Adaptimmune Therapeutics PLC Form 10-Q November 10, 2016 <u>Table of Contents</u>

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, 2016

OR

0 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.)

101 Park Drive, Milton Park

Abingdon, Oxfordshire OX14 4RY

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post 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, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filerO Non-accelerated filerX Accelerated filerO Smaller reporting companyO

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 10, 2016 the number of outstanding ordinary shares par value £0.001 per share of the Registrant is 424,711,900.

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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 Adaptimm Therapeutics plc and its consolidated subsidiaries, except where the context otherwise requires. Adaptimmune and SPEAR are registered trademarks of Adaptimmune.

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 advance our NY-ESO SPEAR T-cells to a point where GlaxoSmithKline, or GSK, exercises the option to license the product;

• our ability to successfully advance our MAGE-A10 and AFP SPEAR T-cells through clinical development and to advance our MAGE-A4 SPEAR T-cells into clinical development;

• our ability to further develop our commercial manufacturing process for our SPEAR T-cells and transfer such commercial process to third party contract manufacturers;

• the success, cost and timing of our product development activities and clinical trials;

• 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 our SPEAR T-cells;

• government regulation and approval, including, but not limited to, the expected regulatory approval timelines for TCR therapeutic candidates;

• patents, including, any inability to obtain third party licenses, legal challenges thereto or enforcement of patents against us;

• the level of pricing and reimbursement for our SPEAR T-cells, if approved for marketing;

• general economic and business conditions or conditions affecting demand for our SPEAR T-cells in the markets in which we operate, both in the United States and internationally;

- volatility in equity markets in general and in the biopharmaceutical sector in particular;
- fluctuations in the price of materials and bought-in components;

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- our relationships with suppliers and other third-party providers;
- increased competition from other companies in the biotechnology and pharmaceutical industries;
- claims for personal injury or death arising from the use of our SPEAR T-cell candidates;
- changes in our business strategy or development plans, and our expected level of capital expenses;
 - our ability to attract and retain qualified personnel;

• regulatory, environmental, legislative and judicial developments including a regulatory requirement to place any clinical trials on hold or to suspend any trials;

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

• the change in our status from reporting as a foreign private issuer to reporting as a U.S. domestic company now using Securities Act and Exchange Act U.S. domestic company forms;

• uncertainty about the future relationship between the United Kingdom and the European Union; 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 on Form 10-Q 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 expect and similar words are intended to identify estimates and forv intend, words believe, may, will, estimate, continue, anticipate, 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.

PART I FINANCIAL INFORMATION

Item 1. Financial Statements.

ADAPTIMMUNE THERAPEUTICS PLC

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share data)

| | : | September 30, 2016 | December 31, 2015 |
|--|----|---|---|
| Assets | | | |
| Current assets | | | |
| Cash and cash equivalents | \$ | 140,440 | \$ 194,263 |
| Short-term deposits | | 47,064 | 54,620 |
| Accounts receivable, net of allowance for doubtful accounts of \$- and \$- (including amounts due from related parties of \$- and \$2) | | | 744 |
| Other current assets and prepaid expenses (including current portion of clinical materials) | | 12,040 | 13,420 |
| Total current assets | | 199,544 | 263,047 |
| | | , i i i i i i i i i i i i i i i i i i i | , i i i i i i i i i i i i i i i i i i i |
| Restricted cash | | 4,146 | 4,508 |
| Clinical materials | | 2,741 | 4,736 |
| Property, plant and equipment, net | | 15,086 | 13,225 |
| Intangibles, net | | 1,127 | 305 |
| - | | | |
| Total assets | \$ | 222,644 | \$ 285,821 |
| | | | |
| Liabilities and Stockholders equity | | | |
| Current liabilities | | | |
| Accounts payable (including amounts due to related parties of \$125 and \$-) | \$ | 3,193 | \$ 7,884 |
| Accrued expenses and other accrued liabilities (including amounts due to related parties of \$27 and \$288) | | 9,954 | 7,518 |
| Deferred revenue | | 9,514 | 12,487 |
| Total current liabilities | | 22,661 | 27,889 |
| | | , í | , í |
| Deferred revenue, less current portion | | 19,335 | 22,939 |
| Other liabilities | | 644 | |
| | | | |
| Total liabilities | | 42,640 | 50,828 |
| Contingencies and commitments Note 8 | | | |
| | | | |
| Stockholders equity | | | |
| Common stock - Ordinary shares par value £0.001, 574,711,900 authorized and | | | |
| 424,711,900 issued and outstanding (2015: 574,711,900 authorized and | | | |

