

2 November 2021

## **Oncimmune Holdings plc**

("Oncimmune", the "Company" and, together with its subsidiaries, the "Group")

### **Full year results and progress update**

*FY2021 revenues of £3.7 million (over 6x increase on FY2020)*

*Continued delivery against three-year strategy, with FY2022 growth expected to continue to be driven by ImmunoINSIGHTS services business*

Oncimmune Holdings plc (AIM: ONC.L), the leading global immunodiagnostics group, today announces its audited results for the year ended 31 May 2021 ("FY2021") and provides an update on recent progress and the outlook for the current financial year ("FY2022").

#### **Operational and commercial highlights:**

##### ***ImmunoINSIGHTS***

- Continued to strengthen strategic relationships with Roche and Genentech as well as with other global pharmaceutical companies
- Following the successful deployment of UK Government funding for the development of an infectious diseases research tool for use in COVID-19, the period saw the launch of an infectious diseases panel resulting in contracts with Roche and multiple contracts with Cedars-Sinai Medical Center, Los Angeles
- Agreement signed with a leading global pharmaceutical company to utilise the NavigAID autoimmune disease characterisation panel to explore the autoantibody profiles of patients with four key autoimmune diseases
- Agreements with three leading global pharmaceutical companies to utilise the SeroTag immuno-oncology discovery array to explore the autoantibody binding profiles of solid tumour cancer patients treated with immunotherapy
- Renewal of existing partnership with Oncimmune continuing to provide autoantibody biomarker services to a global pharmaceutical company, with two initial projects started to profile patients in autoimmune trials
- Further research published in leading journals including Arthritis Research & Therapy<sup>1</sup> and PLOSOne<sup>2</sup>, alongside pre-publication of the first results from collaboration with Cedars-Sinai<sup>3</sup>

##### ***EarlyCDT Lung***

- Pilot in Norfolk and Waveney Clinical Commissioning Group initiated, representing the first sales of the EarlyCDT Lung test into the NHS
- iDx Lung<sup>4</sup> programme launched, with 350 patients recruited to date in Southampton and Leeds
- US partner for EarlyCDT Lung, Biodesix, seeing a recovery in demand, with planned expansion of its national sales team from 32 to 76 by the end of 2022
- EarlyCDT Lung authorised for use by the Spanish Public Health Service with the Galician Health Service (SERGAS), the first public health service in Spain to use the EarlyCDT Lung test
- Diagnosticos da America, Latin America's largest medical diagnostic company, to offer EarlyCDT Lung across its extensive laboratory, private hospital and clinic network
- Successful return of the IP and distribution rights for EarlyCDT in the People's Republic of China and Hong Kong from Genostics Company Limited, allowing Oncimmune to pursue the optimum route to market

- Results from the ECLS study published in the European Respiratory Journal<sup>5</sup> and pre-publication of the three-year follow-up data<sup>6</sup> supports a trend towards a mortality benefit of the EarlyCDT Lung blood test, confirming the number of late-stage cancers and deaths to be lower in patients tested with EarlyCDT Lung
- Additional results published in PLOSOne showed that EarlyCDT Lung and CT surveillance has been found to be highly cost-effective in early detection compared to CT surveillance alone<sup>7</sup>

#### **Financial highlights:**

- Revenue of £3.7M (FY2020: £0.5M) validates the Company's core strategy of focusing on building a leading immunodiagnosics group; with significant growth driven by conversion from an expanding pipeline of ImmunoINSIGHTS opportunities
- The revenue reported is lower than the headline £5.6M indicated in the unaudited full-year trading update issued on 8 June, due largely to revenue recognition relating to an invoice for £1.7M to an historic EarlyCDT Lung distributor. The Group is unable to recognise this revenue in the year ended 31 May 2021 as the revenue recognition requirements of IFRS 15 have not been met at this time
- The ImmunoINSIGHTS service business showed strong growth in revenue, profitability and cash generation during the period
- Successful equity placing in March 2021 with gross proceeds of £9M to enable a 4x scale-up in ImmunoINSIGHTS operating capacity to meet increasing demand from customers, and the expansion of commercial team to support customers, particularly in the US
- Continued tight management of cost base following the cost reduction programme initiated in 2018

#### **Recent progress and FY2022 outlook:**

- Scale up of the Dortmund facility in progress and capable of handling upwards of 40,000 samples per annum by Q1 FY2023
- Continued commercial success from the infectious diseases platform across existing and new contracts
- Commercial sales team expansion in the US underway with recent key hires on the East and West coasts. With a clear majority of all ImmunoINSIGHTS contracts currently and historically being awarded are from the US
- Evaluating additional expansion of scientific and bioinformatics capability in the US to deliver US-based projects
- Second pilot to provide EarlyCDT Lung tests into the NHS already signed and expected to commence in Q3 FY2022
- After quieter than expected summer months in which fewer new ImmunoINSIGHTS contracts were signed than originally expected, there has been a healthy resumption of activity and a strong rate of conversion of the commercial pipeline into service contracts, underpinning confidence in FY2022 revenue growth from both new opportunities and follow-on contracts
- Longer term prospects remain compelling, with the conversion of a number of initial services contracts into multiple projects serving to demonstrate the Group's ability to develop deeper and broader strategic commercial partnerships, of increasing value and longevity

