

This announcement contains inside information.

Oncimmune Holdings plc

(“Oncimmune” or the “Company”)

Interim Results for the half year ended 30 November 2016

Nottingham, UK – 10 February 2017: Oncimmune Holdings plc (AIM: ONC.L), a leading early cancer detection company developing and commercialising its proprietary *EarlyCDT*[®] platform technology, announces its interim results for the half year ended 30 November 2016.

Operational highlights

- Established a distributor base of 14 in the US for our *EarlyCDT*[®]-Lung test, all of which are now fully operational.
- Completed development, and now in final validation, of the CE marked and ISO certified kit version of our *EarlyCDT* tests enabling the Company to expand its distributor discussions into new geographical territories.
- Signed research agreements with Egybiotech, a private research company with a broad research portfolio in areas of cancer research and Aarhus University Hospital, Denmark. These agreements are a further step in the final clinical validation of *EarlyCDT*[®]-Liver and *EarlyCDT*[®]-Ovarian.
- Journal of Thoracic Oncology published new data on the effectiveness of Oncimmune’s *EarlyCDT* platform, demonstrating the effectiveness of using *EarlyCDT*-Lung tests to distinguish between malignant and benign lung nodules.
- In final validation of the addition of material new markers to *EarlyCDT*-Lung test to further enhance test performance. Significant progress on our second-generation fingerprint test and companion diagnostics.
- Board and senior appointments - appointment of Andrew Millet as CFO, Carsten Schroeder and Julian Hirst as Non-Executive Directors, Maarten Brusse as Chief Commercial Officer, Asia Pacific and DeeDee Rivas as VP, Americas Sales.

Financial position

- Revenues of £0.1m (FH1 2016: £0.27m) generated from sales of the *EarlyCDT*-Lung test.
- Cash balance at the period end was better than expected at £7.6m (FH1 2016: £1.1m).
- Loss for the period was £2.3m (FH1 2016: £0.8m) reflecting recruitment of staff, product development and commercialisation activities.
- Foreign exchange gain of £0.15m (FH1 2016: £0m) as a result of the strengthening of the US dollar against the pound during the period.

Post period end

- *EarlyCDT*-Lung, the early detection of lung cancer test, is being used in the world’s largest randomised trial for the early detection of lung cancer using biomarkers ever conducted with the National Health Service (NHS) in Scotland. The ECLS study is now fully recruited with over 12,000 high-risk smokers. Positive interim data from the NHS

screening trial was presented in December 2016 at the 17th World Conference on Lung Cancer in Vienna.

Geoffrey Hamilton-Fairley, CEO, of Oncimmune said: “Oncimmune has continued to make significant progress across all areas of the business. We have established a stronger distributor network and a new sales process in the US, we have made improvements to our existing *EarlyCDT-Lung* test and we are encouraged with the positive start we have made since launching the *EarlyCDT-Lung* test with our new distributors.

“We have also made good progress with our wider product development projects, in particular the development of the kit version, which will open significant new markets in Asia and elsewhere, is progressing to plan. We are also advancing in new diseases and with second generation tests which have the potential to drive growth.

“We believe we have laid the foundations on which to build a successful business and I would like to thank our whole team for their commendable efforts to date.”

-Ends-

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Notes to Editors

About Oncimmune Holdings Plc

Oncimmune is a leading early cancer detection company developing and commercialising its proprietary *EarlyCDT*[®] platform technology. Oncimmune has pioneered the development of autoantibody tests that can detect cancer up to four years earlier than other methods and can be applied to a very wide range of solid tumour types.

The Company's first product, *EarlyCDT*[®]-Lung, was launched in 2012, as a CLIA test in the USA and since then over 150,000 commercial tests have been sold. *EarlyCDT-Lung* is available through physicians in the US and also privately in the UK and other regions. *EarlyCDT-Lung* is being used in the largest ever randomised trial for the early detection of lung cancer using biomarkers, the National Health Service (NHS) Scotland ECLS study of 12,000 high-risk smokers. *EarlyCDT*[®] tests for liver and ovarian cancer are in development.