| 424,711,900 issued and outstanding (2015: 574,711,900 authorized and | | |
|--|----------|---------|
| 424,711,900 issued and outstanding) | 682 | 682 |
| Additional paid in capital | 339,188 | 332,363 |
| Accumulated other comprehensive loss | (13,788) | (8,139) |

| Accumulated deficit Total stockholders equity | (146,078) 180,004 | (89,913) 234,993 |
|---|-----------------------------|----------------------------|
| Total liabilities and stockholders equity | \$ 222,644 \$ | 285,821 |

See accompanying notes to unaudited condensed consolidated financial statements.

ADAPTIMMUNE THERAPEUTICS PLC

UNAUDITED CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS

(in thousands, except share and per share data)

| | Three month Septembe 2016 | led 2015 | Nine months Septembe 2016 | ed 2015 |
|--|---------------------------------|---------------|---------------------------------|----------------|
| Revenue | \$ 2,416 | \$ 4,948 | \$ 5,662 | \$ 10,459 |
| Operating expenses | , | , | , | , |
| Research and development | (15,610) | (8,853) | (46,942) | (23,838) |
| General and administrative | (5,424) | (4,403) | (16,863) | (11,643) |
| Total operating expenses (including purchases | | | | |
| from related parties, net of reimbursements | | | | |
| of \$523, \$1,352, \$1,852 and \$2,606) | (21,034) | (13,256) | (63,805) | (35,481) |
| Operating loss | (18,618) | (8,308) | (58,143) | (25,022) |
| Interest income | 289 | 235 | 839 | 533 |
| Other (expense) income, net | (61) | 1,851 | 1,595 | 1,952 |
| Loss before income taxes | (18,390) | (6,222) | (55,709) | (22,537) |
| Income taxes | (104) | (20) | (456) | (218) |
| Net loss | (18,494) | (6,242) | (56,165) | (22,755) |
| Deemed dividend on convertible preferred shares | | | | (8,663) |
| Net loss attributable to ordinary shareholders | \$ (18,494) | \$ (6,242) | \$ (56,165) | (31,418) |
| | | | | |
| Net loss per ordinary share basic and diluted (Note | | | | |
| 4) | \$ (0.04) | \$ (0.01) | \$ (0.13) | \$ (0.10) |
| Weighted average shares outstanding, basic and diluted | 424,711,900 | 424,711,900 | 424,711,900 | 307,943,490 |

See accompanying notes to unaudited condensed consolidated financial statements.

ADAPTIMMUNE THERAPEUTICS PLC

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)

| | Three months ended September 30, | | | Nine months ended September 30, | | |
|--|-------------------------------------|----|------------|------------------------------------|----|----------|
| | 2016 | | 2015 | 2016 | | 2015 |
| Net loss | \$ (18,494) | \$ | (6,242) \$ | (56,165) | \$ | (22,755) |
| Other comprehensive (loss) income, net of | | | | | | |
| tax | | | | | | |
| Foreign currency translation adjustments, net of | | | | | | |
| tax of \$-, \$-, \$- and \$- | (779) | | (2,973) | (5,649) | | (2,440) |
| | | | | | | |
| Total comprehensive loss for the period | \$ (19,273) | \$ | (9,215) \$ | (61,814) | \$ | (25,195) |

See accompanying notes to unaudited condensed consolidated financial statements.