**Dr Adam M Hill, CEO of Oncimmune, commented:** *"We are pleased to announce our full year results for the 2021 financial year. Over the period, the ImmunoINSIGHTS business has allowed us to broaden our pipeline of opportunities whilst deepening our engagement with key customers. As demonstrated by the number of follow-on contracts being signed and our growing commercial pipeline, we are experiencing increased recognition for our services by our partners and customers. With significant momentum moving into the second quarter of FY2022, driven by the highly differentiated ImmunoINSIGHTS service, we look forward to another year demonstrating the success against our three-year strategic plan to unlock the Group's growth potential."*

*"On behalf of the Board, we would like to thank all our employees for their dedication during a period of high growth and investment despite the impact of COVID-19. We would also like to thank investors for their continuing support through the oversubscribed placing during the period in support of our growth"*

*plans and are pleased to be able to report continued strong delivery against the Group's goals over the period."*

### **Investor presentation and conference call**

The Company's management team will host a presentation and conference call for analysts at 10:00 GMT today. For conference call details please contact Alexander Davis of FTI Consulting at [Alexander.Davis@fticonsulting.com](mailto:Alexander.Davis@fticonsulting.com) or 020 3727 1000.

The management team will also host on Investor Meet Company a live presentation of the results at 15:00 GMT this afternoon which will be open to all existing shareholders and potential new investors. Access to Investor Meet Company is free and interested parties can register to attend the presentation via the following link: <https://www.investormeetcompany.com/oncimmune-holdings-plc/register-investor>

1. Vordenbäumen, S., Brinks, R., Schriek, P. et al. Profiling of IgG antibodies targeting unmodified and corresponding citrullinated autoantigens in a multicenter national cohort of early arthritis in Germany. *Arthritis Res Ther* 22, 167 (2020). <https://doi.org/10.1186/s13075-020-02252-6>
2. <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0241189>
3. <https://www.medrxiv.org/content/10.1101/2021.07.15.21260603v1>
4. NHS Lung Health Check Programmes in Wessex and Yorkshire as part of the iDx-LUNG evaluation programme
5. <https://erj.ersjournals.com/content/early/2020/07/09/13993003.00670-2020>
6. <https://medrxiv.org/cgi/content/short/2021.08.17.21262105v1>
7. <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0237492>

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#### **About Oncimmune ([www.oncimmune.com](http://www.oncimmune.com))**

Oncimmune is a leading immunodiagnostics developer, primarily focused on the growing fields of immuno-oncology, autoimmune disease and infectious diseases. Oncimmune has a diversified and growing revenue base, both from its portfolio of diagnostic products to detect early-stage cancer and its contract discovery and development service business whose platform delivers actionable insights into therapies to the Company's pharmaceutical and biotech partners.

Our understanding of the immune system enables us to harness its sophisticated response to disease to detect cancer earlier and to support the development of better therapies. The key to improving cancer survival is early detection and better selection for therapy. As a company, we are driven by our passion to improve cancer survival and to give people extra time.



Oncimmune's ImmunoINSIGHTS platform enables life science organisations to optimise drug development and delivery, leading to more effectively targeted and safer treatments for patients. 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 programmes, globally.

Oncimmune is headquartered at its EarlyCDT product and R&D 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 the US and Europe.

For more information, visit [www.oncimmune.com](http://www.oncimmune.com)

## **CHAIRMAN AND CHIEF EXECUTIVE OFFICER'S REVIEW**

We are pleased to report the Group's audited full year results to 31 May 2021 and provide an update on the further operational and strategic progress made since year end.

Oncimmune is a leading immunodiagnostics developer, 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 to its pharmaceutical and biotech partners, as well as a portfolio of diagnostic products to detect early-stage cancer. Oncimmune is headquartered at its EarlyCDT product and R&D 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 the US and 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 key to improving disease outcomes is early detection and better selection for therapy. The Group has two operational divisions providing immunodiagnostics services:

- 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. Our core immune-profiling technology is underpinned by our library of over 8,800 immunogenic proteins, one of the largest of its kind. This helps identify clinical trial participants and patients in clinically relevant subgroups, enabling the development of targeted, more effective treatments with lower risk of adverse events.
- Oncimmune's immunodiagnostic technology, EarlyCDT, can detect and help identify cancer on average four years earlier than standard clinical diagnosis. The Group's 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 believe we are poised to become an integral component of future lung cancer detection programmes, globally.

### **Business update**

The 2021 financial year has been an important one for Oncimmune, delivering our second full year of trading since announcing the Company's three-year strategic plan and demonstrating its impact on the Group's revenue. Launched in September 2018, the strategy is intended to unlock the latent potential of the Group's proprietary technology platform by establishing a pharma partnering services business, ImmunoINSIGHTS. Core to this strategy was the identification of commercial opportunities leveraging Oncimmune's proprietary autoantibody-based technology platform and the Group's revenue growth in FY2021 is a direct result of this service-oriented strategy.

Beyond the growth of in revenues through unlocking value in the platform, the differentiated product and service offering is also creating additional optionality for future growth. Delivering high quality, differentiated results time and time again for our customers on the ImmunoINSIGHTS side of the business has allowed us to not only broaden our pipeline of opportunities, but also deepen our engagement with key customers, increasingly contributing to the biomarker strategy in support of both pre-clinical and clinical drug development as a valued partner.

As a result of the COVID-19 pandemic and subsequent restrictions imposed globally, since March 2020 the Company has been working remotely where possible to minimise the potential impact on the business, whilst ensuring all laboratory operations are unaffected. Within our Nottingham and Dortmund facilities we organised the staff's working arrangements to mitigate the possible effects on the business and our customers and are pleased to report that COVID-19 has not materially affected our laboratory output.

