Adaptimmune Therapeutics PLC
Form 10-Q
November 06, 2018
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2018

OR

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

Commission File Number 001-37368

ADAPTIMMUNE THERAPEUTICS PLC

(Exact name of Registrant as specified in its charter)

England and Wales	**Not Applicable**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

60 Jubilee Avenue, Milton Park

Abingdon, Oxfordshire OX14 4RX

United Kingdom

(44) 1235 430000

(Address of principal executive offices)

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

Indicate by check mark whether the registrant has submitted electronically, every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). x Yes o No

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standard provided pursuant to Section 13(a) of the Exchange Act. x

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

As of November 2, 2018 the number of outstanding ordinary shares par value £0.001 per share of the Registrant is 627,422,698.

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General information

In this Quarterly Report on Form 10-Q (Quarterly Report), Adaptimmune, the Group, the Company, we, us and our refer to Adaptimmune Therapeutics plc and its consolidated subsidiaries, except where the context otherwise requires.

Information Regarding Forward-Looking Statements

This Quarterly Report contains forward-looking statements that are based on our current expectations, assumptions, estimates and projections about us and our industry. All statements other than statements of historical fact in this Quarterly Report are forward-looking statements.

These forward-looking statements are subject to known and unknown risks, uncertainties, assumptions and other factors that could cause our actual results of operations, financial condition, liquidity, performance, prospects, opportunities, achievements or industry results, as well as those of the markets we serve or intend to serve, to differ materially from those expressed in, or suggested by, these forward-looking statements. These forward-looking statements are based on assumptions regarding our present and future business strategies and the environment in which we expect to operate in the future. Important factors that could cause those differences include, but are not limited to:

- our ability to successfully advance and fund our MAGE-A10, MAGE-A4 and AFP SPEAR T-cells through clinical development and the timing within which we can recruit patients and treat patients in our clinical trials;

- our ability to successfully and reproducibly manufacture SPEAR T-cells in order to meet patient demand;

- our ability to further develop our commercial manufacturing process for our SPEAR T-cells, transfer such commercial process to third party contract manufacturers, if required, and for such third party contract manufacturers or ourselves to manufacture SPEAR T-cells to the quality and on the timescales we require;

- the scope and timing of performance of our ongoing collaboration with GlaxoSmithKline (GSK) including nomination of further targets by GSK under the collaboration;

- our ability to successfully advance our SPEAR T-cell technology platform to improve the safety and effectiveness of our existing SPEAR T-cell candidates and to submit Investigational New Drug Applications, or INDs, for new SPEAR T-cell candidates;

- the rate and degree of market acceptance of T-cell therapy generally, and of SPEAR T-cells;

- government regulation and approval, including, but not limited to, the expected regulatory approval timelines for SPEAR T-cells and the level of pricing and reimbursement for SPEAR T-cells, if approved for marketing;

- the existence of any third party patents preventing further development of any SPEAR T-cells, including, any inability to obtain appropriate third party licenses, or enforcement of patents against us or our collaborators;

- our ability to obtain granted patents covering any SPEAR T-cells and to enforce such patents against third parties;

- volatility in equity markets in general and in the biopharmaceutical sector in particular;

- fluctuations in the price of materials and bought-in components;

- our relationships with suppliers, contract manufacturing organizations or CROs and other third-party providers including fluctuations in the price of materials and services, ability to obtain reagents particularly where such reagents are only available from a single source, and performance of third party providers;

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- increased competition from other companies in the biotechnology and pharmaceutical industries including where such competition impacts ability to recruit patients in to clinical trials;

- claims for personal injury or death arising from the use of SPEAR T-cell candidates;

- our ability to attract and retain qualified personnel;

- a change in our status as an emerging growth company under the Jumpstart Our Business Start-ups Act of 2012, or JOBS Act; and

- additional factors that are not known to us at this time.

