
Benefit from income taxes	(251)	—	(251)
Net loss	\$ (28,476)	\$ (15,904)	\$ (12,572)

Research and Development Expenses

Research and development expenses were \$22.0 million for the nine months ended September 30, 2018, compared to \$10.3 million for the nine months ended September 30, 2017. The increase of \$11.7 million resulted primarily from increases in program-related expenses of \$4.5 million for NSR-REP1 and \$4.2 million for NSR-RPGR, as well as a \$3.7 million increase in personnel-related costs and a \$1.9 million increase in the indirect research and development and pre-clinical expenses. These increased expenses were partially offset by an increase of \$2.6 million of research and development tax credits from HMRC. Research and development personnel-related costs increased due to an increase in headcount to support our growth and to assist in the further development of our product candidates and pipeline. The increase in research and development personnel-related costs includes \$1.0 million of additional non-cash share-based compensation compared to the same period in 2017.

General and Administrative Expenses

General and administrative expenses were \$9.1 million for the nine months ended September 30, 2018, compared to \$3.4 million for the nine months ended September 30, 2017. The increase of \$5.7 million is mainly due to a \$4.4 million increase in personnel-related costs and a \$1.3 million increase in consulting and professional fees, including increased legal, accounting and audit fees and insurance costs. General and administrative personnel-related costs increased due to an increase in headcount to support our increased research and development activities, growth of our company and our status as a public company. The increase in general and administrative personnel-related costs includes \$1.4 million of additional non-cash share-based compensation compared to the same period in 2017.

Total Other (Expense) Income, Net

Total other income, net was \$2.4 million for the nine months ended September 30, 2018, compared to total other expense, net of \$2.2 million for the nine months ended September 30, 2017. The change between periods of \$4.6 million mainly resulted from increase in non-cash loss on foreign currency exchange of \$0.2 million due to exchange rate fluctuations between the pound sterling, our functional currency, and the U.S. dollars, our reporting currency, offset by an increase of \$1.8 million in interest income due to investments in marketable securities of the proceeds from our initial public offering, or IPO, and a \$3.0 million increase in realized foreign currency exchange rate fluctuations on securities maturing during the three months ended September 30, 2018.

Benefit from income taxes

During the nine months ended September 30, 2018, we recognized a total of \$251,000 in benefit from income taxes. The benefit from income taxes recognized during the nine months ended September 30, 2018 resulted from the realization of foreign currency gains on maturing marketable securities and changes in the unrealized gains on those securities. We did not recognize any provision for or benefit from income taxes in the nine months ended September 30, 2017.

B. Liquidity and Capital Resources

Since our inception, we have not generated any revenue and have incurred operating losses and negative cash flows from our operations. We have funded our operations to date primarily with proceeds from the sale of ordinary shares and ADSs. Through September 30, 2018, we had received net cash proceeds of \$178.1 million from sales of our ordinary shares and ADSs. As of September 30, 2018, we had cash, cash equivalents and marketable securities of \$100.8 million. In October 2018, we completed a follow-on public offering of 4,600,000 ADSs resulting in estimated net proceeds of approximately \$77.1 million.

Cash Flows

The following table summarizes our cash flows for each of the periods presented:

	For the Nine Months Ended September 30,	
	2018	2017
	(in thousands)	
Net cash used in operating activities	\$ (28,658)	\$ (15,409)
Net cash used in investing activities	(54,761)	(107)
Net cash provided by financing activities	—	61,814
Effect of exchange rate changes on cash and cash equivalents and restricted cash	47	3,472
Net (decrease) increase in cash and cash equivalents and restricted cash	<u>\$ (83,372)</u>	<u>\$ 49,770</u>

Net Cash Used in Operating Activities

Net cash used in operating activities increased by \$13.2 million to \$28.7 million for the nine-month period ended September 30, 2018 from \$15.4 million for the same period in 2017. The increase in cash used in operations was primarily the result of the increase in research and development costs due to the ongoing advancement of our clinical trials and an increase in general and administrative expenses due to the expansion of our operations.