We would like to take this opportunity to thank our staff, suppliers, and customers for their resourcefulness and resilience over the last year in continuing to deliver against the Group's strategy

throughout this difficult time. In addition, we would like to thank Oncimmune's current shareholders for their continued support in the Group and the management team as we continue to deliver on our three-year strategy plan and beyond.

### **Services - ImmunoINSIGHTS**

The Group launched the ImmunoINSIGHTS service in February 2020 as Oncimmune's contract discovery and development service-based platform and, since then, the pipeline of signed and potential commercial projects with major pharmaceutical and biotechnology companies has increased substantially. The ImmunoINSIGHTS service business leverages Oncimmune's technology platform and methodologies across diseases of the immune system, including cancer, autoimmune disease and infectious diseases, to offer life science organisations with actionable insights for therapies across the development and product lifecycle.

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

During the last financial year, the ImmunoINSIGHTS business signed and delivered a number of contracts with leading global pharmaceutical companies, demonstrating its ability to provide strong growth to the Group's revenue. Throughout the year, we continued to strengthen strategic relationships with partners like Roche and Genentech, as well as developing and signing further contracts with leading biotechs and healthcare providers across the globe.

In July 2020, we signed a substantial extension to the Group's second Roche ImmunoINSIGHTS contract, increasing the number of autoantibody samples to be profiled within the agreed time period. Then, in late September 2020, we signed a collaboration with Genentech, a member of the Roche Group, to characterise the autoantibody profiles of patients in clinical trials for rheumatological diseases, including Systemic Lupus Erythematosus ("SLE"). As with previous contracts with Roche and other international pharmaceutical groups, now that we have delivered the results to Genentech, the contract has the potential to significantly expand with additional samples being profiled in the future under follow-on contracts.

Following the successful award of UK Government funding for development of an infectious disease research tool for use in COVID-19, the Group signed a deal with Cedars-Sinai Medical Center in Los Angeles ("Cedars-Sinai") to collaborate in the use of the development panel to better understand, and therefore stratify, patients infected with COVID-19. Shortly following the contracting of Cedars-Sinai, we were pleased to announce further work with Roche to utilise the Company's SeroTag infectious diseases discovery panel to profile antibody and autoantibody responses in all patient samples from the Roche COVACTA trial, to look for immune signals of response, non-response and adverse events. Whilst this contract is still in its initial stages, it has already produced scientific discoveries that have contributed to the global effort to better understand the evolution of COVID-19, and its potential treatment. We expect much more to come from this collaboration in FY2022, and from additional pharmaceutical customers looking to accelerate their therapeutic assets in this disease.

Since the financial year end, we have continued to pursue a growing number of commercial autoantibody profiling contracts in the ImmunoINSIGHTS business division, with a number of these being substantial follow-on contracts from work previously completed in FY2020.

In September 2021 we signed an agreement with a leading global pharmaceutical company we have worked with previously, this time using the NavigAID autoimmune disease characterisation panel to explore the autoantibody profiles of patients with four key autoimmune diseases, namely systemic lupus erythematosus, Sjögren's syndrome, rheumatoid arthritis, and sicca syndrome.

More recently, in October 2021, we signed three separate contracts with leading global pharmaceutical companies to utilise the SeroTag immuno-oncology discovery array to explore the autoantibody binding profiles of solid tumour cancer patients treated with immunotherapy. Additionally, the strength of the ImmunoINSIGHTS autoantibody biomarker profiling technology has been validated with another global pharmaceutical company renewing their existing relationship with Oncimmune for biomarker services.

### **Product - EarlyCDT**

Much of FY2021 was disrupted by healthcare systems globally dealing with the response to the COVID-19 pandemic, which impacted many critical services, not least cancer diagnosis and care. As such, the sale of EarlyCDT products have been irregular and difficult for the Group to forecast. However, during the year the potential downside has been largely mitigated by agreements with our global distribution partners which require minimum volume sales to continue to be delivered under their contracts.

Since announcing the positive results of the Early detection of Cancer of the Lung Scotland ("ECLS") in June 2019, and particularly since the positive MedTech Innovation Briefing in March 2020, we have been in dialogue with national health systems globally, including the NHS in the UK, over the adoption of EarlyCDT Lung for Indeterminate Pulmonary Nodules ("IPNs") screening. In the UK this has included discussions with both Cancer Alliances and Clinical Commissioning Groups ("CCG's") which has resulted in EarlyCDT Lung being chosen to support the iDx Lung programme, run out of the lung health check programmes in Southampton and Leeds. Following EarlyCDT Lung being chosen as part of the iDx programme, 350 patients have been recruited in Southampton and Leeds to date.

Our discussions over the year have also led to the signing of the distribution of tests to Norfolk and Waveney CCG, representing an important milestone as the first sales of the EarlyCDT Lung test into the UK's NHS. To date, the pilot data in Norfolk and Waveney shows 988 smokers were booked for an EarlyCDT Lung blood test with 277 identified as requiring further investigation following the result of their EarlyCDT Lung test. A full clinical evaluation will be delivered in due course, but we are encouraged with the initial results. In addition, shortly after the end of the reporting period, we were delighted to sign another contract to provide EarlyCDT Lung tests into the NHS, albeit that details of this contract are confidential until the programme is ready to launch later in FY2022.

Further afield, we have experienced a substantial increase in demand for the EarlyCDT Lung from our US partner, Biodesix, which is quickly recovering from the lack of demand early in the reporting period as a result of COVID-19. Given this increase in demand, Biodesix announced that they are planning to expand its national sales team from 32 to 76 by the end of 2022.

