

Adaptimmune Therapeutics PLC
Form 10-Q
November 10, 2016
[Table of Contents](#)

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

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

Commission File Number 001-37368

ADAPT IMMUNE THERAPEUTICS PLC

(Exact name of Registrant as specified in its charter)

England and Wales

Not Applicable

Edgar Filing: Adaptimmune Therapeutics PLC - Form 10-Q

(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. Yes 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). Yes 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 filer
Non-accelerated filer

Accelerated filer
Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes 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.

Edgar Filing: Adaptimmune Therapeutics PLC - Form 10-Q

Table of Contents

PART I FINANCIAL INFORMATION

<u>Item 1.</u>	<u>Financial Statements:</u>	
	<u>Unaudited Condensed Consolidated Balance Sheets as of September 30, 2016 and December 31, 2015</u>	5
	<u>Unaudited Condensed Consolidated Statement of Operations for the three and nine months ended September 30, 2016 and 2015</u>	6
	<u>Unaudited Condensed Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2016 and 2015</u>	7
	<u>Unaudited Condensed Consolidated Cash Flow Statements for the nine months ended September 30, 2016 and 2015</u>	8
	<u>Notes to the Condensed Consolidated Financial Statements</u>	9
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	18
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	32
<u>Item 4.</u>	<u>Controls and Procedures</u>	33
<u>PART II OTHER INFORMATION</u>		
<u>Item 1.</u>	<u>Legal Proceedings</u>	34
<u>Item 1A.</u>	<u>Risk Factors</u>	34
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	73
<u>Item 3.</u>	<u>Defaults Upon Senior Securities</u>	73
<u>Item 4.</u>	<u>Mine Safety Disclosures</u>	73
<u>Item 5.</u>	<u>Other Information</u>	73
<u>Item 6.</u>	<u>Exhibits</u>	74
<u>Signatures</u>		76

Table of Contents

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. 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;

Edgar Filing: Adaptimmune Therapeutics PLC - Form 10-Q

- 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;
- 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;

Table of Contents

- 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 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.

Table of Contents**PART I FINANCIAL INFORMATION****Item 1. Financial Statements.****ADAPT IMMUNE 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
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
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)	682	682
Additional paid in capital	339,188	332,363
Accumulated other comprehensive loss	(13,788)	(8,139)

Edgar Filing: Adaptimmune Therapeutics PLC - Form 10-Q

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

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

ADAPT IMMUNE THERAPEUTICS PLC

UNAUDITED CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS

(in thousands, except share and per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	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.

Table of Contents

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.

Table of Contents

ADAPT IMMUNE THERAPEUTICS PLC

UNAUDITED CONDENSED CONSOLIDATED CASH FLOW STATEMENTS

(in thousands)

	Nine months ended September 30,	
	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
<i>Changes in operating assets and liabilities:</i>		
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	(4,840)	(10,095)
Acquisition of intangibles	(1,024)	(31)
Proceeds from sale of property, plant and equipment		122
Maturity of short-term deposits	49,497	
Investment in short-term deposits	(42,837)	(28,594)
Investment in restricted cash		(3,065)
Net cash provided by (used in) investing activities	796	(41,663)
Cash flows from financing activities		
Proceeds from issuance of common stock upon initial public offering, net of issuance costs 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.

Table of Contents

ADAPT IMMUNE 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

Edgar Filing: Adaptimmune Therapeutics PLC - Form 10-Q

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.

Table of Contents

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	
	As previously reported	After reclassification	As previously reported	After reclassification
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.

Table of Contents

(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.

Table of Contents

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. The guidance can be adopted retrospectively to each prior 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

Edgar Filing: Adaptimmune Therapeutics PLC - Form 10-Q

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.

Table of Contents

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

Edgar Filing: Adaptimmune Therapeutics PLC - Form 10-Q

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.

Table of Contents**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 months ended September 30,		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,		Nine months ended September 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):

September 30, 2016	December 31, 2015
-----------------------	----------------------

Edgar Filing: Adaptimmune Therapeutics PLC - Form 10-Q

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.