Additional factors that could cause actual results, financial condition, liquidity, performance, prospects, opportunities, achievements or industry results to differ materially include, but are not limited to, those discussed under Risk Factors in Part II, Item 1A in this Quarterly Report and in our other filings with the Securities and Exchange Commission (the SEC). Additional risks that we may currently deem immaterial or that are not presently known to us could also cause the forward-looking events discussed in this Quarterly Report not to occur. The words believe, may, will, estimate, continue, anticipate, intend, expect and similar words are intended to identify estimates and forward-looking statements. Estimates and forward-looking statements speak only at the date they were made, and we undertake no obligation to update or to review any estimate and/or forward-looking statement because of new information, future events or other factors. Estimates and forward-looking statements involve risks and uncertainties and are not guarantees of future performance. Our future results may differ materially from those expressed in these estimates and forward-looking statements. In light of the risks and uncertainties described above, the estimates and forward-looking statements discussed in this Quarterly Report might not occur, and our future results and our performance may differ materially from those expressed in these forward-looking statements due to, inclusive of, but not limited to, the factors mentioned above. Because of these uncertainties, you should not make any investment decision based on these estimates and forward-looking statements.

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements.

ADAPTIMMUNE THERAPEUTICS PLC

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share data)

	September 30, 2018	December 31, 2017
Assets		
Current assets		
Cash and cash equivalents	$ 153,081	$ 84,043
Marketable securities - available-for-sale debt securities	84,652	124,218
Accounts receivable, net of allowance for doubtful accounts of $- and $-	2,031	206
Other current assets and prepaid expenses (including current portion of clinical materials)	21,841	21,716
Total current assets	**261,605**	**230,183**
Restricted cash	4,163	4,253
Clinical materials	4,205	4,695
Property, plant and equipment, net	38,137	40,679
Intangibles, net	1,515	1,337
Total assets	**309,625**	**281,147**
Liabilities and stockholders equity		
Current liabilities		
Accounts payable	3,907	8,378
Accrued expenses and other accrued liabilities	24,314	27,201
Deferred revenue	1,345	38,735
Total current liabilities	**29,566**	**74,314**
Other liabilities, non-current	3,904	3,849
Total liabilities	**33,470**	**78,163**
Stockholders equity		
Common stock - Ordinary shares par value £0.001, 701,103,126 authorized and 627,222,076 issued and outstanding (2017: 701,103,126 authorized and 562,119,334 issued and outstanding)	939	854
Additional paid in capital	570,355	455,401
Accumulated other comprehensive loss	(12,813)	(21,641)
Accumulated deficit	(282,326)	(231,630)
Total stockholders equity	**276,155**	**202,984**
Total liabilities and stockholders equity	**$ 309,625**	**$ 281,147**

See accompanying notes to unaudited condensed consolidated financial statements.

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ADAPTIMMUNE THERAPEUTICS PLC

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2018	**2017**	**2018**	**2017**
Development revenue	**$** 1,678	**$** 27,185	**$** 18,912	**$** 33,563
License revenue	39,114		39,114	
Total Revenue	**40,792**	**27,185**	**58,026**	**33,563**
Operating expenses				
Research and development	(23,484)	(24,034)	(75,500)	(62,240)
General and administrative	(10,290)	(8,111)	(32,785)	(22,284)
Total operating expenses	**(33,774)**	**(32,145)**	**(108,285)**	**(84,524)**
Operating income (loss)	**7,018**	**(4,960)**	**(50,259)**	**(50,961)**
Interest income	606	705	1,805	1,465
Other (expense) income, net	(2,249)	3,602	(10,525)	7,242
Income (loss) before income taxes	**5,375**	**(653)**	**(58,979)**	**(42,254)**
Income taxes	(133)	(225)	(362)	(621)
Net income (loss) attributable to ordinary shareholders	**$ 5,242**	**$ (878)**	**$ (59,341)**	**$ (42,875)**
Net income (loss) per ordinary share				
Basic	**$ 0.01**	**$**	**$ (0.10)**	**$ (0.08)**
Diluted	**0.01**		**(0.10)**	**(0.08)**
Weighted average shares outstanding:				
Basic	582,004,954	561,239,864	573,796,275	516,352,141
Diluted	621,764,201	561,239,864	573,796,275	516,352,141

See accompanying notes to unaudited condensed consolidated financial statements.