In line with the Group's strategy to increase the availability of EarlyCDT Lung across the world, our Brazilian partner, Valentech, signed an agreement with Diagnosticos da America, Latin America's largest medical diagnostic company, to offer EarlyCDT Lung across its extensive laboratory, private hospital and clinic network in South America. Then in May 2021, we successfully agreed to return the intellectual property and distribution rights for the EarlyCDT technology in the People's Republic of China and Hong Kong from our strategic partner, Genostics Company Limited, allowing us to pursue the optimum route to market in this important territory. Recently, EarlyCDT Lung has been authorised for use by the Spanish Public Health Service with the Galician Health Service (SERGAS), the first public health service in Spain to use the EarlyCDT Lung test.

### **Scientific presentations and publications**

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 presentations. The scientific and commercial potential of ImmunoINSIGHTS was highlighted early in the reporting period in a high-profile scientific presentation and publication. The research publication entitled '*Profiling IgG antibodies*

*targeting unmodified and corresponding citrullinated autoantigens in a multicentre national cohort of early arthritis in Germany*' was published in *Arthritis Research & Therapy*<sup>1</sup> and demonstrated the autoantibody, cTRA2B-IgG, has the potential to improve diagnosis of early-stage rheumatoid arthritis, which to date has been challenging due to lack of availability of diagnostics in the therapeutic area.

This followed a featured presentation at the American Society of Clinical Oncology 2020 ("ASCO") Virtual Scientific Programme, which demonstrated that data from profiling tumour associated antibodies in melanoma patients receiving checkpoint inhibitors, analysed on the SeroTag immuno-oncology discovery array, had identified that autoantibodies have a role in predicting clinical outcomes or immune-related events.

More recently, the ImmunoINSIGHTS team has collaborated with Roche to undertake a study to develop a panel of predictive biomarkers to identify an early response in rheumatoid arthritis (RA) patients to Methotrexate or Tocilizumab, Roche's interleukin-6 (IL-6) receptor inhibitor; and as a result, '*Comprehensive exploratory autoantibody profiling in patients with early Rheumatoid Arthritis treated with Methotrexate or Tocilizumab*' was published in *PLOSOne* in December 2020.<sup>2</sup>

Following the close of the reporting period, the ImmunoINSIGHTS team were pleased to be able to announce the pre-publication of the first results from our collaboration with Cedars-Sinai Medical Center in Los Angeles, entitled: "*Paradoxical Sex-Specific Patterns of Autoantibodies Response to SARS-CoV-2 Infection*".<sup>3</sup> The pre-publication paper focuses on the characterisation of sex-specific prevalence and selectivity of autoantibody responses to the SARS-CoV-2 virus.

During the period under review, on the EarlyCDT side of the business, results from the Early detection of Cancer of the Lung Scotland ("ECLS") study were published in the *European Respiratory Journal*<sup>5</sup> demonstrating a 36% reduction in late-stage diagnoses of lung cancer. The pre-publication of the three-year follow-up data<sup>6</sup> supports a trend towards a mortality benefit of the EarlyCDT Lung blood test, confirming the number of late-stage cancers and deaths to be lower in patients tested with EarlyCDT Lung. Additionally, EarlyCDT Lung and CT surveillance were found to be highly cost-effective compared to CT surveillance alone. with results published in *PLOSOne* in September 2020<sup>7</sup>

## **Board changes**

At the end of FY2020, Oncimmune's Board of Directors believed it was the right time to restructure the Board in order to be as agile, lean and focused as possible. As such, Geoffrey Hamilton-Fairley, Carsten Schroder and Julian Hirst stepped down from the Board on 4 June 2020. In January 2021, the Board further reduced its number with Dr Cheung To stepping down.

Following these changes, the Board has decreased from nine members to five members and now comprises of one Executive Director and four Non-Executive Directors, two of which are Independent Non-Executive Directors. The Board members are Meinhard Schmidt, Non-Executive Chairman; Dr Adam M Hill, Chief Executive Officer; Dr Annalisa Jenkins, Senior Independent Non-Executive Director; Andrew Unitt, Independent Non-Executive Director; and Tim Bunting, Non-Executive Director.

## **Corporate social responsibility and sustainability**

Advancing medical science through research as well as the provision of a simple and affordable test to detect the earliest signs of cancer is at the core of our Company and drives our ethos and culture. We are committed to diversity and a culture of equal opportunities and respect for the individual, underpinned by compliant and ethical behaviour. The successful delivery of our strategy is dependent on, and bolstered by this culture, the work environment we create and the lasting relationships we build with all our stakeholders.

Oncimmune's approach to product development, subsequent launches, and delivery of its long-term growth is underpinned by a clear set of economic values aimed at protecting the Company from risk and securing its long-term future.

As our business has grown and evolved, during this financial year, and post year end, we have continued to formalise our Corporate Social Responsibility and Sustainability strategy, which includes adopting a new Code of Business Conduct and Ethics, putting patients and the advancement of science at the heart of our business, and ensuring that all our staff are properly trained on our ethos, culture and compliance requirements.

In June 2020 we founded The Lung Foundation, an independent charity whose mission is the reduction of the impact of lung disease globally, through the research and development of effective diagnosis, treatment and preventative strategies. The Lung Foundation has already funded important research into COVID-19 and is actively pursuing new projects and funding sources.