Table of Contents**Note 6 Intangible assets, net**

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

	September 30, 2016	December 31, 2015
Acquired software licenses	\$ 1,234	\$ 399
IP rights for licensed technology	90	399
	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):

	September 30, 2016	December 31, 2015
Accrued purchases and clinical trial expenditure	\$ 8,846	\$ 6,406
Accrued employee compensation and benefits payable	572	368
Other current liabilities	536	744
	\$ 9,954	\$ 7,518

Note 8 Contingencies and commitments*Leases*

Future minimum lease payments under operating leases at September 30, 2016 are presented below (in thousands):

Edgar Filing: Adaptimmune Therapeutics PLC - Form 10-Q

	September 30, 2016
2016	\$ 471
2017	2,560
2018	2,819
2019	3,455
2020	3,331
2021	3,208
Thereafter	18,091
	\$ 33,935

The Company leases property under operating leases expiring through 2027. Lease expenses amounted to \$327,000 and \$433,000 for the three months ended September 30, 2016 and 2015, respectively and \$1,159,000 and \$836,000 for the nine months ended September 30, 2016 and 2015, respectively, which are included within research and development and general and administrative expenses in the Company's consolidated statement of operations.

In July 2015, the Company entered into a long-term lease agreement, with break clauses, for offices and research facilities in Philadelphia, U.S. In October 2016, the lease commenced upon completion of construction. The related lease commitments are included in the table above.

In September 2015, the Company entered into an agreement for a 25-year lease, with break clauses, for a research and development facility in Oxfordshire, U.K. In October 2016, the Company entered into the lease for that facility following the completion of construction. The related lease commitments are included in the table above.

Capital commitments

At September 30, 2016, the Company had commitments for capital expenditure totaling \$15,455,000, which the Company expects to incur within one year.

Table of Contents

Purchase commitments for clinical materials, clinical trials and contract manufacturing

At September 30, 2016, the Company had non-cancellable commitments for purchase of clinical materials, executing and administering clinical trials, and for contract manufacturing of \$54,611,000, of which the Company expects to pay \$25,850,000 within one year, \$20,292,000 in one to three years, \$7,659,000 in three to five years, and \$810,000 after five years. The timing of these payments vary depending on the rate of progress of development and clinical trial enrollment rates. Our subcontracted costs for clinical trials and contract manufacturing were \$6,032,000 and \$3,406,000 for the three months ended September 30, 2016 and 2015, respectively, and \$15,908,000 and \$8,040,000 for the nine months ended September 30, 2016 and 2015, respectively.

MD Anderson Strategic Alliance

On September 26, 2016, the Company announced that it had entered into a multi-year strategic alliance with The University of Texas MD Anderson Cancer Center (MD Anderson) designed to expedite the development of T-cell therapies for multiple types of cancer. The Company and MD Anderson will collaborate in a number of studies including clinical and preclinical development of Adaptimmune's SPEAR T-cell therapies targeting MAGE-A10 and future clinical stage first and second generation SPEAR T-cell therapies such as MAGE-A4 across a number of cancers, including bladder, lung, ovarian, head and neck, melanoma, esophageal and gastric cancers. The Company will make payments to MD Anderson as certain milestones are achieved and these costs will be expensed to research and development as MD Anderson renders the services under the strategic alliance. These milestones are included within Purchase commitments for clinical materials, clinical trials and contract manufacturing above.

Universal Cells Research, Collaboration and License Agreement

On November 25, 2015, the Company entered into a Research, Collaboration and License Agreement relating to gene editing and HLA-engineering technology with Universal Cells, Inc. (Universal Cells). The Company paid an upfront license and start-up fee of \$2.5 million to Universal Cells in November 2015 and a milestone payment of \$3.0 million in February 2016. Further milestone payments of up to \$44 million are payable if certain development and product milestones are achieved. Universal Cells would also receive a profit-share payment for the first product, and royalties on sales of other products utilizing its technology. The upfront and start-up fee was expensed to research and development when incurred.