Oncimmune, headquartered in Nottingham, United Kingdom with testing facilities in the US, joined AIM in May 2016 under the ticker ONC.L. For more information visit www.oncimmune.com

Chairman & Chief Executive's Review

Oncimmune continues to strengthen commercial operations in the US. Following our rigorous partner training programme, our 14 distributors are now fully operational, in line with the statement in our Annual Report 2016. Whilst it is still early in the sales process, we are confident that by the year end 31 May 2017 we will be able to show that we are gaining traction. In order to ensure our distribution partners deliver high quality and long-term sales, we have implemented a new process to support them. This will be led by our new Vice President, Americas Sales, DeeDee Rivas. At year end there should be sufficient evidence to justify investing more aggressively in sales and marketing support for these distributors, which we will do in the knowledge that this should lead to commensurate sales. In light of this more conservative approach, our current cash position is considerably more favourable than projected.

Outside the US, we target further growth in Asian markets. Led by Maarten Brusse, who was appointed to the position of Chief Commercial Officer, Asia Pacific in September 2016, we are pursuing discussions with a number of parties in the region to drive sales and to target out-licensing opportunities.

Other Developments

As previously highlighted, Oncimmune received a European CE mark in July 2016 for the reagents used in its *EarlyCDT-Lung* blood test. The CE mark certifies that the reagents in the blood test meet the European Union standards of manufacturing and quality control to enable the product to be sold more aggressively in Europe. This internationally recognised CE mark should also support certification in other territories, including Asia. In addition, Oncimmune signed research agreements with private research company Egybiotech and Aarhus University Hospital in Denmark in order to further validate its *EarlyCDT* platform for liver and ovarian cancer.

In September 2016, the Journal of Thoracic Oncology published new data on the effectiveness of the Company's *EarlyCDT* platform, demonstrating the effectiveness of using *EarlyCDT-Lung* tests to distinguish between malignant and benign lung nodules. The study showed a positive *EarlyCDT-Lung* test indicates a nodule is 2-3 times more likely to be a cancer. At the time of the IPO, we pointed to independent projections by Health Advances in Boston that a significant proportion of the projected sales for lung cancer would be for the assessment of risk in pulmonary nodules already identified by CT. There is a real need for pulmonologists to have a new test to help them identify the nodules that need more immediate investigation, given that CT has a 50% false positive rate. This need is likely to increase as the volumes of CT screening for high-risk patients starts to grow, as has been seen in the United States in particular. To address this potentially valuable use, we have commenced discussions with a number of specialist sales forces visiting pulmonologists both in the US and in other territories.

We have also previously referred to work being done to improve the performance of the current *EarlyCDT-Lung* test by the addition of certain new markers that will enhance its sensitivity (detection rate) whilst maintaining our excellent specificity (low false positive rate). This work is nearly complete and we expect to be able to add these markers to the test based in our CLIA lab in Kansas during 2017. We believe this added performance will aid sales significantly.

R&D and Trials

Oncimmune's R&D programme is moving forward as planned. We anticipate the *EarlyCDT-Liver* test will be ready for commercialisation before the end of 2017 and the test for ovarian cancer, for which approval by Aarhus for the collection of samples for final validation has been slower than expected, will follow, along with tests for further cancers that we are beginning to target.

As emphasised at the time of the IPO last May, the conversion of the test from a central lab test to a fully CE marked and ISO certified "kit" is key to entering certain new markets, such as Asia. The kit has the advantage of running on existing machines in practically all hospital labs worldwide with no need for additional training of machine operators as 96-well ELISA's have been used for testing for infectious disease for over 30 years. We are still on course for the kit to be ready, as planned, in Q2 2017.

In December last year, the NHS in Scotland presented the second review of their data from their over 12,000 patient ECLS study using *EarlyCDT-Lung* at the World Conference for Lung Cancer in Vienna. The study was fully recruited at 12,210 patients in June 2016, which is the largest randomised control trial ever conducted with biomarkers in lung cancer. The results remain very encouraging with a shift to early and curative cancer (stage 1 & 2) from 20% in normal practice today to 75%. It is the identification of these early stage cancer patients that saves money as well as lives, as generally these patients do not need expensive chemotherapy. The ECLS study will report full results in June 2018 when the final recruited patient has been followed up for two years. This trial should provide sufficient validation of the *EarlyCDT-Lung* test for it to start being adopted as a lung cancer screening test nationally in the UK as well as in other territories, including the US.

