
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

**Current Report
Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **November 6, 2018**

ADAPT IMMUNE THERAPEUTICS PLC

(Exact name of registrant as specified in its charter)

England and Wales
(State or other jurisdiction of
incorporation)

1-37368
(Commission File Number)

Not Applicable
(IRS Employer Identification No.)

**60 Jubilee Avenue, Milton Park
Abingdon, Oxfordshire OX14 4RX
United Kingdom**
(Address of principal executive offices, including zip code)

(44) 1235 430000
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

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

Item 2.02 Results of Operations and Financial Conditions

On November 6, 2018, Adaptimmune Therapeutics plc (the “Company”) issued a press release announcing its financial results for the third quarter ended September 30, 2018 and providing a business update. The text of the press release is attached as Exhibit 99.1 and is incorporated by reference herein.

The information contained in Item 2.02 of this Form 8-K, including the attached Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by the Company by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
99.1	Press release regarding third quarter 2018 financial results and business update dated November 6, 2018.

SIGNATURES

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

ADAPTIMMUNE THERAPEUTICS PLC

Date: November 6, 2018

By: /s/ Margaret Henry
Name: Margaret Henry
Title: Corporate Secretary



Adaptimmune Reports Third Quarter 2018 Financial Results and Business Update

Progressed to expansion phase for MAGE-A10 triple tumor and MAGE-A4 basket studies after favorable safety review of Cohort 3 data with target doses of 5 billion cells

Continued dosing in Cohort 1 of AFP study, with anticipated dose escalation to Cohort 2 early 2019

~\$26 million upon completion of transition of NY-ESO SPEAR T-cell program IND to GSK

Closed registered direct offering with net proceeds of ~\$100 million; guidance updated, funded to late 2020

Conference call to be held today at 8:00 a.m. EST (1:00 p.m. GMT)

PHILADELPHIA, Pa. and OXFORD, UK., November 6, 2018 — Adaptimmune Therapeutics plc (Nasdaq:ADAP), a leader in T-cell therapy to treat cancer, today reported financial results for the third quarter ended September 30, 2018, and provided a business update.

“We have now completed the three dose escalation cohorts of the studies with MAGE-A4 and MAGE-A10, our leading wholly owned programs. The Safety Review Committee has agreed that the higher pre-conditioning regimen and cell doses are tolerable and there were no dose limiting toxicities. These studies will now move into the expansion phase, which allows us to treat patients with up to ten billion cells, without a pre-determined stagger across a broad range of tumor types. We have also continued dosing patients in the AFP study with 100 million cells and anticipate escalating to Cohort 2 in early 2019. We expect to report our next clinical data by no later than our first quarter financial results in May 2019,” said James Noble, Chief Executive Officer.

Clinical momentum in wholly owned programs

Ongoing MAGE-A10 and MAGE-A4 studies

- There are three ongoing studies with MAGE-A10 and MAGE-A4 SPEAR T-cells
 - Two MAGE-A10 studies: one in non-small cell lung cancer (NSCLC) and a triple tumor study in bladder, melanoma, and head & neck cancers
 - A MAGE-A4 basket study in NSCLC, bladder, melanoma, synovial sarcoma, myxoid/round cell liposarcoma (MRCLS), head & neck, ovarian, gastric, and esophageal cancers
- All three studies are first-in-human trials utilizing a modified 3+3 design with escalating target doses of 100 million (Cohort 1), 1 billion (Cohort 2), and 5 billion (Cohort 3) transduced SPEAR T-cells to evaluate safety, including dose limiting toxicities (DLTs)
- The preconditioning regimen in the first two cohorts was cyclophosphamide (600mg/m²/day) and fludarabine (30 mg/m²/day) on days -7, -6 and -5, and an extra day of fludarabine was added to the third cohorts and expansion phases, as clinical and translational data indicate that this extra day may be important for optimal T-cell expansion post-infusion
- Following the initial three cohorts, the Safety Review Committee (SRC) meets to decide whether to progress to the expansion phase, which has a target dose of 5 billion cells (range 1.2 to 10B) without pre-determined intervals between patient dosing
- The SRC recommended moving into the expansion phase for the MAGE-A10 triple tumor and MAGE-A4 basket studies
- As in the first two cohorts of these studies, there was no evidence of toxicity related to off-target binding or alloreactivity in the third cohorts at target doses of 5 billion cells
- Most adverse events were consistent with those experienced by cancer patients undergoing chemotherapy or other immunotherapies

