RNS Number : 0666R
Oncimmune Holdings PLC
27 February 2023

**This announcement contains inside information
for the purposes of the UK Market Abuse Regulation**

27 February 2023

Oncimmune Holdings plc

("Oncimmune" or the "Company")

Final results for the 15-month period to 31 August 2022

Continued ImmunoINSIGHTS penetration into top 15 global pharma companies

ImmunoINSIGHTS moving to preferred or master service contract model with large pharma

Medicare coverage in US for EarlyCDT Lung Blood Test

Stronger growth in current financial year, with first half FY2023 revenue already exceeding level for the 15 months to 31 August 2022

In discussions for realization of value from non-core assets

Oncimmune Holdings plc (AIM: ONC.L), the leading global immunodiagnostics group, today announces its audited results for the 15-month period ended 31 August 2022 ("FY2022") and provides and update on recent trading and the outlook for the current financial year ("FY2023").

Operational and commercial highlights for FY 2022

- ImmunoINSIGHTS pharma services business continued to progress in the face of a challenging global economic environment. The number of commercial contracts delivered increased in the period, as it has done in the prior two financial years.

- ImmunoINSIGHTS commercial pipeline was dominated by large pharma customers and increasingly populated by multiple contracts from the same customers. The number of customers awarding repeat contracts grew, as did the overall value of the commercial pipeline.

- ImmunoINSIGHTS business transitioned towards a master service agreement model, which brings benefits including speed of contracting on future projects and extensions, a deepening of customer engagement and preferred supplier status for autoantibody profiling services.

- EarlyCDT® Lung product business was restructured in the period, substantially reducing the ongoing cost base, which, combined with increased contracted revenues, has created an EBITDA profitable business (before the allocation of central overheads).

- Contracted customers in the UK and US for the EarlyCDT® Lung business delivered increasing revenues. The Company's US distributor, Biodesix, Inc. (NASDAQ: BDSX), received Medicare coverage for EarlyCDT® Lung at an in-market selling price which was nine times the average in-market selling

price achieved prior to the determination.

Financial highlights (including post period)

- Revenue for the period was £3.79M (2021: £3.72M).
- Gross profit for the period was £1.83M (2021: £2.86M) which reflects the planned expansion of the ImmunoINSIGHTS Dortmund team.
- Administrative expenses were £8.70M (2021: £5.65M), which incorporates the planned investment in the ImmunoINSIGHTS Commercial team, particularly in the US.
- Research & development expenses were stable at £1.85M (2021: £1.62M).
- Share-based payments were £1.69M (2021: £1.41M), representing the non-cash cost of expensing the Group's LTIP, share options plans and warrants.
- Loss after tax was £11.52M (2021: £5.08M).
- Gross cash balance at the period end of £1.43M (2021: £8.63M) and net debt at the period end of £9.2M (2021: £0.8M), after investment including capacity expansion. The Company drew down an additional €3.0M (c.£2.50M) in December 2021 from its debt facility with IPF Partners to fund the acceleration in the expansion of the US-based Commercial team, serviceable by cash generation from ImmunoINSIGHTS.

Business highlights and outlook

- Revenue for first 6 months of FY2023 expected to exceed the revenue generated in the whole of the 15-month period to 31 August 2022.
- Business continues to perform in line with previously reported expectations, and the Group is now expecting to be operating cashflow positive in FY2023.

ImmunoINSIGHTS

- Over the past 12 months an increasing number of top 15 global pharma companies have required Master Service Agreements ("MSA") to be put in place to cover the supply of services. In some cases this has been an evolution from using ad hoc purchase orders, indicating the development of customer relationships and the increasing importance of the ImmunoINSIGHTS offering to customers. This trend has continued post year end.
- Notwithstanding the difficult global economic conditions, the pipeline of potential contracts continues to grow. In December 2022, the pipeline for the ImmunoINSIGHTS service business stood at approximately £13M and was growing steadily at approximately £0.75M a month, bolstered by an increased number of larger repeat customer projects than previously seen. Although the timelines between initial discussions and contracting are lengthening, partly due to increasing financial constraints experienced by customers, the impact of this is countenanced through an enlarged commercial team, leading to more contact points being made and an increase in the number of commercial opportunities.

EarlyCDT® Lung

- In July 2022 the product business, based in Nottingham, was restructured to substantially lower its cost base and ensure the business became EBITDA profitable (before the allocation of central overheads) on existing contracted revenues. These contracted revenues are expected to continue to grow.
- At the same time, Biodesix, Inc. (Nasdaq: BDSX) ("Biodesix"), the Group's US distributor of the EarlyCDT Lung product (marketed in the US as NodifyCDT®), announced that WPS Government Health Administrators, the Medicare Administrative Contractor with jurisdiction for Biodesix's Kansas laboratory,

has provided a coverage determination for the NodifyCDT® Lung nodule test at an in-market selling price which is nine times the current price. Medicare coverage is expected to drive faster and wider adoption of the test across the US which will in turn provide increased revenues to the Group.

- Biodesix also recently announced that Royal Philips is to incorporate the results from tests performed on the NodifyCDT® Lung nodule into the Philips Lung Cancer Orchestrator lung cancer patient management system.

Other events (including post period)

New Board appointments

- On 8 July 2022 Alastair Macdonald was appointed as Non-Executive Chair. Alistair succeeds Meinhard Schmidt, who has retired from the Board.

- On 13 January 2023 John Goold was appointed as Non-Executive Director, bringing additional capital markets and investment relations experience to the Board.

Queen's Award for Enterprise in Innovation 2022

- Oncimmune was awarded the Queen's Award for Enterprise 2022 in the innovation category, endorsing Oncimmune as a leading developer of applied immunodiagnostics for the early detection of disease, drug discovery and development.