Personalised Medicine & Companion Diagnostics

Validation of Oncimmune's second generation test, the autoantibody "fingerprint", is on track. We have run a large set of sequential samples to show the increased accuracy of the platform where an individual can compare on-going test results with a previous test result taken when the individual was cancer free. By the patient becoming their own control, the test results will be more accurate than population-based case control studies. The initial analysis using our current commercial test shows that the sample set has both good signal (cancer/normal differentiation) and shows early detection of cancer more than three years before other methods. This confirmation of a good signal and early detection means that we can move to the next stage of analysis, which will be to create the personalised algorithm and thus see how much more accurate this approach will be when compared to the population-based test that we have today.

Finally, we have found that our data showing that autoantibodies can be used to identify patients who will or will not be receptive to certain drugs has been well received. We now have a number of studies running with leading drug developers to identify which antigens act as markers for the relevant patient population for a particular drug in development. This has the potential of developing into a distinct separate companion diagnostic business. A decision as to the best approach for maximising value for the Company in companion diagnostics will be taken once we have the data from the current trials.

Outlook

The overall outlook for the uptake of *EarlyCDT-Lung* is increasingly positive in view of the increasing focus on early cancer detection testing, as recently highlighted by the World Health Organisation on World Cancer day, across all territories, in particular Asia, Europe and the US.

The Company's progress with distributors and potential partners remains positive but the precise timing of new contracts is difficult to predict. However, we are confident that we will build revenues during 2017.

This is an exciting period for Oncimmune. We have several product development projects maturing, including the *EarlyCDT-Lung* kit, the fingerprinting test, liver and ovarian cancer tests and companion diagnostics.

We remain confident for the prospects of Oncimmune and that we have created a company that is strategically valuable in the field of early cancer detection.

Financial position

The Group's results for the six months to 30 November 2016 are presented in the financial statements and show trading revenues of £0.1m (FH1 2016: £0.27m), lower than expected due to being earlier in the sales process than anticipated, and a gross profit of £0.005m (FH1 2016: gross profit £0.25m).

General administrative expenses before one-offs and non-cash items increased to £2.42m (FH1 2016: £1.61m) as we build our commercial capabilities.

The total comprehensive loss was £2.32m (FH1 2016: £0.84m) and the loss per share was £0.05 (FH1 2016: £0.04).

Consolidated income statement for the six months ended 30 November 2016

	Unaudited 6 months to 30 November 2016	Unaudited 6 months to 30 November 2015	Audited 12 months to 31 May 2016
Notes	£'000	£'000	£'000
Continuing Operations			
Revenue	114	272	430
Cost of sales	(109)	(24)	(147)
Gross profit	5	248	283
Administrative expenses	(1,992)	(1,229)	(4,269)
Research and development expenses	(435)	(388)	(789)
Share-based payments charge	(16)	(872)	(939)
Total administrative expenses	(2,432)	(2,489)	(5,997)
Operating loss	(2,438)	(2,241)	(5,714)
Gain arising on debt settlement	-	1,564	1,564
Finance costs on derivative liabilities	-	-	(4,126)
Finance income	-	2	5
Finance expense	(38)	(421)	(737)
Loss on ordinary activities before taxation	(2,476)	(1,096)	(9,008)
Tax on loss on ordinary activities	-	252	566
Loss from continuing operations	(2,476)	(844)	(8,442)
Other comprehensive income			
Exchange translation differences	154	3	24
Total comprehensive loss	(2,322)	(841)	(8,418)
Attributable to:			
Owner of the parent	(2,322)	(841)	(8,418)
	(2,322)	(841)	(8,418)
Loss per share:			
Basic and diluted (£)	3	0.05	0.04
		0.24	