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ADAPTIMMUNE THERAPEUTICS PLC

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(In thousands)

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
Net income (loss)	**$ 5,242**	**$ (878)**	**$ (59,341)**	**$ (42,875)**
Other comprehensive income (loss), net of tax				
Foreign currency translation adjustments, net of tax of $-, $-, $- and $-	1,521	(1,623)	5,103	(2,932)
Unrealized holding gains (losses) on available-for-sale debt securities, net of tax of $-, $-, $- and $-	85	(1,578)	1,252	(2,874)
Reclassification adjustment for losses on available-for-sale debt securities included in net loss, net of tax of $-, $-, $- and $-			2,473	
Total comprehensive income (loss) for the period	**$ 6,848**	**$ (4,079)**	**$ (50,513)**	**$ (48,681)**

See accompanying notes to unaudited condensed consolidated financial statements.

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ADAPTIMMUNE THERAPEUTICS PLC

UNAUDITED CONDENSED CONSOLIDATED STATEMENT OF CHANGE IN EQUITY

(In thousands, except share data)

	Common stock	Common stock	Additional paid in capital	Accumulated other comprehensive loss: Accumulated foreign currency translation adjustments	Accumulated other comprehensive loss: Accumulated unrealized losses on available-for-sale debt securities	Accumulated deficit	Total stockholders equity
Balance as of 1 January 2018 (under previous guidance)	562,119,334	$ 854	$ 455,401	$ (17,867)	$ (3,774)	$ (231,630)	$ 202,984
Cumulative effect of applying new accounting standards						8,645	8,645
Balance as of 1 January 2018 (adjusted)		854	455,401	(17,867)	(3,774)	(222,985)	211,629
Net loss						(59,341)	(59,341)
Issuance of shares upon exercise of stock options	5,102,742	7	2,926				2,933
Issuance of shares upon completion of registered direct offering	60,000,000	78	99,575				99,653
Other comprehensive loss before reclassifications							
Foreign currency translation adjustments				5,103			5,103
Unrealized holding gains on available-for-sale debt securities, net of tax of $-					1,252		1,252
Reclassification from accumulated other comprehensive loss of losses on available-for-sale debt securities included in net loss, net of tax of $-					2,473		2,473
Share-based compensation expense			12,453				12,453
Balance as of September 30, 2018	**627,222,076**	**$ 939**	**$ 570,355**	**$ (12,764)**	**$ (49)**	**$ (282,326)**	**$ 276,155**

See accompanying notes to unaudited condensed consolidated financial statements.

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ADAPTIMMUNE THERAPEUTICS PLC

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Nine months ended September 30,	
	2018	**2017**
Cash flows from operating activities		
Net loss	$ (59,341)	$ (42,875)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	5,248	3,418
Amortization	464	267
Share-based compensation expense	12,453	7,956
Realized loss on available-for-sale debt securities	2,473	
Unrealized foreign exchange gain (losses)	4,921	(6,886)
Other	262	606
Changes in operating assets and liabilities:		
(Increase) decrease in receivables and other operating assets	(4,140)	4,180
Decrease (increase) in non-current operating assets	490	(484)
(Decrease) increase in payables and deferred revenue	(35,533)	859
Net cash used in operating activities	**(72,703)**	**(32,959)**
Cash flows from investing activities		
Acquisition of property, plant and equipment	(3,823)	(22,791)
Acquisition of intangibles	(666)	(288)
Proceeds from disposal of property, plant and equipment		550
Maturity of short-term deposits		40,645
Investment in short-term deposits		(18,000)
Maturity or redemption of marketable securities	114,988	7,032
Investment in marketable securities	(75,545)	(93,218)
Net cash provided by (used in) investing activities	**34,954**	**(86,070)**
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs $347 and $4,774	99,653	103,167
Proceeds from exercise of stock options	2,933	401
Net cash provided by financing activities	**102,586**	**103,568**
Effect of currency exchange rate changes on cash, cash equivalents and restricted cash	4,111	2,223
Net increase (decrease) in cash, cash equivalents and restricted cash	68,948	(13,238)
Cash, cash equivalents and restricted cash at start of period	88,296	162,796
Cash, cash equivalents and restricted cash at end of period	**$ 157,244**	**$ 149,558**

See accompanying notes to unaudited condensed consolidated financial statements.