ThermoFisher License Agreement

In 2012, the Company entered into a series of license and sub-license agreements with Life Technologies Corporation, part of ThermoFisher Scientific, Inc. (ThermoFisher Scientific) that provide the Company with a field-based exclusive license under certain intellectual property rights owned or controlled by ThermoFisher Scientific. The Company paid upfront license fees of \$1.0 million relating to the license and sublicense agreements and has an obligation to pay minimum annual royalties (in the tens of thousands of U.S. dollars prior to licensed product approval and thereafter at a level of 50% of running royalties in the previous year), milestone payments and a low single-digit running royalty payable on

Edgar Filing: Adaptimmune Therapeutics PLC - Form 10-Q

the net selling price of each licensed product. The upfront payment made in 2012 was expensed to research and development when incurred. Subsequent milestone payments have been recognized as an intangible asset due to the technology having alternative future use in research and development projects at the time of the payment. The minimum annual royalties have been expensed as incurred.

On June 16, 2016, the Company entered into a supply agreement with ThermoFisher Scientific for the supply of the Dynabeads® CD3/CD28 technology. The Dynabeads® CD3/CD28 technology is designed to isolate, activate and expand human T-cells, and is being used in the manufacturing of the Company's affinity enhanced T-cell therapies. The supply agreement runs until December 31, 2025. Under the supply agreement the Company is required to purchase its requirements for CD3/CD28 magnetic bead product exclusively from ThermoFisher Scientific for a period of 5 years and there are also minimum purchasing obligations, which are included within Purchase commitments for clinical materials, clinical trials and contract manufacturing set forth above. ThermoFisher Scientific has the right to terminate the supply agreement for material breach or insolvency.

Table of Contents**Note 9 Share-based compensation**

The following table shows the total share-based compensation expense included in the consolidated statements of operations (thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
Research and development	\$ 1,170	\$ 389	\$ 3,438	\$ 3,887
General and administrative	1,116	1,012	3,387	3,807
	\$ 2,286	\$ 1,401	\$ 6,825	\$ 7,694

There were 2,414,576 share options granted in the three months ended September 30, 2016. No share options were granted in the three months ended September 30, 2015 and 17,758,373 and 11,069,577 share options granted in the nine months ended September 30, 2016 and 2015, respectively. The weighted average fair value of stock options granted was \$0.74 in the three months ended September 30, 2016 and \$0.74 and \$0.94 in the nine months ended September 30, 2016 and 2015, respectively.

The fair value of the share options granted during the period was calculated using the Black-Scholes option-pricing model using the following assumptions:

	Nine months ended September 30,	
	2016	2015
Expected term (years)	5 years	5 years
Expected volatility	68-73%	60%
Risk free rate	0.17-1.07%	1.03-1.39%
Expected dividend yield	0%	0%

The expected term of the option is based on management judgment. Forfeitures are recognized when they occur. To date, our forfeitures have been minimal. Due to the Company's lack of sufficient history as a publicly traded company, management's estimate of expected volatility is based on the average volatilities of seven public companies with similar attributes to the Company. The risk free rate is based on the Bank of England's estimates of gilt yield curve as of the respective grant dates.

At September 30, 2016, there were 3,074,600 share options granted to nonemployees outstanding. These share options are measured at the current fair values at each reporting date until the share options have vested and recognized in the consolidated statement of operation over the requisite service period. The total share based payment expense relating to these options was a benefit of \$24,000 and \$450,000 in the three months ended September 30, 2016 and 2015, respectively, and a benefit of \$139,000 and an expense of \$2,056,000 in the nine months ended September 30, 2016 and 2015,

respectively.

Table of Contents

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

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 and Forward-Looking Statements in this Quarterly Report on Form 10-Q. 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 consolidated financial statements and accompanying notes included elsewhere in this report, the Company's consolidated financial statements and accompanying notes for the period ended December 31, 2015 included in Item 9.01 of the Company's Current Report on Form 8-K filed with the SEC on July 8, 2016, the Company's Transition Report on Form 20-F for the six months ended December 31, 2015, prepared under IFRS and presented in pounds sterling and the Company's Annual Report on Form 20-F for the year ended June 30, 2015, prepared under IFRS and presented in pounds sterling.