## **Outlook**

The year to 31 May 2021 and the period post year end have seen significant and continuing progress for the Company, both operationally and commercially. Our ImmunoINSIGHTS service business is a critical enabler of this success, having developed a pipeline of in excess of 160 commercial opportunities in FY2021 and continues to secure follow-on contracts with customers of strategic importance.

Given the demand for our services and products, coupled with the opening up of the health economy as the world emerges from the COVID-19 pandemic, the Directors have confidence in the continuation of Oncimmune's positive trajectory, underpinned by our world class technology platform, its market leading position and expanding pipeline of contractual discussions and future prospects.

The Board sees the potential for further step changes in revenue growth and improving visibility, as the momentum in the commercial ImmunoINSIGHTS pipeline is converted into service contracts. As we are already starting to see, these initial contracts have the scope to broaden subsequently into multiple projects and deeper strategic commercial partnerships, with associated opportunities for additional, long-term revenue.

On behalf of the Board, we would like to thank our shareholders for their continued support throughout FY2021, and we look forward to updating the market on Oncimmune's further progress.

**Meinhard Schmidt**  
Chairman

**Dr Adam M Hill**  
Chief Executive Officer

2 November 2021

## CHIEF FINANCIAL OFFICER'S REVIEW

A summary of the financial highlights of the year ended 31 May 2021, including post year end, is as follows:

- Revenue for the year of £3.7M (2020: £0.5M) reflecting the increase in ImmunoINSIGHTS contracts signed and executed
- R&D costs for the year were £1.6M (2020: £1.7M) as a result of the Group's continued focus on developing world leading science
- Administrative expenses for the year were 30% lower at £5.7M (2020: £8.2M)
- Loss for the financial year was £4.6M (2020: £8.5M), significantly reduced as a result of the growth in the ImmunoINSIGHTS business and stated after the effect of increased share-based payment charges of £1.1M (2020: £0.2M)
- Cash balance at year end of £8.6M (2020: £4.2M) and net debt of £0.8M including lease liabilities (2020: net debt £4.0M), with net cash of £0.1M excluding lease liabilities (2020: net debt £3.0M)

### Revenues and commercial progress

Revenue for the year was £3.7M (2020: £0.5M), validating the core business strategy of focusing on building a leading immunodiagnostics group. The Group's commercial progress materially benefited from the growth of the ImmunoINSIGHTS' business, reflecting the increase in the number of contracts awarded and executed. Since the end of FY2021, in particular following the summer period, business activity within ImmunoINSIGHTS has remained high with further contracts signed, and a growing pipeline of contracts nearing signing as well as an increase in the number of proposals out with customers.

During the year the ImmunoINSIGHTS business signed and delivered a number of contracts, including for Roche Pharmaceuticals ("Roche") and Genentech, a member of the Roche Group, as well as a number of further contracts for global biotechs and leading healthcare providers. The launch of the infectious diseases panel, in Q2 FY2021, facilitated the signing of further substantial contracts with Roche and Cedars-Sinai Medical Center ("Cedars-Sinai"). The pipeline of potential contracts across the full range of oncology, autoimmune and infectious diseases continues to expand, with an increasing number of these progressing to late-stage commercial negotiation and legal documentation. Two of these late-stage potential contracts are substantial follow-on validation contracts with major pharmaceutical companies. As a consequence of the current and forecast levels of ImmunoINSIGHTS business activity, we expect further growth in commercial revenues throughout FY2022 which will in turn consolidate the dominance of this autoantibody profiling services business within the Group.

In March 2021, the Company completed an equity fundraise raising gross proceeds of £9M to provide additional funding principally to the ImmunoINSIGHTS business. These funds are being deployed to increase the commercial team headcount, with a focus on the US where over 90% of all contracts are now awarded, as well as expanding the operational capacity at the Group's laboratory facility in Dortmund, Germany. This expansion programme is designed to increase capacity to approximately 40,000 samples per annum by Q1 FY2023 in order to meet the anticipated increase in demand from customers for the ImmunoINSIGHTS service offering.

The impact of COVID-19 restrictions in countries where we have distributors has meant that the sale of EarlyCDT products have been irregular therefore more difficult for the Group to forecast. In particular, earlier during the year the Group invoiced one of its historic distributors for £1.7M, however, the commercial pressures faced by this distributor as a consequence of the COVID-19 pandemic mean that the invoice has not met the revenue recognition requirements of IFRS 15 at this time and therefore is unable to be recognised as revenue in the year ended 31 May 2021. At the point this invoice is paid, such revenue will then be recognised. As the COVID-19 pandemic comes under control and restrictions ease, sales by our global distributors are expected to begin to pick up once again.

Within the UK, sales of EarlyCDT Lung improved markedly on the previous year. In December 2020, the Group signed its first commercial contract with the NHS; the contract with Norfolk and Waveney focuses on recruiting people at risk of lung cancer from community GP practices. The aim of the pilot study is a real-world assessment of the practicality of introducing the EarlyCDT Lung blood test into primary and secondary care settings within the NHS in England, to support the earlier diagnosis of lung cancer. The positive support for EarlyCDT Lung within the NHS has also led to a further supply contract being signed and we expect additional contracts to be signed over the remainder of FY2022. In December 2020, Oncimmune was also selected to supply the EarlyCDT Lung blood tests to the iDx Lung programme in Southampton and Leeds. This supply contract is ongoing and is expected to last three years.