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ADAPTIMMUNE THERAPEUTICS PLC

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1 - General

Adaptimmune Therapeutics plc is registered in England and Wales. Its registered office is 60 Jubilee Avenue, Milton Park, Abingdon, Oxfordshire, OX14 4RX, United Kingdom. Adaptimmune Therapeutics plc and its subsidiaries (collectively Adaptimmune or the Company) is a clinical-stage biopharmaceutical company focused on providing novel cell therapies to patients, particularly in solid tumors. The Company s comprehensive and proprietary SPEAR (Specific Peptide Enhanced Affinity Receptor) T-cell platform enables it to identify cancer targets, find and genetically engineer T-cell receptors (TCRs), and produce therapeutic candidates for administration to patients. Using its affinity engineered TCRs, the Company aims to become a fully integrated cell therapy company and to have the first TCR T-cell approved.

The Company is subject to a number of risks similar to other biopharmaceutical companies in the early stage of clinical development including, but not limited to, the need to obtain adequate additional funding, possible failure of preclinical programs or clinical programs, the need to obtain marketing approval for its SPEAR T-cells, competitors developing new technological innovations, the need to successfully commercialize and gain market acceptance of the Company s SPEAR T-cells, the need to develop a suitable commercial manufacturing process and protection of proprietary technology. If the Company does not successfully commercialize any of its SPEAR T-cells, it will be unable to generate product revenue or achieve profitability. The Company had an accumulated deficit of $282.3 million as of September 30, 2018.

Note 2 - Summary of Significant Accounting Policies

(a) Basis of presentation

The condensed consolidated interim financial statements of Adaptimmune Therapeutics plc and its subsidiaries and other financial information included in this Quarterly Report are unaudited and 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 on consolidation.

The unaudited condensed interim financial statements presented in this Quarterly Report should be read in conjunction with the consolidated financial statements and accompanying notes included in the Company s Annual Report on Form 10-K filed with the SEC on March 15, 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. The Company s significant accounting policies are described in Note 2 to those consolidated financial statements.

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.

On January 1, 2018, the Company adopted new guidance on revenue recognition, which has been codified within Accounting Standard Codification Topic 606, *Revenue from Contracts with Customers* (ASC 606). The comparative financial information for the three and nine months ended September 30, 2017 and as of December 31, 2017 has not been restated.

(b) Use of estimates in interim financial statements

The preparation of interim financial statements, in conformity with U.S. GAAP and SEC regulations, requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the consolidated financial statements and reported amounts of revenues and expenses during the reporting period. Estimates and assumptions are primarily made in relation to the valuation of share options, valuation allowances relating to deferred tax assets, revenue recognition, estimating clinical trial expenses and estimating reimbursements from R&D tax and expenditure credits. If actual results differ from the Company s estimates, or to the extent these estimates are adjusted in future periods, the Company s results of operations could either benefit from, or be adversely affected by, any such change in estimate.

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(c) Fair value measurements

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. The fair value hierarchy prioritizes valuation inputs based on the observable nature of those inputs. The hierarchy defines three levels of valuation inputs:

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

Level 2 Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly

Level 3 Unobservable inputs that reflect the Company s own assumptions about the assumptions market participants would use in pricing the asset or liability

The carrying amounts of the Company s cash and cash equivalents, restricted cash, accounts receivable, accounts payable and accrued expenses approximate fair value because of the short-term nature of these instruments. The fair value of marketable securities, which are measured at fair value on a recurring basis is detailed in Note 6, *Fair value measurements*.