Consolidated statement of financial position as at 30 November 2016

	Notes	Unaudited 30 November 2016 £'000	Unaudited 30 November 2015 £'000	Audited 31 May 2016 £'000
Assets				
Non-current assets				
Intangible assets		117	39	131
Property, plant and equipment		258	286	253
Total non-current assets		375	325	384
Current assets				
Inventories		213	183	188
Asset held for sale		-	94	-
Trade and other receivables		294	400	339
Cash and cash equivalents		7,623	1,066	10,197
Tax receivable		100	-	100
Total current assets		8,230	1,743	10,824
Total assets		8,605	2,068	11,208
Equity and liabilities attributable to equity holders of the parent company				
Share capital	4	510	348	510
Share premium		16,273	-	16,273
Merger reserve		30,787	30,388	30,787
Other reserves		2,129	1,975	2,113
Own shares		(1,926)	(1,926)	(1,926)
Foreign exchange translation reserve		101	(74)	(53)
Retained earnings		(40,449)	(34,500)	(37,973)
Total equity		7,425	(3,789)	9,731
Liabilities				
Current liabilities				
Trade and other payables		464	2,092	529
Other tax liabilities		35	-	57
Other loans	5	584	-	496
Total current liabilities		1,083	2,092	1,082
Non-current liabilities				
Derivative financial instruments		-	120	-
Convertible loans		-	3,078	-
Other loans	5	97	567	395
Total non-current liabilities		97	3,765	395
Total equity and liabilities		8,605	2,068	11,208

Consolidated statement of changes in equity for the six months ended 30 November 2016

	Share capital	Share premium	Other reserves	Merger reserve	Foreign currency translation reserve	Own shares	Retained earnings	Total equity
	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000
Six months ended 30 November 2016 - unaudited								
Balance at 1 June 2016	510	16,273	2,113	30,787	(53)	(1,926)	(37,973)	9,731
Loss for the period	-	-	-	-	-	-	(2,476)	(2,476)
Total comprehensive expense for the period	-	-	-	-	-	-	(2,476)	(2,476)
Transactions with owners								
Share-based payment charge	-	-	16	-	-	-	-	16
Foreign currency reserve	-	-	-	-	154	-	-	154
Total transactions with owners	-	-	16	-	154	-	-	170
Balance at 30 November 2016	510	16,273	2,129	30,787	101	(1,926)	(40,449)	7,425

	Share capital	Share premium	Other reserves	Merger reserve	Foreign currency translation reserve	Own shares	Retained earnings	Total equity
	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000
12 months ended 31 May 2016 - audited								
Balance at 1 June 2015	7	30,729	1,103	-	(77)	(1,926)	(33,656)	(3,820)
Loss for the period	-	-	-	-	-	-	(8,442)	(8,442)
Other comprehensive expense	-	-	-	-	24	-	-	24
Total comprehensive income/(expense) for the period	-	-	-	-	24	-	(8,442)	(8,418)
Transactions with owners								
share option charge	-	-	939	-	-	-	-	939
Shares issued in group reconstruction	348	(348)	-	-	-	-	-	-
Reorganisation of share capital	(7)	7	-	-	-	-	-	-
Issue of equity shares	162	20,797	-	-	-	-	-	20,959
Exercise of conversion option	-	(4,126)	71	-	-	-	4,126	71
Creation of Merger reserve	-	(30,787)	-	30,787	-	-	-	-
Total transactions with owners	503	(14,456)	1,010	30,787	-	-	4,126	21,969
Balance at 31 May 2016	510	16,273	2,113	30,787	(53)	(1,926)	(37,973)	9,731

Consolidated statement of changes in equity for the six months ended 30 November 2016

	Share capital	Share premium	Merger reserve	Other reserves	Currency translation reserve	Own Shares	Retained earnings	Total equity
	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000
Six months ended 30 November 2015 - unaudited								
Balance at 1 June 2015	7	30,729	-	1,103	(77)	(1,926)	(33,656)	(3,820)
Loss for the period	-	-	-	-	-	-	(844)	(844)
Other comprehensive expense	-	-	-	-	3	-	-	3
Total comprehensive expense for the period	-	-	-	-	3	-	-	(841)
Transactions with owners								
Issue of share capital	348	(348)	-	-	-	-	-	-
Adjusted on reorganisation	(7)	7	-	-	-	-	-	-
Creation of Merger reserve	-	(30,388)	30,388	-	-	-	-	-
Share-based payment charge	-	-	-	872	-	-	-	872
Total transactions with owners	341	(30,729)	30,388	872	-	-	-	872
Balance at 30 November 2015	348	-	30,388	1,975	(74)	(1,926)	(34,500)	(3,789)