ADAPTIMMUNE THERAPEUTICS PLC

UNAUDITED CONDENSED CONSOLIDATED CASH FLOW STATEMENTS

(in thousands)

| | Nine mont Septem 2016 | 2015 |
|--|--|---|
| Cash flows from operating activities | | |
| Net loss | \$ (56,165) | \$ (22,755) |
| Adjustments to reconcile net income to net cash used in operating activities: | | |
| Depreciation | 2,290 | 828 |
| Amortization | 122 | 25 |
| Share-based compensation expense | 6,825 | 7,694 |
| Unrealized foreign exchange (gains) losses | (1,943) | 329 |
| Changes in operating assets and liabilities: | | |
| Increase in receivables and other operating assets | (912) | (5,327) |
| Decrease in non-current operating assets | 2,041 | |
| (Decrease) increase in payables and deferred revenue | (2,796) | 5,385 |
| Net cash used in operating activities | (50,538) | (13,821) |
| Cash flows from investing activities Acquisition of property, plant and equipment Acquisition of intangibles Proceeds from sale of property, plant and equipment Maturity of short-term deposits Investment in short-term deposits Investment in restricted cash Net cash provided by (used in) investing activities Cash flows from financing activities Proceeds from issuance of common stock upon initial public offering, net of issuance costs | (4,840) (1,024) 49,497 (42,837) 796 | (10,095) (31) 122 (28,594) (3,065) (41,663) |
| of \$13,387 | | 175,989 |
| Net cash provided by financing activities | | 175,989 |
| Effect of currency exchange rate changes on cash and cash equivalents | (4,081) | (4,951) |
| Net (decrease) increase in cash and cash equivalents | (53,823) | 115,554 |
| Cash and cash equivalents at start of period | 194,263 | 101,664 |
| Cash and cash equivalents at end of period | \$ 140,440 | \$ 217,218 |

See accompanying notes to unaudited condensed consolidated financial statements.

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 101 Park Drive, Milton Park, Abingdon, Oxfordshire, OX14 4RY, United Kingdom. Adaptimmune Therapeutics plc and its subsidiaries (collectively Adaptimmune or the Company) is a clinical-stage biopharmaceutical company focused on novel cancer immunotherapy products based on its proprietary SPEAR (Specific Peptide Enhanced Affinity Receptor) T-cell platform. It has developed a comprehensive proprietary platform that enables it to identify cancer targets, find and genetically engineer T-cell receptors (TCRs), and produce TCR therapeutic candidates for administration to patients. The Company engineers TCRs to increase their affinity to cancer specific peptides in order to destroy cancer cells in patients.

The Company is subject to a number of risks similar to other biopharmaceutical companies in the early stage including, but not limited to, the need to obtain adequate additional funding, possible failure of preclinical programs or clinical trials, 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 \$146.1 million as of September 30, 2016.

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 Item 9.01 of the Company s Current Report on Form 8-K filed with the SEC on July 8, 2016. The balance sheet as of December 31, 2015 was derived from audited consolidated financial statements included in Item 9.01 of the

Company s Current Report on Form 8-K filed with the SEC on July 8, 2016 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.

(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.

(c) Reclassification

In the three months ended September 30, 2016, an immaterial error in the classification of legal expenses for patent applications, which had been incorrectly classified as research and development expenditure in prior periods, was identified. The Company has reclassified the legal expenses relating to patents of \$149,000 in the six months ended June 30, 2016 and \$65,000 and \$215,000 in the three and nine months ended September 30, 2015, respectively, from research and development expenses to general and administrative expenses to conform the presentation of prior periods to the current period presentation.

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The Company has also identified that certain property and insurance costs relating to research and development facilities have been misclassified as general and administrative expenses in prior periods resulting in an immaterial error in the financial statements in prior periods. The Company has reclassified expenses relating to property and insurance used in research and development of \$1,373,000 in the six months ended June 30, 2016 and \$641,000 and \$1,397,000 in the three and nine months ended September 30, 2015, respectively, from general administrative expenses to research and development expenses to conform the presentation of prior periods to the current period presentation.