(d) Revenue from contracts with customers

On January 1, 2018, the Company adopted new guidance on revenue recognition, which has been codified within ASC 606. The accounting policy applicable from January 1, 2018 is described below and further details on the transition are available in Note 2(f). The comparative financial information for the three and nine months ended September 30, 2017 and as of December 31, 2017 has not been restated and is prepared in accordance with the accounting policies that are described in Note 2 to the consolidated financial statements included in the Annual Report.

The Company has one contract with a customer, which is the GSK Collaboration and License Agreement. The GSK Collaboration and License Agreement consists of multiple performance obligations, including the transition of the NY-ESO SPEAR T-cell program to GSK, the development of a second target, PRAME, and an exclusive license (the NY-ESO License) to research, develop, and commercialize the Company s NY-ESO SPEAR T-cell therapy program.

In September 2017, GSK exercised its option to obtain the NY-ESO License and the first tranche ($26.6 million or £20 million) of the option exercise payment became payable to the Company. In connection with the option exercise, in September 2017, the GSK Agreement was amended to, among other things, include a detailed transition plan identifying the steps needed to complete transition of the Investigational New Drug Application (IND) process with the Food and Drug Administration (FDA) for the NY-ESO SPEAR T-cell program to GSK. On July 23, 2018, the transition activities were substantially completed and the IND for the NY-ESO SPEAR T-cell program transferred to GSK.

The aggregate transaction price consists of an upfront payment of $42,123,000 received in June 2014, development milestones achieved of $66,404,000, an option exercise fee of $39,785,000. There was no variable consideration at September 30, 2018.

The Company determines the variable consideration to be included in the transaction price by estimating the most-likely amount that will be received and then applies a constraint to reduce the consideration to the amount which is probable of being received. The determination of whether a milestone is probable includes consideration of the following factors:

- Whether achievement of a development milestone is highly susceptible to factors outside the entity s influence, such as milestones involving the judgment or actions of third parties, including regulatory bodies or the customer;

- Whether the uncertainty about the achievement of the milestone is not expected to be resolved for a long period of time;

- Whether the Company can reasonably predict that a milestone will be achieved based on previous experience; and.

- The complexity and inherent uncertainty underlying the achievement of the milestone.

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The Company may also be entitled to development and regulatory milestones upon successful development of the NY-ESO SPEAR T-cells by GSK. The amount of the milestones is dependent on the nature of the product that GSK further develops, the indication relevant to any product and the territory in relation to which the milestone is achieved. These amounts have not been included within the transaction price as of September 30, 2018 because they are not considered probable. The Company may also receive commercial milestones based on the indication and the territory and mid-single to low double-digit royalties on worldwide net sales. These amounts have not been included within the transaction price as of September 30, 2018 because they are sales or usage based royalties promised in exchange for a license of intellectual property, which will be recognized when the subsequent sale or usage occurs.

The Company may be entitled to one small-dollar development milestone for the pre-clinical development of PRAME, which is not included in the transaction price because it is not considered probable.

The payments to the Company under the contract are typically due upon achievement of milestones and within standard payment terms (approximating to 45 days). The contract does not include a significant financing component.

The upfront payment of $42,123,000 was allocated between the performance obligations using the Company s best estimate of the relative selling price. In determining the best estimate, the Company considered internal pricing objectives it used in negotiating the contract, together with internal data regarding the cost and margin of providing services for each deliverable taking into account the different stage of development of each development program included in the contract. The variable consideration is allocated to the performance obligation to which it relates.

The amount of the transaction price allocated to the performance obligation is recognized as or when the Company satisfies the performance obligation. The Company satisfies the performance obligations relating to the transition of the NY-ESO SPEAR T-cell program and the development of a second target, PRAME, over time and recognizes revenue based on an estimate of the percentage of completion of the project determined based on the costs incurred on the project as a percentage of the total expected costs. The Company considers that this depicts the progress of the project, where the significant inputs are internal project resource and third-party clinical and manufacturing costs. The determination of the percentage of completion requires the Company to estimate the costs-to-complete the project. The Company makes a detailed estimate of the costs-to-complete on an annual basis as part of the Company s budgeting process, which is re-assessed every reporting period based on the latest project plan and discussions with project teams. If a change in facts or circumstances occurs, the estimate is adjusted and the revenue is recognized based on the revised estimate. The difference between the cumulative revenue recognized based on the previous estimate and the revenue recognized based on the revised estimate is recognized as an adjustment to revenue in the period in which the change in estimate occurs.