Divestment of non-core assets

- As previously indicated, the Directors are considering several options for the realisation of value from non-core assets, including discussions on a possible divestment or separate IPO.

Funding strategy

In December 2022, at the time of the successful capital raising which raised gross proceeds of £2.1M, the Directors expected that following the capital raising the Company would have sufficient cash headroom to meet its short-term working capital, debt service and growth needs, based on current trading and the ongoing growth of the ImmunoINSIGHTS pipeline and expectations for higher revenues from the EarlyCDT® business, with the understanding that, in the event that trading volumes and cash generation were lower than anticipated, the Board, if required, would need to take actions to generate further cash inflows and/or conserve cash. In preparing the audited accounts on a going concern basis the Company has prepared a budget for the 12 months to 31 August 2023 and a forecast for the period to 31 March 2024, both of which include certain assumptions including the impact of the Group's debt obligations (base case scenario). The Company's debt facility with IPF Partners is subject to a covenant which requires the Group to ensure that cash plus forecast operating cashflows for the following nine months exceed the total debt service requirement for same period. Whilst the base case scenario indicates that resources would be sufficient to cover interest and debt repayments in the near term, it also illustrates that the growth in cashflow would be insufficient to meet the capital repayments currently due from September 2023. This forecast therefore indicates a possible breach of the financial covenant in March 2023. Following discussions, IPF Partners has confirmed that, in the event of a breach and subject to certain conditions being met, it is prepared to consider a waiver in respect of the requirement to submit a compliant financial covenant. The Directors have ensured that the conditions for the waiver can be satisfied and, in light of actions being taken, have therefore formed a judgement that there is a reasonable expectation that the Group has sufficient resources to continue in operational existence for the foreseeable future. Further detail of the Company's debt position is contained in the Chief Financial Officer's Review below and in the notes to the Company's financial statements contained within the Annual Report and Accounts.

Dr Adam M Hill, CEO of Oncimmune commented:

"FY2022 was a period of investment in the ImmunoINSIGHTS platform following a successful, oversubscribed fundraise in March 2021, which allowed us to evolve our offering, substantially increase capacity and drive our pipeline. The short-term impact of investment and effort has been to increase the quality of our revenue, with more partners opting for multi-year Master Service Agreements in order to access the platform across multiple studies. The medium-term impact is likely to result from the development of novel IP related to immune-related diseases, in which Oncimmune is recognised as expert,

and their treatment. These developments would not have been possible without both our people and all of our stakeholders, including our finance providers, who remain steadfast in their commitment and unwavering support and who we would like to thank.

"The ImmunoINSIGHTS business is now seeing improving growth in the first half of this financial year and has a growing number of contracts. Whilst short-term challenges remain in the operating environment and in financing, the Board is determined to meet these and to enable conversion of the growing pipeline of opportunities to deliver the significant returns available from our differentiated offering and expertise."

For further information:

Oncimmune Holdings plc
Dr Adam M Hill, Chief Executive Officer
Matthew Hall, Chief Financial Officer
contact@oncimmune.co.uk

Singer Capital Markets (Nominated Adviser and Broker)
Aubrey Powell, Harry Gooden, George Tzimas, James Fischer
+44 (0)20 7496 3000

Zeus (Joint Broker)
Dominic King, Victoria Ayton, Dan Bate
+44 (0)20 3829 5000

About Oncimmune

ImmunoINSIGHTS Service Business

Oncimmune is a leading immunodiagnostics developer, primarily focused on the growing fields of immuno-oncology, autoimmune disease and infectious diseases. The ImmunoINSIGHTS service business leverages Oncimmune's technology platform and methodologies across multiple diseases, to offer life-science organizations actionable insights for therapies across the development and product lifecycle. Our core immune-profiling technology is underpinned by our library of over eight thousand immunogenic proteins, one of the largest of its kind. This helps identify trial participants and patients into clinically relevant subgroups, enabling development of targeted and more effective treatments.

Oncimmune's ImmunoINSIGHTS service business is based at the Company's discovery research centre in Dortmund, Germany. The business platform enables life science organizations to optimize drug development and delivery, leading to more effectively targeted and safer treatments for patients.

The ImmunoINSIGHTS development team is based in the US and Europe and Oncimmune is seeking to replicate the Dortmund facility in the US in the medium term.

EarlyCDT® Product Business

Oncimmune's immunodiagnostic technology, EarlyCDT®, can detect and help identify cancer on average four years earlier than standard clinical diagnosis. Our lead diagnostic test, EarlyCDT® Lung, targets a vast market estimated to grow to £3.8bn by 2024. With over 200,000 tests already performed for patients worldwide and its use being supported by peer reviewed data in over 12,000 patients, we are poised to become an integral component of future lung cancer detection programs, globally.

Oncimmune's diagnostic products business is located at its laboratory facility in Nottingham, UK.

For more information, visit www.oncimmune.com

historical facts. These forward-looking statements, which may use words such as "aim", "anticipate", "believe", "could", "may", "intend", "estimate", "expect" and words of similar meaning, include all matters that are not historical facts. These forward-looking statements involve risks, assumptions and uncertainties that could cause the actual results of operations, financial condition, liquidity and dividend policy and the development of the industries in which the Company's businesses operate to differ materially from the impression created by the forward-looking statements. These statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties and other factors that could cause actual results to differ materially from those expressed or implied by such forward-looking statements. Given those risks and uncertainties, prospective investors are cautioned not to place undue reliance on forward-looking statements. Forward-looking statements speak only as of the date of such statements and, except as required by the FCA, the London Stock Exchange or applicable law, the Company undertakes no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

CHAIRMAN AND CHIEF EXECUTIVE OFFICER'S REVIEW

We are pleased to report the Group's audited results to 31 August 2022, a 15-month accounting period following a decision to move Oncimmune's year end, and provide an update on the further operational and strategic progress made since period end.