In the US, the Group's EarlyCDT Lung partner, Biodesix, announced its expectation of growth in its core lung diagnostic test service, driven by the US's emergence from the COVID-19 pandemic, increasing productivity from its national salesforce, and its continued building of evidence supporting the use of its tests. Biodesix also commented that Nodify CDT (the name under which EarlyCDT Lung is marketed in the US) and Nodify XL2<sup>®</sup> are the primary growth drivers for its revenues. Based on Biodesix's forward order schedule, we expect sales to continue to recover throughout 2021 and beyond.

### **Commentary on financial statements**

Research and development activities remain a key priority for the UK-based product scientific group, with a focus on further developments to the EarlyCDT Lung blood test and as a result, in the year the Group's research and development spend was £1.6M (FY2020: £1.7M).

Administrative expenses for the year were £5.7M, a substantial reduction on the previous year (FY 2020: £8.2M). The Group is focused on managing the overall monthly operating costs and seeks to reduce costs wherever possible. In September 2020, a new incentivisation scheme for senior management was implemented which materially increased the IFRS 2 non-cash IFRS 2 charge for the year to £1.1M (FY2020: £0.2M).

The loss for the year was £4.6M, a substantial reduction on the prior year (FY2020: loss of £8.5M) and reflects the continued growth in the high margin ImmunoINSIGHTS services business. The Group received £502k of R&D tax credit payments in the year (FY2020: £853k), reflecting the Group's continued focus on new and innovative cancer diagnostic projects, building on its library of immunogenic proteins, and validating additional NavigAID panels to facilitate the investigation of more disease types.

Cash balances at year end were £8.6M (FY2020: £4.2M) reflecting the equity fundraise conducted in March 2021. Net debt was £0.8M including lease liabilities (FY2020: net debt £4.0M) and net cash of £0.1M excluding lease liabilities (FY2020: net debt £3.0M).

The Company entered into an €8.5M credit facility with IPF Management SA in September 2019 which was further extended by €6.0M in October 2020, of which €3.0M has been drawn. The Company did not exercise its option to draw down the remaining €3.0M before the deadline of 30 June 2021. 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. There is a cash covenant requiring the Group to maintain nine months of cash which is tested each quarter. The total loan has been used to support the Group's operational activities, in particular the growth of the ImmunoINSIGHTS service business.

### **Financial outlook**

The Group's ImmunoINSIGHTS service business has emerged as the growth driver for the Group, and this is expected to be increasingly the case for the Group's foreseeable future. The ImmunoINSIGHTS business is a high margin business and therefore as its revenues continue to grow, it is anticipated that the Group's profitability and cash generation will improve. There has been an increase in the level of business activity since the quieter summer months. A number of contracts have recently been signed and these will be delivered and invoiced before the end of the current financial year (FY 2022). Accordingly, management is comfortable with its expected delivery of growth for the ImmunoINSIGHTS

business for the full year. The expansion of the commercial team is expected to further enlarge the ImmunoINSIGHTS commercial pipeline.

Within our EarlyCDT product business, sales in the UK continue to grow as do sales for our US partner, Biodesix. Elsewhere, as the world emerges from the COVID-19 pandemic we are expecting an uptick in distributor sales activity.

The Directors are confident that current cash and other available financial resources are sufficient to deliver the Group's continued growth. The Board continues to review the Group's activities to ensure it maintains a differentiated offering and will consider the most appropriate capital base from which to optimise this growth at the same time as maximising returns to stakeholders.

**Matthew Hall**  
Chief Financial Officer

2 November 2021

**Consolidated statement of comprehensive income**

	Notes	Year to 31 May 2021 £'000 Total	Year to 31 May 2020 £'000 Total
<b>Revenue</b>	4	3,722	509
Cost of sales		(865)	(537)
<b>Gross profit/(loss)</b>		2,857	(28)
Research and development expenses		(1,615)	(1,677)
Administrative expenses		(5,652)	(8,174)
Share-based payment	24	(1,046)	(174)
Gain on disposal of assets	9	-	579
Total administrative expenses	5	(8,313)	(9,446)
Other income	6	311	206
<b>Operating loss</b>		(5,145)	(9,268)
Finance income	10	403	111
Finance costs	10	(954)	(626)
Finance costs - net		(551)	(515)
<b>Loss before income tax</b>		(5,696)	(9,783)
Income tax credit	11	1,068	1,324
<b>Loss for the financial year</b>		(4,628)	(8,459)
<b>Other comprehensive income</b>			
<b>Items that may be subsequently reclassified to profit or loss, net of tax</b>			
Currency translation differences		(91)	84
<b>Loss after tax and total comprehensive income for the year attributable to equity holders</b>		(4,719)	(8,375)
<b>Basic and diluted loss per share</b>	28	(7.17)p	(13.36)p

All activities of the Group in the current and prior period are classed as continuing.

All of the comprehensive income for the year is attributable to the shareholders of Oncimmune Holdings Plc.

The accompanying notes form an integral part of these consolidated financial statements and can be found in the annual report and accounts being made available on the Company's website later today.

