1. Are you able to give any update on the DHSC contract dispute and the new contract award announced today?

As you will have seen this morning, we’ve announced a new contract with the DHSC under the Public Health England National Microbiology Framework. This applies primarily to the NHS, which confirms the continued relationship we have with the DHSC and the NHS hospital system, here in the UK.

Based on the DHSC estimates for the nine-month supply of our PROmate® reagent, the contract could be valued at £4.7 million, although it is important to note that there are no minimum purchase levels specified.

The PROmate® reagent is being supplied and used by the q16 and q32 instruments, which were deployed under the second contract. That specifically answers one of the many questions that have just come into the forum during the last 36 minutes.

The UK is a key market for Novacyt and throughout the pandemic the NHS testing demand has remained a key priority for us. We’re therefore delighted to announce this contract award as a testament to our continued commitment to the UK and the NHS.

Unfortunately, we have no update on the dispute with the DHSC regarding the second supply contract, with no further news since the disclosure in June this year. Both sides are bound by confidentiality clause of the contract, so there is no further clarity that we can give on the dispute at this time.

2. In the event you said you see no reason for the outlook for FY2021 to change. What update can you provide on 2022?

To 2021 first, as we confirmed today, we are reiterating the £100 million revenue guidance for the full year, excluding DHSC, and we’re feeling confident about that number. As we mentioned, we see a growing private testing market and we also expect overall demand to increase as we head into the winter, with the potential for a higher infection rate.

It’s too early to talk about 2022. As mentioned in the presentation, COVID revenues won’t be around forever and our working assumption is that they probably have a half-life every year. But we still need to do more work and get a bit more certainty before we really can start talking about targets for 2022.

3. Given the cash position, do you expect to pay a dividend or undertake a share buyback in the short to medium-term?

If we take the short to medium term and if you refer to our annual report which we published recently, the Board confirmed we’re not proposing to pay a dividend for the year 2020. The reason for that is to continue to invest in R&D, manufacturing and the more commercial aspects of the business – some of that, hopefully, you’ve seen in this presentation – to really try and build a post COVID business. We feel there are still plenty of opportunities, this market is still emerging and we think that’s the priority for our cash.

We will always keep this under review annually, if not more frequently, and the dividend policy would form part of a wider review of capital requirements and capital structure as the business moves forward. We will let shareholders know on any change of policy.

4. Do you believe Novacyt communicates with its shareholders enough and how can you improve this?

We understand that shareholders are eager to learn and understand more about Novacyt’s business and operations, but we also need to be cognisant of operating in the group’s best commercial interest. This means that certain commercial information, such as who we are working with in certain key markets may not be divulged for competitive reasons. It also means, as an example, through most of last year, the company did not give many media interviews, although we were invited almost on a weekly basis at certain points during the year. We also deliberately kept an appropriate profile when working with government organisations, particularly here in the UK, but also with NGOs such as UNICEF.
To reflect on our communications to date, last year we issued 62 material announcements and, so far, this year we’ve issued 21. And we work hard at communicating through the regulatory framework with our shareholder base. We take communication very seriously and to update the market, and we’ll continue to do so through the appropriate channels.

5. You talk about your post-COVID activities without specifying any specific disease areas you are looking at as crucial to your next generation of diagnostics, can you update us please, what disease areas and why chosen?

The areas we’ve chosen are infectious diseases, respiratory and transplant. Within these areas, we’ve targeted niches where we believe there is still very high unmet medical need. So, within these niches, we believe we can provide faster, more accurate or easier diagnosis, and thereby provide better patient care. Within these areas of high unmet need, we have deep expertise, and we believe our innovation can drive better diagnosis.

We’re going to focus on expanding our COVID-19 portfolio and maintaining an industry leading position, particularly focusing on the rapidly evolving variant market. We’re also developing COVID plus assays in areas such as flu B, flu A and RSV. Our post COVID-19 portfolio includes areas like sepsis and transplant, CMV, EBV and BKV.

This portfolio is continuing to support both large central labs and near patient testing and therefore we can continue to provide the broadest range of assays in the infectious disease, respiratory and transplant markets.

To add a comment in relation to our platform strategies, and as mentioned a couple of times during the presentation, with the acquisition of IT-IS, we are now in a unique position to optimise development of complete system architecture for the various different applications we have already mentioned and for different market segments.

We will continue to leverage our capabilities and develop our platform strategy and by doing this, we will be able to optimise and control the full molecular workflow. In doing that, we’ll be able to deliver vastly improved workflow solutions, performance outcomes and clinical outcomes for our customers in both decentralised, centralised and near-to-patient testing settings.

6. How does the distribution network work? Novacyt’s sales force seems very strong in the UK, with heavy recruitment, but how big/effective are the distributors in the rest of the world?