Oncimmune is a leading immunology testing business, primarily focused on the growing fields of immuno-oncology, autoimmune disease and infectious diseases. As a specialist immunology testing business, the Group has a diversified and growing revenue stream from its discovery and development service-based platform, delivering actionable insights into therapies under development to its pharmaceutical and biotech partners, as well as a portfolio of diagnostic products to detect early-stage cancer. Oncimmune is headquartered at its product laboratory facility in Nottingham, UK, and its ImmunoINSIGHTS pharma services commercial laboratory facility is based in Dortmund, Germany. The ImmunoINSIGHTS commercial team is based in Boston, USA, and across Europe.

Our understanding of the immune system enables us to harness its sophisticated response to disease, in order to detect cancer earlier and to support the development of better therapies. The lowest hanging fruit able to improve disease outcomes is early detection and better selection for therapy, and hence the Group has two operational divisions providing immune services to meet these needs:

- Oncimmune's ImmunoINSIGHTS platform enables life science organisations to optimise drug development and delivery, leading to more effective targeting, as well as safer, treatments for patients. Underpinned by our proprietary library of over 8,000 immunogenic proteins, we help identify clinical trial participants and patients in clinically relevant subgroups, enabling the development of more effective treatments with lower risk of adverse events.

- Oncimmune's immunodiagnostic technology, EarlyCDT®, can detect and help identify cancer earlier than standard clinical diagnosis. With over 200,000 tests already performed for patients worldwide and a substantial evidence base, we believe EarlyCDT Lung will increasingly become integral to lung cancer diagnosis globally.

Business update

2022 has been a period of challenge, as global economies have emerged from the COVID-19 pandemic into a cost-of-living crisis and conflict on Europe's borders. Not only has this economic instability affected company valuations, but it also meant that the life science sector has struggled to access capital, impacting our biotech customers most significantly. However, the technology platform we have established, led by the ImmunoINSIGHTS service offering to pharmaceutical partners, we believe will prove itself robust and resilient in the medium term.

Once again, delivering high quality, differentiated results every time for our ImmunoINSIGHTS customers has allowed us to not only broaden our pipeline of opportunities, but also further deepen our engagement with key customers; increasingly, we have been focused on signing preferred or master service agreements

(MSAs), rather than one-off pilot projects, and we have had the benefit of an increasing percentage of our pipeline made up of repeat customers. This strategy will persist through 2023, where we will look to not only maximise the value of those MSAs in place, but also continue to mature relationships at the pilot stage through to multi contract commercial engagements with top 20 pharma companies.

Once again, we would like to take this opportunity to thank our staff, suppliers and customers for their continued support over the last financial period, without whom our performance would not have been as robust throughout this challenging time. In addition, we would like to thank Oncimmune's current shareholders for their continued support to the Group during turbulent market conditions, and to both Oncimmune's Board and management team for their resourcefulness and resilience.

Services - ImmunoINSIGHTS

Since launching ImmunoINSIGHTS in February 2020, Oncimmune has delivered 31 commercial projects for 18 customers, seven of whom are in the top 15 pharma companies by revenue. In FY2022, the Oncimmune team doubled the number of ImmunoINSIGHTS contracts year-on-year - 18 new contracts or extensions signed in the period, an increase from nine contracts signed in the 12 months to 31 May 2021 and three contracts signed in the 12 months to 31 May 2020. ImmunoINSIGHTS utilises two proprietary biomarker discovery platform technology tools:

- SeroTag discovery arrays: drawing from our library of over 8,800 immunogenic proteins, one of the largest of its kind, to discover and validate biomarkers which can support life science partners in stratifying patients in multiple cancer indications, infectious diseases and with different autoimmune diseases. SeroTag acts as the primary discovery engine that drives the creation of Oncimmune's NavigAID panels.

- NavigAID disease-specific characterisation panels: thoroughly validated and containing well-defined antigens of interest for each of the disease types being investigated, these tools can be used for targeting identifiable patients for whom a treatment may be more effective, whilst avoiding those patients more likely to experience adverse drug effects.

As at January 2023, Oncimmune was contracted to deliver a further six projects over the coming months, and has a building pipeline of contracts, 50% of which are with repeat customers. This is all testament to the quality of our ImmunoINSIGHTS deliverable, completing every project to time and budget.

Product - EarlyCDT®

Much of FY2022, like FY2021 before it, was disrupted by healthcare systems globally dealing with the response to the COVID-19 pandemic which impacted critical services, not least cancer diagnosis and care. As such, the sale of EarlyCDT® products has been difficult for the Group to forecast. However, as global economies have emerged from the pandemic, we have seen a stabilisation of demand for EarlyCDT® products, and important developments in the US affecting the sale of the product.

In the fifth quarter, the Board agreed to restructure the EarlyCDT® Lung product business, substantially reducing the ongoing cost base by £0.5M. This, combined with increased contracted revenues, created an immediately EBITDA profitable EarlyCDT® Lung product business. Now that the business has been right sized, it is delivering more efficiently than before, and is on a clear growth trajectory underpinned largely by long-term contracts with its major customers.

Biodesix, Inc. (Nasdaq: BDSX) (Biodesix), which is the US partner of our EarlyCDT® Lung product, announced in the fifth quarter that WPS Government Health Administrators, the Medicare Administrative Contractor with jurisdiction for Biodesix's Kansas laboratory, has provided a coverage determination for the NodifyCDT® lung nodule test (the marketing name for EarlyCDT Lung in the US) at an in-market selling price which was nine times the average in-market selling price achieved prior to the determination. This represented a significant milestone and has assisted access and availability to the NodifyCDT® lung nodule test, for US patients with lung nodules. Medicare coverage also ensures physicians have access to the NodifyCDT® lung nodule test, which is expected in turn to drive faster and wider adoption of the

NodifyCDT® lung nodule test across the US. Oncimmune receives royalties on every in-market sale of a NodifyCDT® lung nodule test, as well as revenue from the supply of the test to Biodesix.