Consolidated statement of cash flows for the six months ended 30 November 2016

	Notes	Unaudited 6 months to 30 November 2016 £'000	Unaudited 6 months to 30 November 2015 £'000	Audited 12 months to 31 May 2016 £'000
Cash flow from operating activities				
Loss before tax		(2,476)	(844)	(8,442)
Adjustments for :				
Settlement of costs via equity shares		-	-	1,142
Settlement with US distributor		-	(1,564)	-
Depreciation and amortisation		50	36	78
Gain arising on debt settlement		-	-	(1,564)
Loss on derivative financial instrument		-	-	4,126
Interest received		-	(2)	(5)
Interest expense		38	421	737
Share-based payment expense		16	872	939
Foreign exchange movements		9	(7)	(11)
Taxes received		-	(252)	(566)
		(2,363)	(1,340)	(3,566)
Changes in working capital:				
Increase in inventories		(25)	(183)	(8)
Asset held for sale		-	(94)	-
Increase/(Decrease) in trade and other receivables		46	129	(304)
Increase/(Decrease) in trade and other payables		(88)	243	133
Cash generated from operating activities		(2,430)	(1,245)	(3,745)
Interest paid		(38)	(58)	-
Taxes received		-	252	566
Net cash (used in) operating activities		(2,468)	(1,051)	(3,179)
Cash flow from investing activities				
Development expenditure capitalised		-	(14)	(108)
Purchase of property, plant and equipment		(1)	(270)	(64)
Interest received		-	2	5
Net cash (used in) from investing activities		(1)	(282)	(167)
Cash flow from financing activities				
Convertible loan		-	1,250	-
Proceeds from issue of shares		-	-	11,448
Repayment of long term borrowings		(210)	(206)	(423)
New other loans		-	-	1,250
Net cash (used in)/generated from financing activities		(210)	1,044	12,275
Movement in cash attributable to foreign exchange		105	11	(76)
Net change in cash and cash equivalents		(2,679)	(289)	8,929
Cash and cash equivalents at beginning of period		10,197	1,344	1,344
Cash and cash equivalents at end of period		7,623	1,066	10,197

Oncimmune Holdings PLC

NOTES TO THE INTERIM FINANCIAL STATEMENTS

1. General information

The principal activity of Oncimmune Holdings PLC (the "Company") and its subsidiaries (together, the "Group") is that of early cancer detection for research into, and the development and commercialisation of autoantibody tests that can detect cancer up to four years earlier than other methods and can be applied to a very wide range of solid tumour types. The Company is incorporated and domiciled in the United Kingdom. The address of its registered office is Clinical Sciences Building City Hospital, Hucknall Road, Nottingham, UK, NG5 1PB. The registered number is 09818395.

As permitted, this Interim Report has been prepared in accordance with the AIM rules and not in accordance with IAS 34 "Interim Financial Reporting".

The consolidated financial statements are prepared under the historical cost convention.

This Consolidated Interim Report and the financial information for the six months ended 30 November 2016 does not constitute full statutory accounts within the meaning of section 434 of the Companies Act 2006 and are unaudited. This unaudited Interim Report was approved by the Board of Directors on 9 February 2017.

The Group's financial statements for the period ended 31 May 2016 have been filed with the Registrar of Companies. The Group's auditor's report on these financial statements was unqualified and did not contain a statement under section 498 (2) or (3) of the Companies Act 2006.

Electronic communications

The Company is not proposing to bulk print and distribute hard copies of this Interim Report for the six months ended 30 November 2016 unless specifically requested by individual shareholders.

The Board believes that by utilising electronic communication it delivers savings to the Company in terms of administration, printing and postage, and environmental benefits through reduced consumption of paper and ink, as well as speeding up the provision of information to shareholders.