ESMO data

- Initial safety data from the first two cohorts of the MAGE-A10 and MAGE-A4 studies were presented at the European Society for Medical Oncology (ESMO) 2018 Congress (<https://bit.ly/2PdB3CR>)
- In brief, these data showed:
 - Disease progressed for all eight patients treated in the first dose cohorts of the two MAGE-A10 studies (five patients with lung cancer, two with head & neck cancer, and one with melanoma)
 - For the three patients treated in Cohort 2 of the MAGE-A10 study (all lung cancer patients), one patient died of pneumonia (unrelated to therapy) and two had stable disease (SD), albeit transient
 - Of the six patients treated in Cohorts 1 and 2 of the MAGE-A4 basket study, best response was SD in four patients and progressive disease (PD) in two patients
 - One patient in the MAGE-A4 basket study with SD had an overall 27% reduction of target lesions observed at Week 6, and was assessed as PD at the time of the second scan, which took place after the ESMO poster cut-off date
 - No evidence of toxicity related to off-target binding or alloreactivity at target doses of 100 million or 1 billion cells
 - Most adverse events consistent with those experienced by cancer patients undergoing chemotherapy or other immunotherapies
 - Transduced cells detectable in peripheral blood at levels consistent with dose

Data from ongoing AFP study

- Dosing in Cohort 1 of AFP study is ongoing
- Anticipate dose escalation to Cohort 2 in early 2019.

NY-ESO data updates to be presented at SITC

- The NY-ESO program transitioned to GSK in July 2018
- An abstract summarizing NY-ESO SPEAR T-cells in MRCLS was accepted for presentation at SITC, and is available online today
- Data in the abstract state that out of ten MRCLS patients, there were four with partial responses (PRs) and four with SD, as per investigator assessment
- These data will be updated in a poster at SITC
- Overall, there was evidence of reduction in target lesions in seven patients out of eight evaluable patients
- The data submitted in the abstract included investigator assessments. These assessments showed a best response of four confirmed PR, one unconfirmed PR, and three patients with SD out of eight evaluable patients
- Two of the responses were confirmed before the minimum 28 days required by RECIST v1.1 (22 and 25 days), and the patients subsequently progressed
- Therefore, the response rate by RECIST, which will be presented in the poster, is two confirmed PRs and six patients with SD out of the eight evaluable patients
- Patients in the MRCLS study received the same preconditioning regimen as was used in Cohort 4 of the synovial sarcoma study, and these patients had less durable responses compared to Cohort 1 patients in the synovial sarcoma study, who received a more intense preconditioning regimen
- The most frequent AEs were consistent with those experienced by patients with cancer who are undergoing cytotoxic chemotherapy or other immunotherapies
- A second poster with NY-ESO data will also be presented at SITC summarizing translational research conducted in the context of the NY-ESO synovial sarcoma study examining serum factors that lead to T-cell expansion with different preconditioning regimens (including the impact of fludarabine), tumor micro-environment analyses pre- and post-infusion, and SPEAR T-cell functionality post-infusion. This abstract is also available online.

Manufacturing

Adaptimmune on its way to becoming a fully integrated cell therapy company

- 2018 has been a successful year for manufacturing with the Navy Yard facility regularly producing target cell doses > 1 billion cells with more than 50% producing > 5 billion cells
- Producing cell doses across multiple solid tumor indications
- Cells have been manufactured for a number of patients who could enter the MAGE-A4 and/or MAGE-A10 expansion phases, once eligible

Other corporate news

Adaptimmune is focused on its next stage of development and in a strong position to deliver success with SPEAR T-cell therapies

- Announced the closing of a registered direct offering of Adaptimmune's American Depositary Shares ("ADSs") (<https://bit.ly/2MZFEIH>) with net proceeds of approximately \$100 million
- Adaptimmune intends to use the net proceeds from this offering to advance the Company's wholly owned pipeline of SPEAR T-cell candidates through clinical trials as well as for other general corporate purposes
- Completed transition of NY-ESO IND to GSK and received approximately \$26 million in milestone payments
- Funded through to late 2020 with cash and cash equivalents of \$153.1 million and total liquidity(1) of \$237.7 million
- Held annual Scientific Advisory Board meeting in October with Adaptimmune R&D leaders and external experts in immunology and oncology (bios available here: <https://bit.ly/2PvHH4w>); focused on optimal employment of NY-ESO learnings in ongoing and future studies as well as strategies for novel target identification