Furthermore, Biodesix announced in the same quarter that Royal Philips (Philips) had agreed to incorporate the results from tests performed on the NodifyCDT® lung nodule into the Philips Lung Cancer Orchestrator lung cancer patient management system. This important commercial agreement is expected to drive an increase in NodifyCDT® lung nodule test volumes and act as a force multiplier to raise the profile of the NodifyCDT® lung nodule test markedly across the US.

In the UK, we continued our collaboration with the Eastern Academic Health Science Network, delivered through five GP practices a screening pilot using EarlyCDT® Lung in a community setting in high-risk patients. Positive test results were triaged into CT imaging. Both clinical evaluation and health economic assessment are due for publication in 2023, but early data[1.] has had an impact on the ongoing discussions with the screening community in the UK, which we anticipate will impact activities in 2023.

Scientific publications, reports and awards

In line with the Group's core objectives, during the period we have continued to demonstrate the leading potential of our platforms in world class scientific publications and awards.

The versatility of the ImmunoINSIGHTS platform was demonstrated during the pandemic as the Oncimmune team rapidly developed an infectious disease programme, which was validated in June 2021 with the pre-publication of the initial work of Oncimmune's collaboration with Cedars-Sinai Medical Center in Los Angeles, entitled: 'Paradoxical Sex-Specific Patterns of Autoantibodies Response to SARS-CoV-2 Infection'. The paper focuses on the characterisation of sex-specific prevalence and selectivity of autoantibody responses to the SARS-CoV-2 virus, using the SeroTag Infectious Diseases discovery array to detect autoantibodies to over 90 antigens previously linked to a range of classic autoimmune diseases. The collaborators sought to comprehensively examine the diversity of autoantibody responses in male and female healthcare workers who were exposed to SARS-CoV-2 and were asymptomatic, or experienced minor symptoms, and the paper reveals a remarkable sex specific prevalence and selectivity of autoantibody responses to SARS-CoV-2.

This work was later published in the Journal of Translational Medicine[2.] and then supplemented in September 2021 with the pre-publication of 'Predominance of Distinct Autoantibodies in Response to SARS-CoV-2 Infection' from the same collaboration, in which we were able to map the serological diversity underlying the clinical heterogeneity of COVID-19 infection and its sequelae, including the long-Covid phenotypes.

Following successful profiling of patients with urothelial carcinoma undergoing immunotherapy in collaboration with Dana-Faber Cancer Institute, the team were able to demonstrate further utility of the ImmunoINSIGHTS platform as an orthogonal data source to genomic and transcriptomic data; this work was published in the Journal of Clinical Oncology entitled 'Multiplexed autoantibody (AA) profiling of patients (pts) with metastatic urothelial carcinoma (mUC) receiving immune checkpoint inhibitors or platinum-based chemotherapy[3].

After a number of years of collaboration with the RA-MAP consortia, the ImmunoINSIGHTS team was able to participate in the publication of the most comprehensive map of molecular immunological landscapes in rheumatoid arthritis[4].

This seminal work required the aggregation of data from a number of different lenses through which to view the immune response in rheumatoid arthritis, and clearly evidenced the role of ImmunoINSIGHTS in profiling these patients.

In August 2021, the three-year follow-up data for the Early detection of Cancer of the Lung Scotland (ECLS) trial in was pre-published entitled 'Targeted screening for lung cancer with autoantibodies'. The pre-publication shows that after three years, the number of late-stage cancers and deaths were lower in patients tested with the EarlyCDT® Lung blood test. Crucially, all-cause mortality, as well as cancer specific and lung cancer mortality was reduced. The ECLS trial, believed to be the largest randomised controlled

and lung cancer mortality was reduced. The 2020 trial, believed to be the largest randomised controlled trial for the detection of cancer using blood-based biomarkers, published two-year follow-up results in 2020 in the European Respiratory Journal showing a 36% reduction in late-stage diagnoses of lung cancer, and the three-year data now shows a continued trend towards a reduction in mortality.

More recently, in April 2022, Oncimmune was awarded the Queen's Award for Enterprise 2022 in the innovation category, endorsing the company as a leading developer of applied immunodiagnostics for the early detection of disease, drug discovery and development. The Queen's Award for Enterprise 2022 acknowledges the innovation behind Oncimmune's immunodiagnostic and discovery technology.

Finally, our collaboration with the Eastern Academic Health Science Network (EAHSN) in Norfolk throughout 2021 delivered a community-led screening programme for patients at high risk of lung cancer to evaluate the role of EarlyCDT® Lung in the community setting, 4,890 patients were invited for screening, 1,919 attended (39.2% response rate), 298 (15.53%) had a positive test, of which 291 had follow-up CT scan leading to 20 patients (6.87%) requiring further investigations, and nine patients (45%) found to have lung cancer, with the remaining 11 patients sufficiently at risk to warrant six-12 monthly follow-up. Of the nine patients diagnosed with cancer, seven had primary lung tumours, all early stage (five stage 1; two stage 2). This work is expected to be published in 2023.

Board changes

In the fifth quarter of the year, Oncimmune's Board of Directors appointed Alistair Macdonald as Chair of the Board, bringing to the Board a wealth of experience in delivering Clinical Research services to the Pharmaceutical sector. Alistair replaced Meinhard Schmidt, who had served six successful years on Oncimmune's Board. In addition, and following the end of the reported period, the Board decided to also appoint John Goold as Non-Executive Director, bringing with him a depth of experience in small cap markets in the UK.