News updates, Regulatory News and Financial statements can be viewed and downloaded from the Company's website, www.oncimmune.com. Copies can also be requested from: The Company Secretary, Oncimmune Holdings PLC, Clinical Sciences Building, City Hospital, Hucknall Road, Nottingham, UK, NG5 1PB or by email: oncimmune@consilium-comms.com

2. Accounting policies

Basis of preparation

This financial information has been prepared in accordance with International Financial Reporting Standards (IFRS), including IFRIC interpretations issued by the International Accounting Standards Board (IASB) as adopted by the European Union and in accordance with the accounting policies which were adopted in presenting the Group's Annual Report and Financial Statements for the year ended 31 May 2016.

Going concern

The Group meets its day-to-day working capital requirements through its cash and cash equivalents, through management of its working capital cycle and its bank facilities. The Directors have carefully considered the adequacy of these arrangements in light of the current and future cash flow forecasts and they believe that the Group is appropriately positioned to ensure the conditions of its funding will continue to be met and therefore enable the Group to continue in operational existence for the foreseeable future by meeting its liabilities as they fall due for payment.

Taxation

Taxes on income in the interim periods are accrued using the rate of tax that would be applicable to expected total annual earnings.

UK Tax credits on qualifying research and development expenditure are recognised when received.

3. Loss per share

Basic

Basic loss per share is calculated by dividing the loss after tax attributable to the equity holders of the parent company for the period of £2,321,908 (May 2016: £8,441,550) (November 2015: £841,301) by the weighted average number of ordinary shares in issue during the period of 51,024,404 (May 2016: 35,866,359) (November 2015: 23,203,600).

Diluted

Due to losses in the period there is no calculation of a diluted earnings (loss) per share.

4. Share Options

On 8 November 2016, the Company granted options of 1,334,390 ordinary shares in the Company to certain directors and employees. The options are broken down into 2 exercise prices, 528,273 options with a price £0.01 per share and 806,117 options with a price of £1.08, being the mid-market closing price of the Company's ordinary shares on 7 November 2016. Both sets of options expire after 6 years. The options are subject to the rules of 2016 Share Option plan (an amalgamation of the Company's 2005 and 2007 Share option Plans). Due to the timing of the awards, only a small amount will be charged in this period. The options will vest in five equal annual parts, the first fifth vesting on 7 November 2017 and each year thereafter for a further 4 years, subject to continued employment.

On 30 November 2016, the Company granted options over 252,615 ordinary shares in the Company to certain directors and employees. The options have an exercise price £1.19 per share and expire after 5 years. The options are subject to the rules of 2016 Share Option plan (an amalgamation of the Company's 2005 and 2007 Share option Plans). The options will vest in five equal annual parts, the first fifth vesting on 30 November 2017 and each year thereafter for a further 4 years, subject to continued employment. The options are exercisable at £1.19 being the mid-market closing price of the Company's ordinary shares on 30 November 2016.

The share option charge for the interim period was £16k (FH1 2016: £872k)

5. Borrowing

The Group uses other loans to finance operations, the following balances remain outstanding

	30 November 2016	31 May 2016
	£'000	£'000
Current		
Other loans	<u>584</u>	<u>496</u>
	<u>584</u>	<u>496</u>
Non-Current		
Other loans	<u>97</u>	<u>395</u>
	<u>97</u>	<u>395</u>

Other loans at 30 November 2016 include a venture loan facility originally of €1,862,649 (£1.5m), from Harbert European Speciality Lending Company Limited ('Harbert') repayable in equal instalment over the period to 31 January 2018 at an interest rate of 10% pa, plus a further 3% to be paid with the final instalment. The facility is secured by a fixed and floating charge over the Company's assets and undertaking. As at the period end £584,013 was falling due within one year and £97,336 was falling due after one year (May 2016: £495,920 and £394,882).

6. Events after the reporting period

On 6 December 2016, the Company announced positive interim data from the National Health Service (NHS) Scotland ECLS Lung Cancer Screening Trail. This study uses Oncimmune's EarlyCDT®-Lung test, and was presented at the International Association for the Study of Lung Cancer's 17th World Conference on Lung Cancer in Vienna, Austria. The trial is the largest randomised trial for the early detection of lung cancer using biomarkers ever conducted.

No financial changes occurred.