The operating expenses for comparative periods as previously reported and as presented after the reclassification are as follows (in thousands):

| | Three months ended September 30, 2015 | | | | Nine months ended September 30, 2015 | | | |
|----------------------------|--|-------|-----------------------|----|---|------|-----------------------|--|
| | reviously eported | recla | After assification | А | s previously reported | recl | After assification | |
| Research and development | \$ 8,277 | \$ | 8,853 | \$ | 22,656 | | 23,838 | |
| General and administrative | 4,979 | | 4,403 | | 12,825 | | 11,643 | |
| Total operating expenses | \$ 13,256 | \$ | 13,256 | \$ | 35,481 | \$ | 35,481 | |

(d) **Revenue**

Revenue is recognized when earned and realized or realizable, which is generally when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the seller s price to the buyer is fixed or determinable, and collectability is reasonably assured. Where applicable, all revenues are stated net of value added and similar taxes.

The Company s revenue currently arises from a Collaboration and License Agreement with GSK entered into in June 2014 and amended in February 2016 (the GSK Collaboration and License Agreement), which requires the Company to provide multiple deliverables to GSK. The Company recognizes revenue for arrangements with multiple deliverables by identifying the separable deliverables within the arrangement, whereby a deliverable is considered separable if it has value to the customer on a standalone basis. Contingent deliverables, such as the right to nominate further development targets, which represent a substantive option (i.e. the customer is not required or compelled to purchase the optional products or services) and not priced at a significant and incremental discount are not considered to be a deliverable at inception of the arrangement.

The non-contingent arrangement consideration is allocated between the separate deliverables using the relative selling price. The relative selling price is determined using vendor-specific objective evidence (VSOE), if available, third party evidence if VSOE is not available, or a best estimate of the standalone selling price if neither VSOE nor third party evidence is available. The best estimate of the selling price is estimated after considering all reasonably available information, including market data and conditions, entity-specific factors such as the cost structure of the deliverable, internal profit and pricing objectives and the stage of development, if appropriate. Revenue allocated to each deliverable is recognized as it is delivered. Where delivery occurs over time, revenue is systematically recognized over the period which the Company will be providing services.

Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue in the Company s consolidated balance sheet. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue in current liabilities. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as

deferred revenue, less current portion.

Milestone payments which are non-refundable, non-creditable and contingent on achieving clinical milestones are recognized as revenues either on achievement of such milestones if the milestones are considered substantive or over the period the Company has continuing performance obligations, if the milestones are not considered substantive. When determining if a milestone is substantive, the Company considers the following factors:

- The degree of certainty in achieving the milestone,
- The frequency of milestone payments,
- The Company s efforts, which result in achievement of the milestone,
- The amount of the milestone payment relative to the other deliverables and payment terms, and
- Whether the milestone payment is related to future performance or deliverables.

(e) Intangible assets

Intangibles includes intellectual property (IP) rights for licensed technology used in research and development with an alternative future use, which are recorded at cost and amortized over the estimated useful life of the related product. The weighted-average amortization period for IP rights for licensed technology at September 30, 2016 is seven years.

Intangibles also include acquired computer software licenses, which are recorded at cost and amortized over the estimated useful lives of the software.

Intangibles are assessed for impairment whenever events or changes in circumstances indicate that an asset s carrying amount may not be recoverable.

(f) Related parties

Adaptimmune and Immunocore Limited (Immunocore) have a shared history, some overlap in board membership (which will cease effective on December 31, 2016) and substantial overlap in shareholder base. The Company has entered into several agreements with Immunocore regarding the shared use of certain services including licensing and research collaboration. The Company believes its agreements are structured on an arm s length basis.

During the periods presented Immunocore and the Company have invoiced each other in respect of a transitional services agreement (under which certain staff resources and other administration services are supplied by each company to the other company for a transitional period). Additionally, during the periods presented Immunocore has invoiced the Company in respect of services provided under a target collaboration agreement (under which certain target identification services were provided by Immunocore), costs related to joint patents and in respect of property rent.