Following these changes, the Board is now comprised of one Executive Director and five Non-Executive Directors, two of which are Independent Non-Executive Directors. The Board members are Alistair Macdonald, Non-Executive Chairman; Dr Adam M Hill, Chief Executive Officer; Dr Annalisa Jenkins, Senior Independent Non-Executive Director; Andrew Unitt, Independent Non-Executive Director; Tim Bunting, Non-Executive Director; and John Goold, Non-Executive Director.

Outlook

The financial period to 31 August 2022 and the period post year-end have seen significant and continuing progress for the Company. In December 2022, the pipeline for our ImmunoINSIGHTS service business stood at approximately £13M and was growing steadily at approximately £0.75M a month, bolstered by more larger repeat customer projects than previously seen. As we started to see last year, initial pilot contracts have indeed broadened into multiple projects and deeper strategic commercial partnerships, with associated opportunities for additional, long-term revenue.

The Board sees the potential to not only build upon the MSAs established so far, but also to continue to add new customers to the portfolio. In addition, the Board is increasingly excited about the potential to further evolve Oncimmune's business model by exploiting the substantial intellectual property developed throughout 2022, albeit a medium-term investment of resource.

On behalf of the Board, we would like to thank our shareholders for their continued support throughout FY2022, and we look forward to updating the market on Oncimmune's further progress periodically.

Alistair Macdonald
Chairman

Dr Adam M Hill
Chief Executive Officer

1. https://www.easternahsn.org/impact-story/detectinglung-cancer-earlier/

2. Liu, Y., Ebinger, J.E., Mostafa, R. et al. Paradoxical sex-specific patterns of autoantibody response to SARS-CoV-2 infection. J Transl Med 19, 524 (2021). https://doi.org/10.1186/s12967-021-03184-8

3. Sonpavde, G et al. Multiplexed autoantibody (AA) profiling of patients (pts) with metastatic urothelial carcinoma (mUC) receiving immune checkpoint inhibitors or platinum-based chemotherapy. Journal of Clinical Oncology 40, no. 6_suppl (20 February, 2022) 558-558. DOI: 10.1200/JCO.2022.40.6_ suppl.558

4. The RA-MAP Consortium. RA-MAP, molecular immunological landscapes in early rheumatoid arthritis and healthy vaccine recipients. Sci Data 9, 196 (2022). https://doi.org/10.1038/s41597-02201264-y

CHIEF FINANCIAL OFFICER'S REVIEW

Revenues and commercial progress

Revenue for the 15-month period to 31 August 2022 reflects the steady progression of commercial activities within the ImmunoINSIGHTS and EarlyCDT® businesses. Within the ImmunoINSIGHTS business, the Group has particularly benefited from the considerable time and resources devoted to our growing portfolio of global pharmaceutical clients. These clients are providing a growing base of ongoing commercial contracts, which improves the overall quality of our commercial pipeline. The EarlyCDT® business is largely underpinned by existing commercial contracts which are providing growing revenues. The reorganisation of the EarlyCDT® business, which was undertaken in July 2022, has substantially reduced the ongoing cost base of this business, to ensure it is EBITDA profitable on existing revenues.

ImmunoINSIGHTS

During the reporting period, the business signed 18 new or extensions to existing contracts, compared with nine in the 12 months to 31 May 2021. Encouragingly, this increase coincided with a period of challenging market conditions.

Furthermore, the value of the commercial pipeline of potential contracts also increased throughout the period and has continued this momentum post the period end. Throughout the reporting period, there has been a focus on generating the majority of revenue from large pharmaceutical companies, and as at the end of the reporting period, ImmunoINSIGHTS counted seven of the top fifteen global pharma companies as clients.

Since the end of the reporting period, the business has continued to sign commercial contracts, notably in December 2022, when it signed further contracts with an existing global pharma client, with a combined value of approximately $1.25M. Also in December 2022 the business signed a MSA with another global pharma client, which is expected to support multiple autoantibody profiling projects throughout calendar 2023.

EarlyCDT® Lung

In July 2022, the Nottingham-based product business was restructured, to substantially lower its cost base and ensure that this business is immediately EBITDA profitable on existing contracted revenues before the benefit of any further product volume growth.

Biodesix, Inc. (Nasdaq: BDSX) (Biodesix), the Group's US distributer of the EarlyCDT® Lung product (marketed in the US as NodifyCDT®), recently announced that WPS Government Health Administrators, the Medicare Administrative Contractor with jurisdiction for Biodesix's Kansas laboratory, has provided a coverage determination for the NodifyCDT® Lung nodule test.

Medicare coverage is expected to drive faster and wider adoption of the test across the US, which will in turn provide increased revenues to the Group over time. Overall sales in the US are also underpinned by our existing commercial contract with Biodesix, which provides minimum sales volumes.

EarlyCDT® Lung revenues are also derived from an ongoing contract with the iDx-Lung programme, a collaboration between the University of Leeds and the Southampton Clinical Trials Unit at the University of Southampton. The Group also anticipates an uplift in sales volumes following the recently published real-world screening evaluation pilot with the Norfolk and Waveney Clinical Commissioning Group.

Equity fundraise

In December 2022, the Company completed an equity fundraise, raising gross proceeds of £2.1M to provide the Group with additional near-term working capital and enable funding of future collaborations in biomarker tool development.

Debt funding

In October 2022, the Group reprofiled its debt banking facility (the "IPF Facility") with IPF Management SA ("IPF Partners"). The new terms provide for a deferral of all principal repayments until June 2023, no further issue of warrants and the continued repayment of interest as from September 2022. An arrangement fee of €1.5M has been agreed, which is payable at final maturity of the debt, with up to 50% (€0.75M) of this fee able to be offset against any warrants already issued to IPF Partners.