**Consolidated statement of financial position**

		<b>31 May 2021 £'000</b>	31 May 2020 £'000
	Notes		
<b>Assets</b>			
<b>Non-current assets</b>			
Goodwill	12	<b>1,578</b>	1,578
Intangible assets	13	<b>4,116</b>	1,138
Property, plant and equipment	14	<b>664</b>	390
Right-of-use assets	15	<b>930</b>	982
Deferred tax asset	30	<b>937</b>	-
		<b>8,225</b>	4,088
<b>Current assets</b>			
Inventories	17	<b>143</b>	174
Trade and other receivables	16	<b>7,079</b>	1,716
Contract assets	4	<b>200</b>	97
Cash and cash equivalents	18	<b>8,631</b>	4,240
		<b>16,053</b>	6,227
<b>Total assets</b>		<b>24,278</b>	10,315
<b>Equity</b>			
<b>Capital and reserves attributable to the equity holders</b>			
Share capital	23	<b>691</b>	635
Share premium	23	<b>40,497</b>	31,459
Other reserves		<b>4,094</b>	3,048
Merger reserve		<b>31,882</b>	31,882
Foreign currency translation reserve		<b>88</b>	179
Own shares		<b>(1,926)</b>	(1,926)
Retained earnings		<b>(70,099)</b>	(65,471)
<b>Total equity</b>		<b>5,227</b>	(194)
<b>Liabilities</b>			
<b>Non-current liabilities</b>			
Deferred tax	30	<b>374</b>	133
Lease liability	22	<b>671</b>	762
Other liabilities	20	<b>2,000</b>	-
Borrowings	21	<b>6,239</b>	6,147
		<b>9,284</b>	7,042
<b>Current liabilities</b>			
Trade and other payables	19	<b>1,979</b>	1,037
Contract liabilities	4	<b>5,175</b>	570
Other statutory liabilities		<b>55</b>	65
Lease liability	22	<b>310</b>	227
Other liabilities	20	<b>-</b>	428
Borrowings	21	<b>2,248</b>	1,140
		<b>9,767</b>	3,467
<b>Total liabilities</b>		<b>19,051</b>	10,509
<b>Total equity and liabilities</b>		<b>24,278</b>	10,315

The accompanying notes form an integral part of these consolidated financial statements and can be found in the annual report and accounts being made available on the Company's website later today.

The financial statements were approved by the board on 2 November 2021.

Dr Adam M Hill  
Director and Chief Executive Officer  
Company registration number: 09818395 (England and Wales)

**Consolidated statement of changes in equity**

	Share capital	Share premium	Other reserves	Merger reserve	Foreign currency translation reserve	Own shares	Retained earnings	Total
	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000
<b>As at 1 June 2019</b>	<b>633</b>	<b>31,382</b>	<b>3,295</b>	<b>31,736</b>	<b>95</b>	<b>(1,926)</b>	<b>(57,350)</b>	<b>7,865</b>
Loss for the year	-	-	-	-	-	-	(8,459)	<b>(8,459)</b>
Other comprehensive income:								
Currency translation differences	-	-	-	-	84	-	-	<b>84</b>
<b>Total comprehensive income</b>	-	-	-	-	<b>84</b>	-	<b>(8,459)</b>	<b>(8,375)</b>
Transactions with owners:								
Share warrants issued	-	-	142	-	-	-	-	<b>142</b>
Shares issued on acquisition	2	77	(563)	146	-	-	338	-
Share option charge	-	-	174	-	-	-	-	<b>174</b>
<b>As at 31 May 2020</b>	<b>635</b>	<b>31,459</b>	<b>3,048</b>	<b>31,882</b>	<b>179</b>	<b>(1,926)</b>	<b>(65,471)</b>	<b>(194)</b>
Loss for the year	-	-	-	-	-	-	(4,628)	<b>(4,628)</b>
Other comprehensive income:								
Currency translation differences	-	-	-	-	(91)	-	-	<b>(91)</b>
<b>Total comprehensive income</b>	-	-	-	-	<b>(91)</b>	-	<b>(4,628)</b>	<b>(4,719)</b>
Transactions with owners:								
Shares issued in year	50	8,331	-	-	-	-	-	8,381
Options exercised	2	106	-	-	-	-	-	108
Shares issued in relation to prior year acquisition	4	601	-	-	-	-	-	605
Share option charge	-	-	1,046	-	-	-	-	1,046
<b>As at 31 May 2021</b>	<b>691</b>	<b>40,497</b>	<b>4,094</b>	<b>31,882</b>	<b>88</b>	<b>(1,926)</b>	<b>(70,099)</b>	<b>5,227</b>

The accompanying notes form an integral part of these consolidated financial statements and can be found in the annual report and accounts to be made available on the Company's website later today.

**Consolidated statement of cash flows**

		Year to 31 May 2021 £'000	Year to 31 May 2020 £'000
	Notes		
<b>Cash flows from operating activities</b>			
Loss before income tax		(5,696)	(9,783)
Adjusted by:			
Depreciation and amortisation	13,14,1 5	740	500
Share based payment charge		1,046	174
Interest received	10	(403)	(111)
Interest expense	10	954	626
Gain on disposal of assets		-	(579)
Fair value movement on contingent consideration and liabilities		176	78
Changes in working capital:			
Decrease in inventories		31	107
Increase in trade and other receivables		(5,837)	(807)
Increase / (decrease) in trade and other payables		4,841	591
<b>Cash used by operations</b>		<b>(4,148)</b>	<b>(9,204)</b>
Interest paid		(885)	(663)
Interest received		3	111
Income tax received		503	853
<b>Net cash used by operating activities</b>		<b>(4,527)</b>	<b>(8,903)</b>
<b>Cash flows from investing activities</b>			
Purchase of property, plant and equipment		(446)	(236)
Purchase of intangible assets		(625)	-
Proceeds from sale of assets		215	583
<b>Net cash (used in)/ generated from investing activities</b>		<b>(856)</b>	<b>347</b>
<b>Cash flows from financing activities</b>			
Net funds raised through share issues		8,489	-
Loan advances		2,728	7,598
Loan repayments		(1,135)	-
Principal elements of lease repayments		(303)	(138)
Net cash generated from financing activities		9,779	7,460
Movement in cash attributable to foreign exchange		(5)	(22)
<b>Net increase / (decrease) in cash and cash equivalents</b>		<b>4,391</b>	<b>(1,118)</b>
Cash and cash equivalents at the beginning of the year		4,240	5,358
<b>Cash and cash equivalents at the end of the year</b>	18	<b>8,631</b>	<b>4,240</b>



The accompanying notes form an integral part of these consolidated financial statements and can be found in the annual report and accounts to be made available on the Company's website later today.