Update on Clinical Pipeline Progress

We have three SPEAR T-cell therapies either in clinical trials or with an Investigational New Drug Application, or IND, open. An IND for a further SPEAR T-cell directed to the MAGE-A4 target, the MAGE-A4 SPEAR T-cell, is anticipated to be filed in late 2016 or first quarter of 2017. In addition, preclinical and preparatory work for second generation SPEAR T-cells has continued.

Our Sponsored NY-ESO SPEAR T-cell trials

Our first SPEAR T-cell targets the NY-ESO-1 target peptide and is currently in clinical trials in the United States. Pilot studies are ongoing in synovial sarcoma, multiple myeloma, non small cell lung cancer (NSCLC) and ovarian indications and a pilot trial in myxoid round cell liposarcoma (MRCLS) is due to start in late 2016 or early 2017.

Our NY-ESO SPEAR T-cell therapy has received orphan drug designation from the FDA and European Commission for the treatment of soft tissue sarcoma. The European Medicines Agency, or EMA, has also granted PRIME regulatory access for the Company's NY-ESO SPEAR T-cell therapy for the synovial sarcoma indication. NY-ESO SPEAR T-cells continue to demonstrate a generally acceptable benefit:risk profile in all treated patient populations to date. The most common (>15%) adverse events considered by investigators to be at least possibly related to our NY-ESO SPEAR T-cell include: rash, diarrhea, fever, fatigue, nausea, anemia, low white blood cell, neutrophil, lymphocyte and platelet counts, vomiting, abnormal liver chemistry tests, cough, and cytokine release syndrome. For further details on adverse events please see Part II Item 1A Risk Factors. Our SPEAR T-cells may have undesirable side effects or have other properties that could halt their clinical development, prevent regulatory approval, limit their commercial potential or otherwise result in significant negative consequences.

- **Synovial sarcoma:** Four cohorts are currently ongoing for synovial sarcoma.
- Cohort 1 (patients with high NY-ESO-1 antigen expression and lymphodepletion with cyclophosphamide and fludarabine) enrollment in this first cohort is now complete.
- Cohort 2 (patients with low NY-ESO-1 antigen expression and lymphodepletion with cyclophosphamide and fludarabine) enrollment continues in this cohort.
- Cohort 3 (patients with high NY-ESO-1 antigen expression and lymphodepletion with cyclophosphamide alone) no objective responses have been observed to date in the first five patients treated in cohort 3 and as a result, this cohort has now closed. The data from this cohort 3 suggest that fludarabine may be required as part of the pre-conditioning regimen.
- Cohort 4 (patients with high NY-ESO-1 antigen expression and lymphodepletion with a modified (lower) dose of cyclophosphamide and fludarabine) given the lack of response seen in cohort 3 to date, cohort 4 is now open and active at sites.

The current synovial sarcoma trials are also being extended to sites outside of the United States with submissions made to the Medicines and Healthcare Products Regulatory Agency, or MHRA, in the United Kingdom and to Health Canada in Canada. Health Canada has approved the clinical trial application and the MHRA has granted conditional approval of the clinical trial application in the United Kingdom.

In the synovial sarcoma trial, NY-ESO SPEAR T-cells continue to demonstrate a generally acceptable benefit:risk profile to date. The most common (>30%) adverse events in this trial considered by investigators to be at least possibly related to our NY-ESO SPEAR T-cell include pyrexia, lymphopenia, decreased white blood cell (WBC) count, nausea, anemia, neutropenia, fatigue, decreased platelet count (PLT), sinus tachycardia, and rash.

Table of Contents

We are in discussions with the FDA in relation to the initiation of a pivotal trial in the synovial sarcoma indication, including discussions relating to trial design and the requirement for comparability testing for use of our commercial-ready manufacturing process. The pivotal trial is currently anticipated to start in the second half of 2017 which will allow for the performance of analytical comparability studies between the current and the commercial processes and the submission of a Special Protocol Assessment as recommended by the FDA.