Under the terms of the renewed facility, the Group is required to make total capital repayments of €11.6M, of which, €6.9M is required to be repaid in the 2023 calendar year. The Group is also required to satisfy a cash covenant which is reported quarterly at month end in March, June, September and December of each year, and which requires the Group to maintain sufficient cash to cover operating cash flows as well as all scheduled interest and principal debt repayments for a period of nine months from each quarterly test point. In the process of preparing the Company's accounts the Directors have a budget for the 12 months to 31 August 2023 and a forecast for the period to 31 March 2024, both of which include the impact of the Group's debt obligations (base case scenario). Whilst the forecast operating cash flow for the Group to December 2023 in the base case scenario is sufficient to cover operating cash flow and interest repayments, under the base case scenario the Group does not expect to be able to generate sufficient cash to meet the capital repayments from September 2023 and, therefore, is forecast to breach its March 2023 debt covenant. Such a situation gives rise to a material uncertainty which may cast doubt about the Group's ability to continue as a going concern.

The Board is in the process of reviewing its options for the potential sale or IPO of certain of the Group's assets, with the intention that a proportion of any proceeds received will be directed towards the repayment of debt. Furthermore, the Board has discussed with IPF Partners the possible breach of the financial covenants, and the Group's inability to pay the principal amounts scheduled under the reprofiled IPF Facility during the forecast period, together with the strategic options currently being considered by the Board. IPF Partners has confirmed to the Board that it is prepared to consider a waiver in respect of the requirement to submit a compliant financial covenant certificate in the event of a breach provided the Group complies with certain conditions. At the date of approval of the financial statements the Directors have ensured the actions requested by IPF Partners have been completed.

Commentary on financial statements

Research and development activities continued throughout the period, with two major projects successfully delivered. The Group's strategy is centred on the commercial exploitation of its ImmunoINSIGHTS services and EarlyCDT® product businesses and, in future years, research and development costs are anticipated to be materially lower.

For the 15-month period to 31 August 2022, gross profit for the period was £1.8M (2021: £2.9M), which for the reporting period includes the majority of the costs of the ImmunoINSIGHTS Dortmund production team. During the reporting period the planned head count in Dortmund increased substantially compared to the prior year, in order to deliver the increase in commercial contracts.

Administrative expenses for the 15-month period were £8.7M (2021: £5.7M). Certain costs were higher in the reporting period, including one-off recruitment costs of £0.2M associated with the buildout of our ImmunoINSIGHTS production head count and US commercial team, £0.1M of IT costs to move staff to home-working during the COVID-19 pandemic, £2.6M of increased staff remuneration and £0.4M of increased insurance costs. Also included is a non-cash £0.8M increased amortisation charge against Intangible assets. The restructuring of the cost base of the EarlyCDT Lung business is delivering lower ongoing costs.

Cash balance at period end was £1.4M (2021: £8.6M) and net debt was £9.2M including lease liabilities (FY2021: net debt £0.8M), with net debt of £8.6M excluding lease liabilities (2021: net cash £0.1M).

During the year the Company continued to invest in the ImmunoINSIGHTS services business. This continued funding together with the approval and procurement process associated with awarding by large pharmaceutical companies of new contracts, has resulted in funding challenges. However, the growing number of awarded contracts, the signing of MSAs and the increasing percentage of signed contracts and pipeline made up of repeat customers, gives the Board confidence for the future of the Group.

Matthew Hall
Chief Financial Officer

Consolidated statement of comprehensive income
For the period ended 31 August 2022

	Period to 31 August 2022 £'000 Total	Year to 31 May 2021 (restated) £'000 Total
Revenue	**3,788**	3,722
Cost of sales	**(1,962)**	(865)
Gross profit/(loss)	**1,826**	2,857
Research and development expenses	**(1,851)**	(1,615)
Administrative expenses	**(8,702)**	(5,652)
Share-based payment	**(1,691)**	(1,046)
Total administrative expenses	**(12,244)**	(8,313)
Other income	**413**	311
Operating loss	**(10,005)**	(5,5509)

Finance income	**8**	403
Finance costs	**(1,562)**	(1,318)
Finance costs - net	**(1,554)**	(915)
Loss before income tax	**(11,559)**	(6,060)
Income tax credit	**173**	1,068
Loss for the financial period/year	**(11,386)**	(4,992)
Other comprehensive income		
Items that may be subsequently reclassified to profit or loss, net of tax		
Currency translation differences	**(130)**	(91)
Loss after tax and total comprehensive income for the period/year attributable to equity holders	**(11,516)**	(5,083)
Basic and diluted loss per share (pence)	**(16.49)p**	(7.73)p

All activities of the Group in the current and prior periods are classed as continuing. All of the comprehensive income for the period is attributable to the shareholders of Oncimmune Holdings Plc.

The accompanying notes form an integral part of these consolidated financial statements.

Consolidated statement of financial position
As at August 2022

	Audited 31 August 2022 £'000	Audited 31 May 2021 £'000
Assets		
Non-current assets		
Goodwill	**1,578**	1,578
Intangible assets	**3,017**	4,116
Property, plant and equipment	**788**	664
Right-of-use assets	**552**	930
Deferred tax asset	**613**	937
	6,548	8,225
Current assets		
Inventories	**430**	143
Trade and other receivables	**1,340**	2,161
Contract assets	**417**	200
Cash and cash equivalents	**1,425**	8,631
	3,612	16,053
Total assets	**10,160**	19,360
Equity		
Capital and reserves attributable to the equity holders		
Share capital	**695**	691
Share premium	**40,634**	40,497
Merger reserve	**31,882**	31,882
Foreign currency translation reserve	**(42)**	88
Own shares	**(1,926)**	(1,926)
Retained earnings	**(75,422)**	(66,005)
Total equity	**(4,179)**	5,227
Liabilities		
Non-current liabilities		
Deferred tax	**311**	374
Lease liability	**295**	671
Borrowings	**3,917**	6,239
Other liabilities	**2,000**	2,000

	6,523	9,284
Current liabilities		
Trade and other payables	**1,176**	1,979
Contract liabilities	**180**	257
Other statutory liabilities	**34**	55
Lease liability	**321**	310
Borrowings	**6,105**	2,248
	7,816	4,849
Total liabilities	**14,339**	14,133
Total equity and liabilities	**10,160**	19,360

Adam M Hill
Director and Chief Executive Officer

The accompanying notes form an integral part of these consolidated financial statements.
The financial statements were approved by the Board on 27 February 2023.