Immunocore and the Company have mutually agreed to end their target collaboration agreement effective March 1, 2017. The companies entered into the target collaboration agreement in January 2015, to facilitate joint target identification activities and specific T-cell cloning work, and jointly create a target database of peptides. Both companies will continue to have access to the target database and associated target information even after termination of the target collaboration agreement. The Company now has its own dedicated target identification capability and as a result has no requirement for ongoing target collaboration with Immunocore. The companies decision to end the target collaboration agreement has no impact on other agreements between them. In particular, the companies will continue to co-own the patents, patent applications and know-how relating to the underlying core TCR technology under a previously executed and irrevocable assignment and license agreement.

(g) New accounting pronouncements

Adopted with effect from January 1, 2016

Customer s accounting for fees paid in a cloud computing arrangement

The Company has adopted Accounting Standards Update (ASU) 2015-05 - *Internal-Use Software: Customer s Accounting for Fees Paid in a Cloud Computing Arrangement* issued by the Financial Accounting Standards Board (FASB) in April 2015 which clarifies a customer s accounting for fees paid in a cloud computing arrangement. The guidance provides a customer with guidance on whether a cloud computing arrangement includes a software license and clarifies that the customer should account for the software license element of the arrangement consistent with the acquisition of other software licenses. If a cloud computing arrangement does not include a software license, the customer should account for the arrangement as a service contract. The guidance has been adopted prospectively to all arrangements entered into or materially modified after January 1, 2016. The adoption of this guidance did not have any impact on the financial position, results of operations or cash flows.

To be adopted in future periods

Classification of certain cash receipts and cash payments

In August 2016, the FASB issued ASU 2016-15 - *Statement of Cash Flows - Classification of Certain Cash Receipts and Cash Payments*, which provides clarification on the classification of certain cash receipts and cash payments where current U.S. GAAP either is unclear or does not include specific guidance. The amendments are effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted. The amendments must be adopted using a retrospective transition method to each period presented. The Company does not believe the adoption of the guidance will have a material impact on the consolidated financial statements.

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 Company is currently evaluating the impact of the guidance on the consolidated financial statements.

Recognition and measurement of financial assets and financial liabilities

In January 2016, the FASB issued 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 is effective for the fiscal year beginning January 1, 2018, including interim periods within that fiscal year. The Company does not believe the adoption of the guidance will have a material impact on the consolidated financial statements.

Revenue from contracts with customers

In May 2014, the FASB issued ASU 2014-09 - *Revenue from Contracts with Customers* which supersedes nearly all existing revenue recognition guidance under U.S. GAAP. 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. Additionally, qualitative and quantitative disclosures are required about customer contracts, significant judgments and changes in judgments, and assets recognized from the costs to obtain or fulfill a contract. The guidance is effective for the fiscal year beginning January 1, 2018, including interim reporting periods within that reporting period. Earlier application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period presented, subject to certain practical expedients, or retrospectively with the cumulative effect of initially applying the guidance recognized at the date of initial application. The Company is currently assessing the impact of adopting the guidance. The Company intends to adopt the guidance in the fiscal year beginning January 1, 2018.

In March 2016, the FASB issued ASU 2016-08 - Revenue from Contracts with Customers: Principal versus Agent Considerations (Reporting Revenue Gross versus Net), which provided further clarification on the principal versus agent considerations included within the new revenue

recognition guidance. This guidance will be effective upon the adoption of the new revenue recognition guidance. The Company is currently assessing the impact of adopting the guidance.

In April 2016, the FASB issued ASU 2016-10 - *Revenue from Contracts with Customers: Identifying Performance Obligations and Licensing*, which provided further clarification on identifying performance obligations in a contract with a customer and provided implementation guidance on whether licenses are satisfied at a point in time or over time. This guidance will be effective upon the adoption of the new revenue recognition guidance. The Company is currently assessing the impact of adopting the guidance.

In May 2016, the FASB issued ASU 2016-12 - *Revenue from Contracts with Customers: Narrow-Scope Improvements and Practical Expedients*, which provided further clarification on the new revenue recognition guidance. This clarification did not change the core principles but provided narrow-scope improvements to the guidance and certain practical expedients available upon transitioning to the guidance. The Company is currently assessing the impact of adopting the guidance.