The Company has determined that the performance obligation relating to the NY-ESO License is recognized at a point-in-time, upon commencement of the license, which occurred in September 2018.

The Company recognizes a contract asset, when the value of satisfied (or part satisfied) performance obligations is in excess of the payment due to the Company, and deferred revenue (contract liability) when the amount of unconditional consideration is in excess of the value of satisfied (or part satisfied) performance obligations. Once a right to receive consideration is unconditional, that amount is presented as a receivable.

The timing and amount of milestone payments for the development and transition of the NY-ESO SPEAR T-cell program are intended to be commensurate with the cost and effort involved in achieving the milestones and therefore a contract asset would typically arise. The Company received $26,610,000 of the option exercise fee in September 2017, which was included in deferred revenue at January 1, 2018 and this amount

was recognized as revenue, along with a further option exercise fee of $13,175,000, in September 2018 upon commencement of the license.

Changes in deferred revenue typically arise due to:

- adjustments arising from a change in the estimate of the cost to complete the project, which results in a cumulative catch-up adjustment to revenue that affects the corresponding contract asset or deferred revenue;

- a change in the estimate of the transaction price due to changes in the assessment of whether variable consideration is constrained because it is not considered probable of being received;

- the recognition of revenue arising from deferred revenue; and

- the reclassification of amounts to receivables when a right to consideration to becomes unconditional.

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A change in the estimate of variable consideration constrained (for example, if a development milestone becomes probable of being received) could result in a significant change in the revenue recognized and deferred revenue.

(e) Share-based compensation

The Company has awarded share options to nonemployees for consultancy services. Prior to January 1, 2018, these share options were measured at the fair value of the goods/services received or the fair value of the equity instrument issued, whichever was more reliably measured, and then remeasured at the then-current fair values at each reporting date until the share options have vested and recognized as an expense over the requisite service period. The Company has adopted new guidance with effect from January 1, 2018, which requires that non-employee share-based payment transactions are measured at the grant-date fair value and are no longer remeasured at the then-current fair values at each reporting date until the share options have vested. Further details on the transition are available in Note 2(f).

(f) New accounting pronouncements

Adopted in the period

Revenue from Contracts with Customers

In May 2014, the FASB issued ASU 2014-09 - *Revenue from Contracts with Customers* (ASU 2014-09) which requires a new approach to revenue recognition and, in March, April, May and December 2016, the FASB issued additional clarification related to this guidance. This guidance has been codified within ASC 606. The core principle of the guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve that core principle, an entity should apply the following steps:

Step 1: Identify the contract(s) with a customer.

Step 2: Identify the performance obligations in the contract.

Step 3: Determine the transaction price.

Step 4: Allocate the transaction price to the performance obligations in the contract.

Step 5: Recognize revenue when (or as) the entity satisfies a performance obligation.

The Company has adopted the guidance using the modified retrospective approach, with the cumulative effect of initially applying the guidance recognized as an adjustment to the opening balance of equity at January 1, 2018. Therefore, the comparative information has not been adjusted and continues to be reported under previous guidance. The quantitative impact of the changes on the statement of operations for the three months ended September 30, 2018 are set out below (in thousands):

	Under previous revenue guidance	Adjustment	As reported
Revenue	$ 56,999	$ (16,207)	$ 40,792
Operating income	**23,225**	**(16,207)**	**7,018**
Income before income taxes	**21,582**	**(16,207)**	**5,375**
Net income attributable to ordinary shareholders	**21,449**	**(16,207)**	**5,242**
Net income per ordinary share - Basic	**0.04**		**0.01**
Net income per ordinary share - Diluted	**0.03**		**0.01**