Company registration number: 09818395 (England and Wales)

Consolidated statement of changes in equity
For the period ended 31 August 2022

	Share capital	Share premium	Merger reserve	Foreign currency translation reserve	Own shares	R e
	£'000	£'000	£'000	£'000	£'000	
As at 1 June 2020	**635**	**31,459**	**31,882**	**179**	**(1,926)**	
Loss for the year (restated)	-	-	-	-	-	
Other comprehensive income:						
Currency translation differences	-	-	-	(91)	-	
Total comprehensive expense	**-**	**-**	**-**	**(91)**	**-**	
Transactions with owners:						
Shares issued in year	50	8,331	-	-	-	
Options exercised	2	106	-	-	-	
Shares issued in relation to prior year acquisition	4	601	-	-	-	
Share option charge	-	-	-	-	-	
Warrants issued	-	-	-	-	-	
As at 31 May 2021	**691**	**40,497**	**31,882**	**88**	**(1,926)**	
Loss for the period	-	-	-	-	-	
Other comprehensive income:						
Currency translation differences	-	-	-	(130)	-	
Total comprehensive expense	**-**	**-**	**-**	**(130)**	**-**	
Transactions with owners:						
Options exercised	4	137	-	-	-	
Warrants issued	-	-	-	-	-	
Share option charge	-	-	-	-	-	
As at 31 August 2022	**695**	**40,634**	**31,882**	**(42)**	**(1,926)**	

The accompanying notes form an integral part of these consolidated financial statements.

Consolidated statement of cash flows
For the period ended 31 August 2022

	Period to 31 August 2022	Year to 31 May 2021 (restated)
	£'000	£'000
Cash flows from operating activities		
Loss before income tax	**(11,559)**	(6,060)
Adjusted by:		
Depreciation and amortisation	**1,643**	740
Share-based payment charge	**1,691**	1,046
Interest receivable	**(8)**	(403)
Interest expense	**1,562**	1,318
Fair value movement on contingent consideration and liabilities	**-**	176
	-	-
Changes in working capital:		
(Increase)/decrease in inventories	**(287)**	31
Decrease/(increase) in trade and other receivables	**5,547**	(5,837)
(Decrease)/increase in trade and other payables	**(5,281)**	4,841
Cash used in operating activities	**(6,692)**	(4,148)
Interest paid	**(597)**	(885)
Interest received	**8**	3
Income tax received	**409**	503
Net cash used by operating activities	**(6,872)**	(4,527)
Cash flows from investing activities		
Purchase of property, plant and equipment	**(306)**	(446)
Purchase of intangible assets	**(625)**	(625)
Proceeds from sale of assets	**-**	215
Net cash used in investing activities	**(931)**	(856)
Cash flows from financing activities		
Net funds raised through share issue	**141**	8,489
Loan advances	**2,546**	2,728
Loan repayments	**(1,643)**	(1,135)
Principal elements of lease repayments	**(392)**	(303)
Net cash generated from financing activities	**652**	9,779
Net (decease)/increase in cash and cash equivalents	**(7,151)**	4,391
Movement in cash attributable to foreign exchange	**(55)**	(5)
Cash and cash equivalents at the beginning of the period	8,631	4,240
Cash and cash equivalents at the end of the period	**1,425**	8,631

The accompanying notes form an integral part of these consolidated financial statements.

1. General information

Oncimmune Holdings Plc (the "Company") is a limited company incorporated and domiciled in England and Wales. The registered office of the company is MediCity - D6 Building, 1 Thane

England and Wales. The registered office of the company is MediCity - D6 Building, 1 Thane Road, Nottingham, NG90 6BH. The registered company number is 09818395.

The Group's principal activity is the development and commercialisation of technologies that enable cancer diagnosis.

The Directors of Oncimmune Holdings Plc are responsible for the financial information and contents of the financial information.

Electronic communications

The Company is not proposing to distribute hard copies of the financial statements for the 15 months to 31 August 2022 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 inks, 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, MediCity D6 Building, 1 Thane Road, Nottingham, NG90 6BH or by email: contact@oncimmune.com

2. Accounting policies

The principal accounting policies applied in the preparation of the consolidated financial information are set out below. These policies have been consistently applied to all periods presented, unless otherwise stated. The financial statements are for the Group consisting of Oncimmune Holdings Plc and its subsidiaries.

Basis of preparation

The Group has prepared its consolidated financial statements in accordance with UK-adopted international accounting standards (IFRSs) in conformity with the requirements of the Companies Act 2006.

The financial statements have been prepared on a historical cost basis, except certain financial assets and liabilities which are measured at fair value.

The Company was incorporated on 9 October 2015 and was re-registered as a public limited company on 14 December 2015. On 23 November 2015, a Group re-organisation was completed, by means of a share for share exchange, as a result of which the newly incorporated company, Oncimmune Holdings Plc, became the parent company of the Group.

The companies involved in the above share for share exchange had not previously been presented in the consolidated financial statements of a single legal entity. However, the underlying business was ultimately controlled and managed by the same parties before and after the share for share exchange, and that control was not transitory. The transactions outlined above, therefore, met the definition of a common control transaction in accordance with IFRS 3 Business Combinations.