Note 3 Revenue

GSK Collaboration and License Agreement

Revenue represents recognized income from the GSK Collaboration and License Agreement. The GSK Collaboration and License Agreement contains the following significant deliverables, which are separate accounting units: (i) the development of, and option to obtain an exclusive license to, the Company s NY-ESO SPEAR T-cells, and (ii) the development of, and option to obtain an exclusive license to a second target nominated by GSK. In addition, GSK also has the right to nominate three additional target peptides, excluding those where the Company has already initiated development of a SPEAR T-cell candidate, which is not considered to be a deliverable at the inception of the arrangement because it represents a substantive option not priced at a significant and incremental discount. The Company received an upfront payment of \$42.1 million (£25 million) in June 2014 and has achieved various non-substantive development milestones resulting in milestone payments of \$14.4 million in the six months ended December 31, 2015 and \$7.2 million in the year ended June 30, 2015. No milestones were achieved in the nine months ended September 30, 2016. The Company is entitled to further non-substantive milestone payments based on the achievement of specified development milestones by the Company. When, and if, GSK exercises its option to obtain an exclusive license to a target, an option exercise fee will be payable and the Company will be entitled to further development and commercialization milestone payments based on achievement of specified milestones by GSK. The non-contingent arrangement consideration was allocated between the separate deliverables 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 GSK Collaboration and License Agreement together with internal data regarding the cost of providing services for each deliverable.

In addition to the development milestones, the Company is entitled to royalties from GSK on all GSK sales of TCR therapeutic products licensed under the agreement, varying between a mid-single-digit percentage and a low-double-digit percentage of net sales. No royalties have been received as of September 30, 2016. Sales milestones also apply once any TCR therapeutic covered by the GSK Collaboration and License Agreement is on the market.

The GSK Collaboration and License Agreement is effective until all payment obligations expire. The agreement can also be terminated on a collaboration program-by-collaboration program basis by GSK for lack of feasibility or inability to meet certain agreed requirements. Both parties have rights to terminate the agreement for material breach upon 60 days written notice or immediately upon insolvency of the other party. GSK has additional rights to terminate either the agreement or any specific license or collaboration program on provision of 60 days notice to us. The Company also has rights to terminate any license where GSK ceases development or withdraws any licensed TCR therapeutic in specified circumstances.

In February 2016, the terms of the GSK Collaboration and License Agreement were expanded to accelerate the development of the Company s NY-ESO SPEAR T-cells towards registrational trials in synovial sarcoma, as well as the exploration of development of NY-ESO SPEAR T-cells in myxoid round-cell liposarcoma. The amendment also provides the opportunity for up to eight combination studies using NY-ESO SPEAR T-cells and increases the potential development milestones that the Company is eligible to receive. These development milestones will be allocated to the separate standalone deliverables within the arrangement once the milestone is achieved.

The revenue recognized to date relates to the upfront fee and non-substantive development milestones payments received, which are being recognized using the proportional performance model in revenue systematically over the period in which the Company is delivering services under the GSK Collaboration and License Agreement, which is determined to be the period until

GSK s option to obtain licenses expires. We regularly review and monitor the performance of the GSK Collaboration and License Agreement to determine the period over which we will be delivering services to GSK. The Company recognized revenue of \$2,416,000 and \$4,948,000 in the three months ended September 30, 2016 and 2015, respectively, and \$5,662,000 and \$10,459,000 in the nine months ended September 30, 2016 and 2015, respectively.

In the three months ended June 30, 2016, the estimate of the period over which the Company will deliver services under the GSK Collaboration and License Agreement was increased. This change in estimate resulted in a decrease in revenue of \$2,785,000 and \$336,000 in the three months ended June 30, 2016 and September 30, 2016, respectively. The change in estimate will also result in a decrease in revenue of \$336,000 and \$1,344,000 in the three months ended December 31, 2016 and the year ended December 31, 2017, respectively, and an increase in revenue of \$1,793,000, \$1,187,000 and \$1,642,000 in the years ended December 31, 2018, 2019 and 2020, respectively, compared to the revenue that would have been recognized based on previous estimates.