- **MRCLS:** A pilot trial in MRCLS is also planned to start in late 2016 or early 2017. The FDA previously issued a partial clinical hold for a pivotal trial in MRCLS prior to the trial becoming active at any sites. Given FDA comments relating to the requirement for comparability testing for start of a pivotal MRCLS trial, we have amended the protocol for the trial. The amendment converts the trial into a pilot trial (rather than the previously proposed pivotal trial design with a futility phase) and this amendment has been approved by the FDA, resulting in a removal of the partial clinical hold. We plan to start screening in the pilot trial in late 2016.
- **Ovarian:** Data from the trial in ovarian cancer were reported at the 2016 American Society of Clinical Oncology, or ASCO, meeting. To date, no objective clinical responses have been reported in patients. The initial patients received a preconditioning regimen which consisted of cyclophosphamide alone. The protocol for the ovarian study has now been amended to include a preconditioning regimen which includes both fludarabine and cyclophosphamide.
- **Melanoma:** Data from the trial in melanoma were reported at the 2016 ASCO meeting. No objective responses were observed in the four patients treated and as a result no further patients will be enrolled on the trial. A combination study with immune check point inhibitors (CPI) was previously being considered but is no longer being considered given the changes in the underlying standard of care for melanoma patients and the likely difficulty in recruiting patients to such a combination study.
- **Myeloma:** Enrollment in the myeloma trial (with autologous stem-cell transplantation, or auto-SCT) has completed. On October 27, 2016, we announced entry into a clinical trial collaboration agreement for the assessment of our NY-ESO SPEAR T-cell in combination with Merck & Co., Inc.'s (Merck) anti-programmed death-1 (PD-1) inhibitor, KEYTRUDA® (pembrolizumab), in patients with multiple myeloma. The study will evaluate the safety, pharmacodynamics, and preliminary efficacy of the combination, and is planned for initiation in the first half of 2017. Given the start of this combination clinical trial, our second myeloma trial (no transplant) will not enroll any further patients.
- **NSCLC:** A trial in NSCLC opened in 2016. Enrollment has been more challenging than anticipated. Initial data is currently anticipated in 2017 but availability of data for publication will depend on the number of patients recruited to the trial. The chemotherapy preconditioning regimen is being modified in a protocol amendment to include both fludarabine and cyclophosphamide.

Edgar Filing: Adaptimmune Therapeutics PLC - Form 10-Q

Our NY-ESO T-cell therapeutic has also been used in an investigator-initiated clinical program funded by the European Union, the Adoptive Engineered T-cell Targeting to Activate Cancer Killing program, or ATTACK 2 program. The therapy, which is produced under a different manufacturing process than Adaptimmune's NY-ESO TCR therapy, is being evaluated for the treatment of patients with advanced gastro-esophageal cancer for the first time. To date, two patients have been treated under this protocol, one of whom passed away 46 days after initial treatment. Enrollment in the trial was temporarily paused pending investigation of the patient fatality but an independent data monitoring committee has recommended that recruitment can resume following a protocol amendment. The European Union has since terminated funding of the trial due to the delays in trial progression and we are in discussions with the sponsor, the Christie NHS Foundation Trust, in relation to continuation of the trial.

Our MAGE-A10 SPEAR T-cell

Our second SPEAR T-cell therapy, targeting the MAGE-A10 peptide is currently in clinical trials in the United States.

The MAGE-A10 trial in NSCLC initiated in late 2015. Enrollment of patients has been challenging and initial data are currently anticipated in 2017.

A three tumor trial in urothelial, melanoma and head and neck cancers received Recombinant DNA Advisory Committee (RAC) approval in May 2016. The first trial site, MD Anderson, is now initiated and the trial is currently being initiated at other sites in the United States and Canada.

Table of Contents

Our AFP SPEAR T-cell

An IND for a clinical trial of our AFP SPEAR T-cell in hepatocellular cancer was opened in 2016 and we anticipate site initiation in the first half of 2017. Enrollment is dependent on the availability of vector used to manufacture our AFP SPEAR T-cell.