Net cash used in operating activities of \$28.7 million for the nine months ended September 30, 2018 comprised of a net loss of \$28.5 million, noncash items, net of \$2.6 million and a net cash outflow of \$2.8 million from changes in operating assets and liabilities. The noncash items consisted primarily of share-based compensation expense of \$3.0 million and accretion on marketable securities of \$0.5 million.

Net Cash Used in Investing Activities

For the nine months ended September 30, 2018, we used \$94.4 million of cash in investing activities for the purchases of marketable securities and received \$40.0 million from maturities of marketable securities. We also used \$0.4 million of cash in investing activities for the purchases of property and equipment, as compared to \$0.1 million used for the purchases of property and equipment in the nine months ended September 30, 2017.

Net Cash Provided by Financing Activities

During the nine months ended September 30, 2018 and 2017, cash provided by financing activities was \$0 and \$61.8 million, respectively, consisting of \$63.4 million net cash proceeds from our sale and issuance of ordinary shares in June 2017 and deferred offering costs of \$1.6 million related to our IPO completed in October 2017.

Credit Arrangement

We have a line of credit arrangement with a bank that allows us to submit payments up to £300,000 per month through the Bankers Automated Clearing Services system. The arrangement does not require us to pay any interest or fees and will remain effective until terminated by either party. There were no amounts outstanding under the arrangement at September 30, 2018 or December 31, 2017.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities as a public company, particularly as we advance the preclinical activities, manufacturing and clinical trials of our product candidates. Our expenses will also increase substantially if and as we:

- continue research and development of our gene therapy product candidates, including our STAR Phase 3 registrational trial for NSR-REP1, our ongoing XIRIUS trial for NSR-RPGR and the advancement of our preclinical product candidates;
- initiate clinical trials and preclinical studies for any additional product candidates that we may pursue in the future;
- prepare a potential future biologics license application, or BLA, and marketing authorization application, or MAA, for each of our retinal gene therapy product candidates;
- manufacture our product candidates in accordance with current good manufacturing practices, or cGMP, for clinical trials or potential commercial sales;
- establish and validate contracted commercial-scale cGMP manufacturing facilities;
- further develop our pipeline of retinal gene therapy product candidates;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain marketing approval;
- develop, maintain, expand and protect our intellectual property portfolio;
- acquire or in-license other product candidates and technologies;
- secure, maintain or obtain freedom to operate for any in-licensed technologies and products;
- expand our operational, financial and management systems and personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company in the United States, Europe and potentially other jurisdictions; and
- continue to operate as a public company.

We believe our existing cash, cash equivalents and marketable securities of \$100.8 million at September 30, 2018, along with the proceeds from the follow-on offering completed in October 2018, will enable us to fund our operating expenses and capital expenditure requirements for at least 12 months from the issuance date of our condensed consolidated financial statements filed as an exhibit to this Report on Form 6-K. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. As we progress with our development programs and the regulatory review process, we expect to incur significant commercialization expenses related to product manufacturing, pre-commercial activities and commercialization.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical product candidates, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on and could increase significantly as a result of many factors, including:

- the scope, progress, results and costs of laboratory testing, manufacturing, and preclinical and clinical development for our current and future product candidates;
- the costs, timing, and outcome of regulatory review of our product candidates;
- our ability to establish and maintain collaborations and license agreements on favorable terms, if at all;
- the costs of expanding our facilities to accommodate our expected growth in personnel;
- the extent to which we acquire or in-license other product candidates and technologies or establish collaboration, distribution or other marketing arrangements for our product candidates;
- the costs, timing and outcome of potential future commercialization activities, including manufacturing, marketing, sales and distribution for our product candidates for which we receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the sales price and availability of adequate third-party coverage and reimbursement for our product candidates, if and when approved; and

- the costs of operating as a public company in the United States.