Note 4 Earnings (loss) per share

Basic earnings (loss) per share is determined by dividing net income or loss attributable to ordinary shareholders by the weighted average number of ordinary shares outstanding during the period. Diluted earnings (loss) per share is determined by dividing net income or loss attributable to ordinary shareholders by the weighted average number of ordinary shares outstanding during the period, adjusted for the dilutive effect of all potential ordinary shares that were outstanding during the period. Potentially dilutive shares are excluded when the effect would be to increase diluted earnings per share or reduce diluted loss per share.

The following table reconciles the numerator and denominator in the basic and diluted earnings (loss) per share computation (in thousands):

| | Three mon Septem | | Nine months ended September 30, | | | |
|--|---------------------|----|------------------------------------|-------------|----|-------------|
| | 2016 | | 2015 | 2016 | | 2015 |
| Numerator for basic and diluted EPS | | | | | | |
| Net loss | \$ (18,494) | \$ | (6,242) \$ | (56,165) | \$ | (22,755) |
| Deemed dividend on convertible preferred | | | | | | |
| shares | | | | | | (8,663) |
| Net loss attributable to ordinary | | | | | | |
| shareholders | \$ (18,494) | \$ | (6,242) \$ | (56,165) | \$ | (31,418) |
| | | | | | | |
| Denominator for basic and diluted EPS | | | | | | |
| Weighted average number of shares used to calculate basic and diluted loss per share | 424,711,900 | | 424,711,900 | 424,711,900 | | 307,943,490 |

The effects of the following potentially dilutive equity instruments have been excluded from the diluted loss per share calculation because they would have an antidilutive effect on the loss per share for the period:

| | | Three months ended September 30, | | ns ended er 30, |
|--|------------|-------------------------------------|------------|--------------------|
| | 2016 | 2015 | 2016 | 2015 |
| Weighted average number of share options | 47,392,118 | 31,432,048 | 44,951,407 | 27,541,366 |

Note 5 Property, plant and equipment, net

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

| Computer equipment | \$ 1,592 \$ | 1,182 |
|-------------------------------|-----------------|---------|
| Laboratory equipment | 11,648 | 11,016 |
| Office equipment | 230 | 258 |
| Leasehold improvements | 1,476 | 1,631 |
| Assets under construction | 4,069 | 1,147 |
| | 19,015 | 15,234 |
| Less accumulated depreciation | (3,929) | (2,009) |
| | \$ 15,086 \$ | 13,225 |

Depreciation expense was \$779,000 and \$463,000 for the three months ended September 30, 2016 and 2015, respectively, and \$2,290,000 and \$828,000 for the nine months ended September 30, 2016 and 2015, respectively.

Note 6 Intangible assets, net

Intangible assets, net consisted of the following (in thousands):

| | Septem 20 | , | 2015 cember 31, |
|-----------------------------------|--------------|----------|-----------------|
| Acquired software licenses | \$ | 1,234 \$ | 399 |
| IP rights for licensed technology | | 90 | |
| | | 1,324 | 399 |
| Less accumulated amortization | | (197) | (94) |
| | \$ | 1,127 \$ | 305 |

Amortization expense was \$40,000 and \$25,000 for the three months ended September 30, 2016 and 2015, respectively, and \$122,000 and \$25,000 for the nine months ended September 30, 2016 and 2015, respectively. The estimated aggregate amortization expense in respect of these assets for each of the five years ended September 30, 2021 is \$410,000, \$364,000, \$309,000, \$13,000 and \$13,000, respectively.

Note 7 Accrued expenses and other current liabilities

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

| | Sep | September 30, Dec 2016 | | December 31, 2015 |
|--|-----|---------------------------|----|----------------------|
| Accrued purchases and clinical trial expenditure | \$ | 8,846 | \$ | 6,406 |
| Accrued employee compensation and benefits payable | | 572 | | 368 |