IFRS does not provide any specific guidance on accounting for common control transactions and IFRS 3 excludes common control transactions from its scope; therefore the Directors had selected an accounting policy in accordance with paragraphs 10-12 of IAS 8 Accounting Policies, Changes in Accounting Estimates and Errors. The consolidated entity met the definition of a Group reconstruction under FRS 102 19,27 and was therefore accounted for under the principals of merger accounting as outlined in FRS 102, paragraphs 19.29 - 19.33, merger accounting. The consolidated financial statements have been prepared as if Oncimmune Limited and its subsidiaries had been held by Oncimmune Holdings Plc from inception, and the

results and position of Oncimmune Limited have been reflected in the comparatives.

The preparation of financial statements in accordance with IFRS requires the use of certain critical accounting estimates. It also requires management to exercise its judgement in the process of applying the Group's accounting policies. The areas involving a high degree of judgement or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements, are disclosed in note 3.

The reporting period for this set of financial statements is the 15-month period to 31 August 2022. The accounting dates were changed in order to better align the year end with the commercial cycle of large pharma companies. Generally pharmaceutical companies' year ends are 31 December, and so they start January with a new budget. An August year end allows the Group to win contracts in the first 6 months of each calendar year and recognise the majority of the revenue. As this period is 3 months longer than the preceding period (the year to 31 May 2021), the amounts presented in these financial statements are not fully comparable.

The consolidated financial statements are presented in Sterling and have been rounded to the nearest thousand (£'000).

Principles of consolidation and equity accounting

Subsidiaries are all entities (including structured entities) over which the Group has control. The Group controls an entity when the Group is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power to direct the activities of the entity. Subsidiaries are fully consolidated from the date on which control is transferred to the Group. They are deconsolidated from the date that control ceases.

The Group uses the acquisition method of accounting to account for business combinations.

Inter-company transactions, balances and unrealised gains and losses on transactions between Group companies are eliminated. Accounting policies of subsidiaries have been changed where necessary, to ensure consistency with the policies adopted by the Group.

Where a Group company has acquired an investment in a subsidiary undertaking and applies merger relief, under section 612 of the Companies Act 2006, the difference between the nominal value and fair value of the shares issued is credited to the merger reserve.

Going concern

In respect of the Group's funding position, the Parent Company's subsidiary (Oncimmune Limited) entered into a €8.5M credit facility with IPF Management SA ("IPF Partners") in September 2019 which was further extended by €6.0M in October 2020 ("IPF Facility"). Each tranche of the total loan is repayable over a four-year term, interest-only for the first 12 months, with principal repayments commencing thereafter. In October 2022, the Group reprofiled its debt banking facility with IPF Partners. The new terms provide for a deferral of all principal repayments until June 2023, no further issue of warrants, and the continued repayment of interest as from September 2022. An arrangement fee of €1.5M has been agreed which is payable at final maturity of the debt, with up to 50% (€0.75M) of this fee able to be offset against any warrants already issued to IPF Partners. As is customary with a debt facility such as this, there is a cash covenant requiring the Group to maintain nine months of cash which is tested each calendar quarter. To monitor compliance with the terms of the IPF Facility, the Board prepares and reviews monthly financial accounts.

The Group has prepared the 2022 financial statements on a going concern basis. In preparing the accounts on a going concern basis the Directors have a budget for the 12 months to 31 August 2023 and a forecast for the period to 31 March 2024, both of which include the impact of the Group's debt obligations (base case scenario). The base case scenario assumes cash from contracts with customers for the forecast period being a mix of contracted amounts, contracts currently under negotiation, repeat business from already contracted work together with contracts from as yet unidentified opportunities. It is assumed under the base case scenario that

contracts from as yet unidentified opportunities. It is assumed under the base case scenario that forecast operating costs are sufficient to support the forecast revenue without the need for material additional cost increases.

However, under the same base case scenario, the Group is forecast to breach the cash covenant under the debt facility in March 2023. The cash covenant requires the Group to have sufficient cash to meet its operating cash flow as well as all interest and principal debt repayments for the following nine months from each quarterly test point. The existing principal debt repayment schedule requires debt repayments of €1.2M in June 2023, €2.4M in September 2023 and €3.3M in December 2023, a total of €6.9M. Whilst the operating forecast cash flow for the Group to December 2023 in the base case scenario is sufficient to cover operating cash flow and interest repayments, under the base case scenario the Group does not expect to be able to generate sufficient cash to meet the capital repayments currently due from September 2023. Such a situation gives rise to a material uncertainty which may cast significant doubt about the Group's ability to continue as a going concern. The Board is in the process of reviewing its options for the potential sale or IPO of certain of the Group's assets, with the intention that a proportion of any proceeds received will be directed towards the repayment of debt. Furthermore, the Board has discussed with IPF Partners the possible breach of the financial covenants, and the Group's inability to pay the principal amounts scheduled under the reprofiled IPF Facility during the forecast period, together with the strategic options currently being considered by the Board. IPF Partners has confirmed to the Board that it is prepared to consider a waiver in respect of the requirement to submit a compliant financial covenant certificate in the event of a breach provided the Group complies with certain conditions. At the date of approval of the financial statements the Directors have ensured the actions requested by IPF Partners have been completed.

Based on the strategic options being considered and the ongoing funding negotiations with IPF Partners, the Board is confident in being able to settle the Group's debt obligations in full or renegotiating the current covenant obligations with IPF Partners to enable the Group and the Company to be able to meet their obligations as and when they fall due for the foreseeable future. However, given that neither sale proceeds have been secured or a formal waiver of covenants has been received at the date of approving these financial statements, a material uncertainty exists that may cast significant doubt on the Group's and the Parent Company's ability to continue as a going concern.

Accepting the material uncertainty, the Directors have a reasonable expectation that the Company has adequate resources to continue in operational existence for the foreseeable future. For these reasons, they continue to adopt the going concern basis in preparing the Annual Report and Accounts.

END

FR NKABBNBKBOBB