Our MAGE-A4 SPEAR T-cell

An IND submission for our next proprietary therapy the MAGE-A4 SPEAR T-cell in multiple tumor types is anticipated to be filed in early 2017.

Significant Events in the Three Months Ended September 30, 2016

Orphan Medicinal Product Designation by European Commission

On July 27, 2016, the Company announced that the European Commission had adopted a decision designating the Company's NY-ESO SPEAR T-cell therapy as an orphan medicinal product for the treatment of soft tissue sarcoma, a solid tumor cancer. Adaptimmune previously received orphan drug designation from the FDA for its NY-ESO SPEAR T-cell therapy in this indication. Orphan drug designation provides certain regulatory and financial incentives for companies to develop and market therapies that treat a life-threatening or chronically debilitating condition affecting no more than five in 10,000 persons in the European Union, and where no satisfactory treatment is available.

Equity Sales Agreement

On July 27, 2016, the Company entered into a sales agreement with Cowen and Company, LLC ("Cowen"), under which the Company may, from time to time, issue and sell through Cowen, American Depositary Shares ("ADSs") of the Company having an aggregate offering price of up to \$75 million (the "Agreement"). Under the Agreement, Cowen may sell ADSs by methods deemed to be an at-the-market offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. The Company will pay Cowen compensation at a commission rate of up to 3.0% of the gross proceeds from sales of ADSs pursuant to the terms of the Agreement. The Company is not obligated to make any sales under the Agreement.

PRIME Regulatory Access Granted for NY-ESO SPEAR T-cell

Edgar Filing: Adaptimmune Therapeutics PLC - Form 10-Q

On July 28, 2016, the Company announced that the EMA granted access to its newly-established Priority Medicines (PRIME) regulatory initiative for the Company's NY-ESO SPEAR T-cell for the treatment of HLA-A0201, HLA-A0205, or HLA-A0206 patients with inoperable or metastatic synovial sarcoma who have received prior chemotherapy. The PRIME initiative provides support to optimize regulatory applications and accelerate the review of medicines that address a high unmet need.

Strategic Manufacturing Agreement

On September 19, 2016, the Company announced that it had entered into a new five-year strategic manufacturing agreement with PCT, a Caladrius company, (PCT) a subsidiary of Caladrius Biosciences for the supply of the SPEAR T-cells. Under the agreement, the Company will benefit from exclusive access to an EU and FDA compliant manufacturing unit at PCT, as well as dedicated, specialist staff.

MD Anderson Strategic Alliance

On September 26, 2016, the Company announced that it had entered into a multi-year strategic alliance with The University of Texas MD Anderson Cancer Center (MD Anderson) designed to expedite the development of T-cell therapies for multiple types of cancer. The Company and MD Anderson will collaborate in a number of studies including clinical and preclinical development of Adaptimmune's SPEAR T-cell therapies targeting MAGE-A10 and future clinical stage first and second generation SPEAR T-cell therapies such as MAGE-A4 across a number of cancers, including urothelial, non small cell lung, ovarian, head and neck, melanoma, esophageal and gastric cancers.

Table of Contents

Recent events

Mutual Termination of Target Collaboration Agreement

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.

Merck Clinical Trial Collaboration Agreement

On October 27, 2016, the Company announced entry into a clinical trial collaboration agreement for the assessment of our NY-ESO SPEAR T-cell therapy in combination with Merck's PD-1 inhibitor, KEYTRUDA® (pembrolizumab) in patients with multiple myeloma. The Company's NY-ESO SPEAR T-cell has previously been evaluated in multiple myeloma in a single agent Phase I/II trial. In that trial, PDL-1 (programmed cell death ligand 1) was found to be upregulated in patients that relapsed. KEYTRUDA is a humanized monoclonal antibody that works by increasing the ability of the body's immune system to help detect and fight tumor cells by blocking the interaction between the PD-1 receptor on T-cells and PD-L1 and PD-L2 (programmed cell death ligands 1 and 2) that are expressed on cancer cells. Blocking this interaction is reported to enable T-cell activation and potentiates antitumor activity. Under the agreement, the trial will be sponsored by Adaptimmune. The agreement also includes a provision for potential expansion to include Phase III registration studies in the same indication.