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The quantitative impacts of the changes on the statement of operations for the nine months ended September 30, 2018 are set out below (in thousands):

	Under previous revenue guidance	Adjustment	As reported
Revenue	$ 69,262	$ (11,236)	$ 58,026
Operating loss	**(39,023)**	**(11,236)**	**(50,259)**
Loss before income taxes	**(47,743)**	**(11,236)**	**(58,979)**
Net loss attributable to ordinary shareholders	**(48,105)**	**(11,236)**	**(59,341)**
Net loss per ordinary share - Basic and diluted	**(0.08)**		**(0.10)**

The quantitative impacts of the changes on the balance sheet as of September 30, 2018 are set out below (in thousands):

	Under previous revenue guidance	Adjustment	As reported
Deferred revenue	$ 1,592	$ (247)	$ 1,345
Total current liabilities	**29,813**	**(247)**	**29,566**
Total liabilities	**33,717**	**(247)**	**33,470**
Accumulated other comprehensive loss	(15,651)	2,838	(12,813)
Accumulated deficit	(279,735)	(2,591)	(282,326)
Total stockholders equity	**275,908**	**247**	**276,155**

The quantitative impacts of the changes on the statement of cash flows for the nine months ended September 30, 2018 are set out below (in thousands):

	Under previous revenue guidance	Adjustment	As reported
Net loss	$ (48,105)	$ (11,236)	$ (59,341)
Decrease in payables and deferred revenue	(46,769)	11,236	(35,533)

The cumulative effect of adopting the guidance on our financial statements at January 1, 2018 is a credit to opening accumulated losses and corresponding decrease in deferred revenue of $8,645,000.

The adoption of ASC 606 has had a material impact on the Company s financial statements due to the following:

- Under the GSK Collaboration and License Agreement, the Company will receive non-substantive milestone payments in the future upon achievement of specified development milestones. Non-substantive milestones are currently included within the transaction price upon achievement of the milestone and recognized over the period during which the Company is delivering services to GSK. ASC 606 requires an entity to estimate the amount of consideration to which the entity will be entitled in exchange for transferring the promised goods or services to a customer. This includes an estimate of variable consideration to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. This results in certain milestone payments being recognized earlier under ASC 606 than under existing guidance, if it is considered probable that the milestone will be achieved.

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- Upfront payments and non-refundable milestone payments were previously recognized in revenue using the proportional performance model ratably over the period that services are rendered, unless another attribution method more closely approximates the delivery of the goods or services to the customer. ASC 606 requires an entity to recognize revenue using a measure of progress that depicts the transfer of control of the goods or services to the customer. The Company considers that an input measure, such as costs incurred, relative to the total expected inputs is the appropriate measure to depict the transfer of control of the services under the GSK Collaboration and License Agreement, which impacts the timing of its revenue from the GSK Collaboration and License Agreement.

The Company has applied the practical expedient for contracts that were modified before the adoption of ASU 2014-09, which permits entities to not retrospectively restate the contract for those contract modifications. Instead, the aggregate effect of all modifications that occurred before the adoption date has been reflected when:

a. Identifying the satisfied and unsatisfied performance obligations

b. Determining the transaction price

c. Allocating the transaction price to the satisfied and unsatisfied performance obligations.

ASC 606 requires an entity to provide financial statement users with sufficient information to understand the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. To help achieve this objective, ASC 606 requires certain quantitative and qualitative disclosures included within Note 2(d) and Note 3, which are more extensive than the previously required revenue disclosures.

Recognition and Measurement of Financial Assets and Financial Liabilities

The Company has adopted ASU 2016-01 - *Financial Instruments - Overall: Recognition and Measurement of Financial Assets and Financial Liabilities*, 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 did not have a material impact on the Company s consolidated financial statements.