Until such time, if ever, that we can generate product revenue sufficient to achieve profitability, we expect to finance our cash needs through equity offerings, debt financings, government or other third-party funding, marketing and distribution arrangements, and other collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, current ownership interests will be diluted, and the terms of such future issuances may include liquidation or other preferences that adversely affect the rights of our current stockholders. If we raise additional funds through government or third-party funding, collaboration agreements, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to raise additional funds when needed or on terms that are favorable to us, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with U.S. GAAP. The preparation of our condensed consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our condensed consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are 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. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

For further information on our critical and other significant accounting policies, see the notes to the condensed consolidated financial statements appearing elsewhere in this Report on Form 6-K and our Annual Report on Form 20-F for the year ended December 31, 2017 filed with the SEC on April 3, 2018. See Note 2 to the unaudited condensed consolidated financial statements in Exhibit 99.1 in this Report on Form 6-K for changes to our significant accounting policies since the year ended December 31, 2017.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of these estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- vendors in connection with preclinical development activities;
- CROs and investigative sites in connection with preclinical studies and clinical trials; and
- CMOs in connection with drug substance and drug product formulation of preclinical study and clinical trial materials.

We base our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple research institutions and CROs that conduct and manage preclinical studies and clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense.

Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of prepaid expenses accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Valuation of Share-Based Compensation

We have granted equity awards in the form of restricted share awards, or RSAs, restricted share units, or RSUs, and share options under our share-based compensation programs, which allows for share-based compensation in the form of share options, RSAs, RSUs and other share-based awards.

Share-based compensation is recognized as an expense in the financial statements based on the grant date fair value over the requisite service period. Currently, all awards granted to our employees and directors vest based on service conditions, and we use the straight-line method to allocate compensation expense to reporting periods. Beginning in the first quarter of 2017, we do not adjust share-based compensation for estimated forfeitures and account for forfeitures when they occur, which did not result in a material change in expense.

We use the Black-Scholes option pricing model to estimate the fair value of share options. This option-pricing model requires the input of various subjective assumptions, including the option's expected life and the price volatility of the underlying stock. Due to the lack of history, our estimated expected ADS price volatility is based on using an average of comparable companies in the same industry. Our expected term of options granted represents the weighted average period of time that options granted are expected to be outstanding giving consideration to vesting schedules and our historical exercise patterns. The risk-free rate for the expected term of the option is based on the U.S. Treasury yield curve in effect at the time of grant. The dividend yield of zero is based on the fact that we have never paid cash dividends and have no present intention to pay cash dividends.

Share-based compensation has been reported in our consolidated statements of operations as follows (in thousands):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2018	2017	2018	2017
Research and development	\$ 337	\$ 131	\$ 1,230	\$ 273
General and administrative	622	297	1,776	390
Total share-based compensation	\$ 959	\$ 428	\$ 3,006	\$ 663

We expect the impact of our share-based compensation expense for equity awards granted to employees, directors and other service providers to grow in future periods due to the potential increases in the value of our ordinary shares and headcount.

Income Taxes

We account for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in our tax returns. Deferred tax assets and liabilities are determined on the basis of the differences between the consolidated financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. We assess the likelihood that our deferred tax assets will be recovered in the future and, to the extent we believe, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

We account for uncertainty in income taxes by recognizing in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed as the amount of benefit to recognize in the consolidated financial statements. The amount of benefits that may be used is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision

for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate, as well as the related net interest and penalties. A full valuation allowance is recorded against our net deferred tax asset position.

As a company that carries out extensive research and development activities, we seek to benefit from one of two U.K. research and development tax credit cash rebate regimes, the Small and Medium-sized Enterprises R&D Tax Credit Scheme, or SME Scheme, and the Research and Development Expenditure scheme, or RDEC Scheme. Under the SME Scheme, our principal research subsidiary company, NightstaRx Limited, may be eligible to surrender the trading losses that arise from its research and development activities for a payable tax credit of up to approximately 33.4% of eligible research and development expenditures. Qualifying expenditures largely comprise employment costs for research staff, consumables and certain internal overhead costs incurred as part of research projects for which we do not receive income. Subcontracted research expenditures are eligible for a cash rebate of up to approximately 21.7%.