Board changes

On October 27, 2016, the Company announced that Mr. Giles Kerr had been appointed as an independent Non-Executive Director effective from November 1, 2016, following a search process, and that Mr. Ian Laing intends to step down from the Board on December 31, 2016, in a planned retirement. Mr. Kerr also serves as a member of the Audit Committee.

On November 8, 2016, the Company announced that Dr. Tal Zaks had been appointed as an independent Non-Executive Director effective from November 14, 2016, following a search process. Dr. Zaks will also serve as a member of the Remuneration Committee.

Financial operations overview

Revenue

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 being achieved of \$14.4 million and \$7.2 million in the six months ended December 31, 2015 and the year ended June 30, 2015, respectively. 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 our 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.

Table of Contents

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 pivotal 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.

Research and Development Expenses

Research and development expenses consist principally of the following:

- salaries for research and development staff and related expenses, including benefits;
- costs for production of preclinical compounds and drug substances by contract manufacturers;
- fees and other costs paid to contract research organizations in connection with additional preclinical testing and the performance of clinical trials;
- costs relating to facilities, materials and equipment used in R&D;
- costs of acquired or in-licensed R&D which does not have alternative future use;
- amortization and depreciation of property, plant and equipment and intangible assets used to develop our SPEAR T-cells; and

- share-based compensation expenses.

Research and development expenditure is expensed as incurred.

Expenses related to clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with multiple Contract Research Organizations, or CROs, that conduct and manage 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. 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 the actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, we may report amounts that are too high or too low in any particular period. To date, there has been no material difference between our estimates and the amount actually incurred.

Upfront and milestone payments to third parties for in-licensed products or technology which has not yet received regulatory approval and which does not have alternative future use in R&D projects or otherwise are expensed as incurred.

Milestone payments made to third parties either on or subsequent to regulatory approval are capitalized as an intangible asset and amortized over the remaining useful life of the product.

Research and development expenditure is presented net of reimbursements from government grants and reimbursable tax credits from the U.K. government, when it is probable that the Company has complied with any attached conditions and will receive the reimbursement.

As a company that carries out extensive research and development activities, we benefit from the U.K. research and development tax credit regime for small and medium sized companies and the U.K. Research and Development Expenditure Credit Scheme, or the U.K. RDEC Scheme, whereby our principal research subsidiary company, Adaptimmune Limited, is able to surrender the trading losses that arise from its research and development activities for a refundable tax credit. A large proportion of costs in relation to our pipeline research, clinical trials management and manufacturing development activities, all of which are being carried out by Adaptimmune Limited, are eligible for inclusion within these tax credit cash rebate claims.

Edgar Filing: Adaptimmune Therapeutics PLC - Form 10-Q

Table of Contents

Our research and development expenses may vary substantially from period to period based on the timing of our research and development activities, which depends upon the timing of initiation of clinical trials and the rate of enrollment of patients in clinical trials.

We may never succeed in achieving regulatory approval for any of our SPEAR T-cells. The duration, costs, and timing of clinical trials and development of our SPEAR T-cells will depend on a variety of factors, including:

- the scope, rate of progress, and expense of our ongoing as well as any additional clinical trials and other research and development activities;
- uncertainties in clinical trial enrollment rates;
- future clinical trial results;
- significant and changing government regulation;
- the timing and receipt of any regulatory approvals; and
- supply and manufacture of lentiviral vector and SPEAR T-cells for clinical trials.

For further detail please see Part II Item 1A Risk Factors Risks Related to the Development of our SPEAR T-cells.

A change in the outcome of any of these variables may significantly change the costs and timing associated with the development of that SPEAR T-cell. For example, if the FDA, or another regulatory authority, requires us to conduct clinical trials beyond those that we currently anticipate will be required for regulatory approval, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

We may not be able to continue to claim certain research and development tax credits in the future as we increase our personnel and expand our business because we may no longer qualify as an SME (small or medium-sized enterprise). In order to qualify as an SME for research and development tax credits, we must continue to be a company with fewer than 500 employees and also have either an annual turnover not exceeding 100 million or a balance sheet not exceeding 86 million.