## 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 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.

## 2. Basis of preparation

The Group financial statements consolidate those of the Company and its subsidiaries (together referred to as the 'Group').

The financial information set out in these preliminary results has been prepared in accordance with international accounting standards in conformity with the requirements of the Companies Act 2006. The accounting policies adopted in this results announcement have been consistently applied to all the years presented and are consistent with the policies used in the preparation of the statutory accounts for the year ended 31 May 2021.

The consolidated financial information is presented in sterling (£), which is the company's functional and the Group's presentation currency.

The financial information set out in these results does not constitute the company's statutory accounts for 2021 or 2020. Statutory accounts for the years ended 31 May 2021 and 31 May 2020 have been reported on by the Independent Auditors. The Independent Auditor's report for the year ended 31 May 2021 was unqualified, contained an emphasis of matter highlighting a material uncertainty related to going concern and did not contain a statement under section 498(2) or (3) of the Companies Act 2006. The Independent Auditor's report for the year ended 31 May 2020 was unqualified, did not draw attention to any matters by way of emphasis and did not contain a statement under section 498(2) or (3) of the Companies Act 2006.

Statutory accounts for the year ended 31 May 2020 have been filed with the Registrar of Companies. The statutory accounts for the year ended 31 May 2021 will be delivered to the Registrar in due course.

### Going concern

The Group's business activities, together with the factors likely to affect its future development, performance and position are set out in the Chairman and Chief Executive Officer's Review and the Chief Financial Officers Review. The Financial detail above describes the financial position of the Group, its cash flows and liquidity position. In addition, note 29 to the financial statements includes the Group's objectives, policies and processes for managing its capital, its financial risk management objectives and its exposure to market risk, including foreign exchange rate risk, interest rate risk and price risk, credit risk and liquidity risk.

In respect of the Group's funding position, the Company entered into a €8.5M credit facility with IPF Management SA in September 2019 which was further extended by €6.0M in October 2020, of which €3.0M was drawn. The Company did not exercise its option to draw down the remaining €3.0M before the deadline of 30 June 2021. 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. There is a cash covenant requiring the Group to maintain nine months of cash which is tested each quarter. The total loan has been used to support the Group's operational activities, in particular the growth of the ImmunoINSIGHTS service business. In order to monitor compliance with this financial covenant, the Board prepares monthly financial accounts including a calculation of covenant compliance for the following 12 months.

The Group has prepared the 2021 financial statements on a going concern basis. In preparing the accounts on a going concern basis the Directors have prepared forecasts and budgets for the period to 31 December 2022 and which also considered the Group's existing debt covenant obligations up until this date. These forecasts and budgets model a range of scenarios, including taking into consideration the impact of COVID-19. 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. The base case scenario shows the Group is able to meet its financial obligations as and when they fall due for the forecast period.

The Directors have also considered downside scenarios that reflect the current unprecedented uncertainty in the UK economy and which the Directors consider to be severe but plausible. The first downside scenario took the base case scenario and removed a total of 50% of forecast EarlyCDT Lung product revenues excluding the US with a corresponding reduction in cost of sales and a reduction in third party R&D subcontract manufacture of EarlyCDT Lung product. The second downside scenario took the base case scenario and removed 50% of forecast EarlyCDT Lung product revenues excluding revenues from the UK and the US as well as a 20% reduction in ImmunoINSIGHTS' revenues and with a corresponding reduction in cost of sales. The results of these scenarios show that the Group has sufficient resources to meet its obligations for the forecast period and will not be in breach of its covenant under the IPF Management SA facility.

In addition to the above the Directors have performed a more severe downside stress test. The most severe of these tests reduced EarlyCDT Lung product revenues outside of the UK but excluding the US by 50% of forecast and reduced ImmunoINSIGHTS revenues by 50% with an appropriate reduction in ImmunoINSIGHTS cost of sales. At the time of approval of the financial statements, the revenue performance for the current financial year reflects the revenue modelled under this stress test. This may mean that under this more severe downside stress test scenario the Group will not comply with the financial covenant attached to its external borrowings for the duration of the going concern review period. Should the financial covenant not be met the Group's borrowings could be recalled by its lender. Such a scenario gives rise to a material uncertainty which may cast significant doubt about the Group's ability to continue as a going concern. However, as has been detailed in the Chief Financial Officer's review, there has been an appreciable uplift in business activity within the ImmunoINSIGHTS business with several contracts signed and a number of other contracts moving into legal contracting and expected to be executed before the end of this calendar year. Furthermore, although not modelled, the Directors have identified costs within the business which could be reduced within a relatively short time period.

After considering the above and after making appropriate enquiries, the Directors have formed a judgement at the time of approving the financial statements that there is a reasonable expectation that the Group has sufficient resources to continue in operational existence for the foreseeable future. For this reason, the Directors consider the adoption of the going concern basis in preparing the consolidated financial statements is appropriate.