Financial Results for the three and nine month period ended September 30, 2018

- **Cash / liquidity position:** As of September 30, 2018, Adaptimmune had cash and cash equivalents of \$153.1 million and Total Liquidity(1) of \$237.7 million.
- **Revenue:** Revenue for the three and nine months ended September 30, 2018 was \$40.8 million and \$58.0 million, respectively, compared to \$27.2 million and \$33.6 million for the same periods of 2017. The revenue in the three and nine months ended September 30, 2018 includes \$39.1 million of revenue for the license to NY-ESO, which commenced in September 2018.
- **Research and development ("R&D") expenses:** R&D expenses for the three and nine months ended September 30, 2018 were \$23.5 million and \$75.5 million, respectively, compared to \$24.0 million and \$62.2 million for the same periods of 2017. The R&D expenses in the nine months ended September 30, 2018 has increased compared to the same period in 2017 due to increased clinical trial and related manufacturing activities. R&D expenses in the three months ended September 30, 2018 compared to the same period in 2017 decreased due to the transfer of the NY-ESO program to GSK.
- **General and administrative ("G&A") expenses:** G&A expenses for the three and nine months ended September 30, 2018 were \$10.3 million and \$32.8 million, respectively, compared to \$8.1 million and \$22.3 million for the same periods of 2017. The increase was primarily due to increased personnel costs consistent with the Company's planned infrastructure growth.
- **Other (expense) income, net:** Other expense for the three and nine months ended September 30, 2018 was \$2.2 million and \$10.5 million, respectively, compared to an income of \$3.6 million and \$7.2 million for the same periods of 2017. Other income primarily comprises unrealized foreign exchange gains, which fluctuate depending on exchange rate movements and the amount of foreign currency assets and liabilities.
- **Net income (loss):** Net income (loss) attributable to holders of the Company's ordinary shares for the three and nine months ended September 30, 2018 was an income of \$5.2 million and a loss of \$59.3 million, respectively, (\$0.01 and \$(0.10) per ordinary share) compared to a loss of \$0.9 million and \$42.9 million, respectively, (\$(0.00) and \$(0.08) per ordinary share) in the same periods of 2017.

(1) Total liquidity is a non-GAAP financial measure, which is explained and reconciled to the most directly comparable financial measures prepared in accordance with GAAP below.

Financial guidance

The Company believes that its existing cash, cash equivalents and marketable securities will fund the Company's current operations through to late 2020.

Conference call information

The Company will host a live teleconference and webcast at 8:00 a.m. EST (1:00 p.m. GMT) today. The live webcast of the conference call will be available via the events page of Adaptimmune's corporate website at www.adaptimmune.com. An archive will be available after the call at the same address. To participate in the live conference call, please dial (833) 652-5917 (U.S.) or +1 (430) 775-1624 (International). After placing the call, please ask to be joined into the Adaptimmune conference call and provide the confirmation code (2458438).

About Adaptimmune

Adaptimmune is a clinical-stage biopharmaceutical company focused on the development of novel cancer immunotherapy products. The Company's unique SPEAR (Specific Peptide Enhanced Affinity Receptor) T-cell platform enables the engineering of T-cells to target and destroy cancer, including solid tumors. Adaptimmune is currently conducting clinical trials with SPEAR T-cells targeting MAGE-A4, -A10, and AFP across several solid tumor indications. The Company is located in Philadelphia, USA and Oxfordshire, U.K. For more information, please visit <http://www.adaptimmune.com>

Forward-looking statements

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 (PSLRA). These forward-looking statements involve certain risks and uncertainties. Such risks and uncertainties could cause our actual results to differ materially from those indicated by such forward-looking statements, and include, without limitation: the success, cost and timing of our product development activities and clinical trials and our ability to successfully advance our TCR therapeutic candidates through the regulatory and commercialization processes. For a further description of the risks and uncertainties that could cause our actual results to differ materially from those expressed in these forward-looking statements, as well as risks relating to our business in general, we refer you to our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on August 2, 2018, and our other SEC filings. The forward-looking statements contained in this press release speak only as of the date the statements were made and we do not undertake any obligation to update such forward-looking statements to reflect subsequent events or circumstances.

Total liquidity (a non-GAAP financial measure)

Total Liquidity is the total of cash and cash equivalents and marketable securities. Each of these components appears in the Consolidated Balance Sheet. The U.S. GAAP financial measure most directly comparable to Total Liquidity is cash and cash equivalents as reported in the Consolidated Financial Statements, which reconciles to Total Liquidity as follows:

(in thousands) (unaudited)	September, 2018	December 31, 2017
Cash and cash equivalents	\$ 153,081	\$ 84,043
Marketable securities	84,652	124,218
Total Liquidity	\$ 237,733	\$ 208,261

The Company believes that the presentation of Total Liquidity provides useful information to investors because management reviews Total Liquidity as part of its management of overall liquidity, financial flexibility, capital structure and leverage.

Condensed Consolidated Statement of Operations
(unaudited, in thousands, except per share data)

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

Condensed Consolidated Balance Sheets
(unaudited, in thousands)

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

Condensed Consolidated Cash Flow Statement
(unaudited, in thousands)

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

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