General and Administrative Expenses

Our general and administrative expenses consist principally of:

- salaries for employees other than research and development staff, including benefits;
- business development expenses, including travel expenses;
- professional fees for auditors, lawyers and other consulting expenses;
- cost of facilities, communication, and office expenses;
- information technology expenses;
- amortization and depreciation of property, plant and equipment and intangible assets not related to research and development activities; and
- share-based compensation expenses.

Other Income (Expense), net

Other income (expense), net primarily comprises foreign exchange gains (losses). We are exposed to foreign exchange rate risk because we currently operate in the United Kingdom and United States. Our revenue from our GSK Collaboration and License Agreement is denominated in pounds sterling and is generated by our U.K.-based subsidiary, which has a pounds sterling functional currency. As a result, these sales are subject to translation into U.S. Dollars when we consolidate our financial statements. Our expenses are generally denominated in the currency in which our operations are located, which are the United Kingdom and United States. However, our U.K.-based subsidiary incurs significant research and development costs in U.S. dollars and, to a lesser extent, Euros.

Our results of operations and cash flows will be subject to fluctuations due to changes in foreign currency exchange rates, which could harm our business in the future. We seek to minimize this exposure by maintaining currency cash balances at levels appropriate to meet foreseeable expenses in U.S. dollars and pounds sterling. To date, we have not used hedging contracts to manage exchange rate exposure, although we may

do so in the future.

Taxation

We are subject to corporate taxation in the United Kingdom. Our subsidiary, Adaptimmune LLC is subject to corporate taxation in the United States. Our tax recognized represents the sum of the tax currently payable or recoverable. No deferred tax assets are recognized on our losses carried forward because there is currently no indication that we shall make sufficient profits to utilize these tax losses.

Table of Contents

Unsurrendered tax losses can be carried forward to be offset against future taxable profits. After accounting for tax credits receivable, there are accumulated tax losses for carry forward in the United Kingdom amounting to \$46.2 million at December 31, 2015. These tax losses do not expire.

We may also benefit in the future from the United Kingdom's patent box regime, which would allow certain profits attributable to revenues from patented products to be taxed at a rate that over time will be reduced to 10%. As we have many different patents covering our products, future upfront fees, milestone fees, product revenues, and royalties may be taxed at this favorably low tax rate.

VAT is charged on all qualifying goods and services by VAT-registered businesses. An amount of 20% of the value of the goods or services is added to all sales invoices and is payable to the U.K. tax authorities. Similarly, VAT paid on purchase invoices paid by Adaptimmune Limited and Adaptimmune Therapeutics plc is reclaimable from the U.K. tax authorities.

Critical Accounting Policies and Significant Judgments and Estimates

The preparation of our unaudited condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities, and the revenues and expenses incurred during the reported periods. We base our estimates on historical experience and on various other factors that we believe are relevant under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The accounting policies considered to be critical to the judgments and estimates used in the preparation of our financial statements are disclosed in the Management's Discussion and Analysis of Financial Condition and Results of Operations included in Item 2.02 of our Current Report on Form 8-K filed with the SEC on July 8, 2016. There has been no change in the accounting policies considered to be critical accounting judgments and estimates.

The estimate of the period over which we are delivering services to GSK is a critical accounting estimate identified in Item 2.02 of our Current Report on Form 8-K filed with the SEC on July 8, 2016. In the three months ended June 30, 2016 we increased our estimate of the period over which we are delivering services, which 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, compared to the revenue that would have been recognized based on previous estimates. 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.

Table of Contents

Results of operations

Comparison of Three Months Ended September 30, 2016 and 2015

The following table summarizes the results of our operations for the three months ended September 30, 2016 and 2015, together with the changes to those items:

(in thousands)	Three months ended September 30,	
	2016	2015