Improvements to Nonemployee Share-Based Payment Accounting

The Company has adopted ASU 2018-07 *Compensation Stock Compensation Improvements to Nonemployee Share-Based Payment Accounting*, which simplifies the accounting for nonemployee share-based payment transactions by expanding the scope of existing guidance on employee share-based payment transactions to include nonemployee transactions. Under the simplified guidance, nonemployee share-based payment transactions are measured at the grant-date fair value and are no longer remeasured at the then-current fair values at each reporting date until the share options have vested. The guidance has been adopted using a modified-retrospective approach, which requires that unsettled equity-classified awards for which a measurement date has not been established are measured at the adoption date fair value. The guidance did not have a material impact on the Company s consolidated financial statements.

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To be adopted in future periods

Accounting for Leases

In February 2016, the FASB issued ASU 2016-02 - Leases. The guidance requires that lessees recognize a lease liability, which is a lessee s obligation to make lease payments arising from a lease, measured on a discounted basis; and a right-of-use asset, which is an asset that represents the lessee s right to use, or control the use of, a specified asset for the lease term at the commencement date. The guidance also makes targeted improvements to align lessor accounting with the lessee accounting model and guidance on revenue from contracts with customers. The guidance is effective for the fiscal year beginning January 1, 2019, including interim periods within that fiscal year. Early application is permitted. 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. The FASB has issued ASU 2018-11 - Leases, which, in addition to the existing requirements to transition, permits an entity to transition to the new guidance by recognizing a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption without restating prior periods and the Company intends to adopt the guidance in this manner. The Company s assessment of the impact of the guidance on its consolidated financial statements is ongoing. We anticipate that the adoption of the guidance will have a material impact on the Company s consolidated balance sheet due to the recognition of a lease liability and corresponding right-of-use asset. We have not finalized the assessment of the amount of the lease liability and right-of-use asset but we anticipate that it will result in the recording of lease assets of approximately $20 million and a corresponding lease liability of approximately $25 million.

Measurement of Credit Losses on Financial Instruments

In June 2016, the FASB issued ASU 2016-13 *Financial Instruments Credit losses*, which replaces the incurred loss impairment methodology for financial instruments in current 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 the guidance on its consolidated financial statements.

Customer s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract

In August 2018, the FASB issued 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, which aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal use software license). 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 may be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. The Company is currently evaluating the impact of the guidance on its consolidated financial statements.

Changes to the Disclosure Requirements for Fair Value Measurement

In August 2018, the FASB issued ASU 2018-13 Fair Value Measurement (Topic 820) - Disclosure Framework Changes to the Disclosure Requirements for Fair Value Measurement, which modifies the disclosure requirements on fair value measurements in Topic 820, Fair Value Measurement. The guidance is effective for the fiscal year beginning January 1, 2020, including interim periods within that fiscal year. Early application is permitted. Certain amendments apply prospectively with the all other amendments applied retrospectively to all periods presented upon their effective date. The Company is currently evaluating the impact of the guidance on its consolidated financial statements.

(g) Related parties

In the three and nine months ended September 30, 2017, research and development expenses includes purchases of $67,000 and $781,000 from Immunocore Ltd (Immunocore). As described in Note 2(w) to the consolidated financial statements included in the Annual Report, the Company no longer considered Immunocore to be a related party with effect from January 1, 2018.

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(h) **Accumulated other comprehensive income (loss)**

The following amounts were reclassified out of other comprehensive income during the three and nine months ended September 30, 2018 (in thousands):

Component of Accumulated Other Comprehensive Income	Amount reclassified: Three months ended September 30, 2018	Amount reclassified: Nine months ended September 30, 2018	Affected line item in the Statement of Operations
Unrealized gains (losses) on available-for-sale securities			
Reclassification adjustment for losses on available-for-sale debt securities	$	$ 2,473	Other income (expense), net

Note 3 Revenue

Revenue from contracts with customers arises from one customer, which is GSK, in one geographic location, which is the United Kingdom.

Revenue comprises the following categories (in thousands):

	Three months ended September 30, 2018	Nine months ended September 30, 2018
Development	$ 1,678	$ 18,912
Licenses	39,114	39,114
	$ 40,792	**$ 58,026**

The deferred revenue balance as of January 1, 2018 and September 30, 2018 is as follows (in thousands):