For certain periods where NightstaRx Limited is not eligible for the SME Scheme, NightstaRx Limited is eligible for the RDEC Scheme, whereby tax relief was given at 11% of allowable research and development costs and increased to 12% from January 1, 2018. The RDEC scheme is more restrictive with qualifying expenditures mainly comprising of employment cost for research staff.

Based on criteria established by HMRC, we expect a proportion of expenditures being carried out by NightstaRx Limited in relation to its pipeline research, clinical trials management and manufacturing development activities is likely to be eligible for inclusion within one of these two tax credit cash rebate regimes.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2, "Summary of Significant Accounting Policies," to our consolidated financial statements included in Exhibit 99.1 in this Report on Form 6-K.

JOBS Act

On April 5, 2012, the Jumpstart Our Business Startups Act, or the JOBS Act, was enacted. The JOBS Act provides that, among other matters, an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. As an emerging growth company, we have irrevocably elected not to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards and, as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth public companies.

In addition, we intend to rely on the other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, we are entitled to rely on certain exemptions as an "emerging growth company." As an emerging growth company, we are not required to, among other things, (i) provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b), (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis), and (iv) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer's compensation to median employee compensation. These exemptions will apply for a period of five years following the completion of our IPO or until we no longer meet the requirements of being an emerging growth company, whichever is earlier.

Foreign Private Issuer Status

As a foreign private issuer, we are exempt from a number of rules under the U.S. securities laws and Nasdaq Stock Market corporate governance rules and are permitted to file less information with the SEC than U.S. companies. This may limit the information available to holders of the ADSs.

We have determined that, as of June 30, 2018, we no longer qualified as a "foreign private issuer" under the rules and regulations of the SEC. We made the determination based on the fact that, as of June 30, 2018, more than 50 percent of our outstanding voting securities were directly or indirectly owned of record by residents of the United States and a majority of our executive officers were U.S. citizens or residents. As a result, beginning January 1, 2019, we anticipate that our future annual filings with the SEC will be made on Form 10-K (including our annual report for the year ending December 31, 2018) rather than on Form 20-F. In addition, commencing on January 1, 2019, we plan to expand our reporting consistent with that of a domestic U.S. filer, including filing

quarterly reports on Form 10-Q and current reports on Form 8-K. We will also be subject to SEC rules governing the solicitation of proxies, consents or authorizations in respect of a security registered under the Securities Exchange Act of 1934, or the Exchange Act; the provisions of Regulation Fair Disclosure, which regulate the selective disclosure of material information; and the sections of the Exchange Act requiring insiders to file public reports of their share ownership and trading activities and establishing insider liability for profits realized from any “short-swing” transactions in our equity securities. In addition, beginning January 1, 2019, we will also be subject to the Nasdaq Stock Market listing requirements applicable to domestic U.S. issuers.

C. Off Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

D. Tabular Disclosure of Contractual Obligations

Our contractual obligations, as of September 30, 2018, relate to the lease of our office space in the United States and the United Kingdom, which are non-cancellable. We have summarized in the table below our fixed contractual obligations as of September 30, 2018.

	<u>Premises Operating Leases</u>	
	(In thousands)	
2018	\$	140
2019		567
2020		426
2021		58
Total contractual obligations	<u>\$</u>	<u>1,191</u>

We enter into contracts in the normal course of business with CROs and other third vendors for clinical trials, clinical and commercial supply manufacturing, support for precommercial activities, research and development activities and other services and products for our operations. Our agreements generally provide for termination within 90 days of notice. Such agreements are cancelable contracts and not included in the table of contractual obligations and commitments. We have included as purchase obligations our commitments under agreements to the extent they are quantifiable and are not cancelable.

We may incur potential contingent payments upon our achievement of clinical, regulatory and commercial milestones, as applicable, or royalty payments that we may be required to make under license agreements we have entered into with various entities pursuant to which we have in-licensed certain intellectual property, including our license agreements with the University of Oxford and Oxford BioMedica plc. Due to the uncertainty of the achievement and timing of the events requiring payment under these agreements, the amounts to be paid by us are not fixed or determinable at this time.

E. Other Matters

None.