The Company experienced unprecedented sales demand for its COVID-19 products during 2020, which transformed our financial position, resulting in our Company significantly exceeding our full year 2020 budget and surpassing any previous performance. Our response to the COVID-19 pandemic has been outstanding across the entire business and this is down to our employees. I could not be more proud and humbled at how hard everyone continues to work during a difficult and challenging time across the globe. This pandemic is causing havoc with our lives and economy in ways that have not been seen since the Second World War, but Novacyt remains at the heart of the response doing our very best to help more than 130 countries diagnose and manage the spread of the virus and its variants that naturally follow.

The Group achieved an increase in revenues of over 20x to £277.2 million, with gross margin of 76.3% and EBITDA profitability £176 million for the full year of 2020. In June 2020, the Company was able to settle all outstanding debt obligations of £7.1 million in total with Harbert European Growth Capital (“HEGC”) and Vatel Capital SAS (“Vatel”), making the Company debt free for the first time in its history. The Company’s cash position at 31 December 2020 was £91.8 million.

In February 2020, the Company produced one of the first CE-mark COVID-19 tests for the 2019 strain of the novel coronavirus, with approval received from both the US Food and Drug Administration (“FDA”) and the World Health Organization (“WHO”) for the test to be eligible for procurement under the Emergency Use Listing (“EUL”). The EUL is a risk-based procedure for assessing and listing unlicensed vaccines, therapeutics and in vitro diagnostics with the ultimate aim of expediting the availability of these products to people affected by a public health emergency. This product has now received regulatory approval from 57 countries.

April was a significant milestone month for the Company. As part of the UK Government’s five pillar plan to increase testing for COVID-19, Novacyt collaborated with AstraZeneca, GSK and the University of Cambridge to take action to support the national effort to fight the COVID-19 pandemic.
the UK Government’s five pillar plan to increase testing for COVID-19.

The Company’s biggest challenge during 2020 was, and remains to be, to develop the organisation and systems required to support scale-up of the business at an unprecedented rate. Whilst managing to retain our ability to hold onto core competitive advantages, such as speed to market, and the quality of our products, our headcount has increased by more than 100 in the last 18 months.

Manufacturing functions have seen the most change, and the largest scale-up during the past 12 months. Chartwell Consulting continue to assist Novacyt as the complexity of this function increases. Despite this, the Company continues to deliver substantial margins through low cost of goods and is continuously adapting to the pandemic with new products being introduced monthly.

Our PCR reagent manufacturing capacity remains high with capacity to scale further. The Company has a number of non-financial key metrics that management use to monitor, control and make decisions balancing demand, supply, stock levels, customer service and capacity decisions, which are reviewed weekly. Multiple QC KPIs are also reviewed weekly and a cross-functional Material Review Board (“MRB”) is active and in control of manufacturing quality.

In parallel with the day-to-day management challenges in the current pandemic, Novacyt is making good progress in developing its strategic plans, which includes engaging with potential acquisition targets.

In October 2020, The Company acquired IT-IS International, a profitable diagnostic instrument development and manufacturing company for a net consideration after earnouts of £8.7m. IT-IS is the exclusive manufacturer of Novacyt’s q16 and q32 rapid PCR instruments. The transaction reinforced our new strategy, securing key IP, expanding our core capabilities in instrument manufacturing and strengthening our product offering in mobile PCR devices with an immediate increase in earnings.

IT-IS has been an important addition to the business’s capability and we now have a guaranteed supply of many thousands of q16 and q32 machines and can scale to virtually any level of capacity the business could require. The deep knowledge of PCR instrumentation that comes with IT-IS means we are well placed for the development of the next generation of machine, the planning of which has already begun.

We seek to predict and stay abreast of the fast pace of product differentiation required in the market to maintain our competitive position, and this is evident with our rapid development and launch of new Variants of Concern (“VOC”) tests branded as SNPsig®. To date, Novacyt has launched over 14 new COVID-19-related products since the beginning of 2020.

In the last 12 months, the business has moved from one to three major product platforms:

i. 96 reaction genesig® product for small laboratories;

ii. PROmate® for near-patient testing; and

iii. High throughput kits for large laboratories.

All three product platforms have proven to be successful and open different
potential markets. There are a number of other exciting and potentially large new business development opportunities that could drive major increases in COVID-19 sales during the remainder of 2021.

Innovative R&D and IP
2020 was a year of agile and innovative product development. The Group’s key strength is to innovatively address market needs with our products. We were quick to respond to COVID-19, producing one of the first tests in January 2020. We maintained this pace through the year and launched new assays and workflow solutions to build a comprehensive COVID-19 product portfolio.

Our broad technology base covers both protein and molecular platforms and a range of testing settings: near-patient, hospital laboratory and high throughput (“HT”). Therefore, we can develop a range of PCR, ELISA and lateral flow antibody and antigen tests for near patient, central labs, HT settings that can run on many laboratory systems as well as our own q16/q32 rapid PCR systems. Our internal R&D is complemented by an expert business development function, which has developed a global network of innovative partners and has successfully in-licensed antibody, antigen and workflow solutions.

Across the COVID-19 market, testing requirements are increasing in complexity. There is a regulatory requirement for multi-gene assays (2 and 3 gene assays) that exclude the (S and N) genes that are most prone to mutations and for suppliers to provide detailed bio-informatics surveillance. We are well positioned with an expert bio-informatics team and will continue to invest in this area especially as we develop our plans for the non-COVID-19 products.

During the period, the Group developed a new patent strategy to protect our novel content with the filing of patents now being a routine part of the Group’s product development process, forming a key part of protecting future value within the business.

We have filed over 20 patents to protect our proprietary assays, the q16/q32 PCR systems and workflow innovations. This culture and practice of developing novel and cutting-edge diagnostic technology underpins the Group’s continued growth and agility. As such, the R&D team has more than doubled in size and now includes a leading bio-informatics team and the Group’s clinical trial function that undertakes clinical trials in the UK, Europe, USA and Latin America. This clinical expertise is a key requirement of the new IVD-R regulation and, as such, the Group has built an industry-leading team, which completed over a dozen product validations in 2020, including the successful TVG validation of PROMate®, the best-in-class direct to PCR COVID-19 assay and the recent launch of VariPLEX™, the first CE-IVD registered COVID-19 variant detection assay. The Group’s clinical expertise also includes over a dozen physicians, clinical and laboratory scientists that provide real-time scientific advice. This, coupled to our leading bio-informatics and surveillance functionality, enables the Group to remain at the forefront of new diagnostic innovation.

By combining a broad technology base with an agile and innovative product development and clinical trial functionality, the Group is well positioned to rapidly address new areas of unmet need with market-leading products. The R&D outlook for 2021 is strong, with a record-breaking number of new products in development that will continue to meet the rapidly changing COVID-19 requirements and address the broader non-COVID-19 respiratory, transplant and infectious disease markets.

Graham Mullis
Chief Executive Officer