As previously presented, we have a very well-established distributor network, with more than 400 distributors currently. This distributor network is essential for our growth strategy going forward. The channel represented approximately 35% of our business, without the DHSE contract, in the first half of the year. Its geographical distribution is also very well balanced, with revenues in the Americas, including Latin America, of approximately 30%; EMEA, which includes Europe, Middle East and Africa, with approximately 55% – of which 25% is UK and Ireland – and in Asia we have 15% of our distributor business.

The indirect sales channel is one of our key enablers for our global presence. If we look into our direct sales, it generated 65% of revenues, again without the DHSE contract, in the first half of 2021. As mentioned during my presentation, a well-balanced sales channel mix will enable our future growth. Increasing our market access is a key pillar of our commercial strategy in increasing our share of all of that customer base and generating market share gains.

7. What about your business outside of molecular diagnostics? What progress is being made with LFTs? How much revenue do you have from LFT? How do you expect LFTs to fit within future COVID testing, what percentage are they likely to make up of sales mix and do you think the technology will receive more attention in the future?

In the last few months, we’ve launched LFT tests for both COVID antigen and COVID antibody detection and these tests have been launched for professional use. We’ve also submitted data to regulatory authorities for patient self-testing applications. Professional use and patient self-testing applications are viewed slightly differently by the different regulatory bodies, but we’re well progressed in the discussions on that second self-testing application.

In relation to sales, as of today, it’s a little bit too soon after launch to give any specific sales data but as far as the UK is concerned, there is an important consideration to be taken into account when we look at this market. And that’s regarding the government freely distributing, free of charge, lateral flow tests. We need to get more of an understanding of when that will cease and what opportunities, therein, are available to us in
the UK market. However, there remains significant opportunities in other non-NHS sectors in the UK, as well as opportunities outside of the UK.

Our COVID-19 LFT portfolio also complements our existing task flow portfolio of lateral flow devices. And, as well as COVID, we’ve now got an extensive portfolio of lateral flow devices which cover calprotectin, adenovirus, streptococcus, as well as legionella.

8. With M&A, could you outline what a ‘good’ acquisition for Novacyt would look like and how you would finance it? Would you finance from cash, or would you need to raise capital?

M&A doesn’t exist in isolation, it is always part of a strategy. It can’t exist in a vacuum and good M&A is one that accelerates our stated strategy. We need capabilities to execute our strategy, whether that’s across building a test menu, instrumentation or going to new countries, we need these capabilities. And, if M&A can accelerate these capabilities then that’s a good acquisition, assuming a fair price.

It is also worth noting our M&A process. The diagnostics industry is very fragmented. Also, COVID has massively accelerated the amount of innovation, start-ups, and different opportunities out there. If we look at our capability, and particularly in R&D – with particular reference to our clinical trials – we’ve got capabilities to screen potential acquisitions better than we’ve ever had before. We shouldn’t underestimate the importance of that capability for Novacyt, which looks at lots of different opportunities.

With regards to financing, there is no hard and fast rule. Smaller acquisitions, more bolt-on type acquisitions, are most likely to be from existing cash. Clearly something larger, or more strategic, might require us to raise capital, be it equity or debt.

9. How transferrable is the PROmate® technology? Can it be used to streamline other products and tests such as Winterplex? If so, are there any plans do so with the existing test menu?

Presuming that the question refers to how transferrable the PROmate® technology is beyond COVID-19 and, if that’s the case, wanting to make certain that everybody understands that with PROmate®, the company has established a really strong position in direct to PCR sample processing. And that’s taking an aliquot of the sample direct into PCR. This processing lends itself well to a number of areas. You’ve already mentioned Winterplex. One of the most interesting areas for the company is the application of the PROmate® technology in the respiratory disease area.

We think that, by leveraging our PROmate® expertise, we’ll develop molecular tests for respiratory diseases that are easy to use in different settings, will provide a much faster time to result and allow much more streamlined testing workflows.

It’s these streamlined and less complex workflows that will serve to significantly improve testing efficiencies in central, decentralised and near-patient testing settings. So, the short answer to the question is, yes, we do believe the PROmate® technology is transferrable and we have targeted some specific areas to expand that PROmate® technology into around respiratory.

10. Are there any plans to change your listings? Will you list in the US?

As of today, we have no plans to change our listings on AIM or Euronext. To remind everybody, two-thirds of our shareholder base are based in France and the remaining one-third, broadly, are based in the UK. Therefore, our dual-listing strategy makes sense for the company today.

11. Can you advise on where we are with the US expansion?

We appreciate there’s lots of questions around the US, particularly being the largest diagnostic market in the world today. To remind everybody, we’ve recently hired new senior management who has joined us in the last few months. We are in the process of developing our plans as we speak and hopefully, in the near future, we will update all shareholders with those plans.

12. Please can you explain what the IT-IS acquisition has done for Novacyt?

The shift towards near-patient testing became clear during the course of last year which is where instrumentation really plays a role. For Novacyt to acquire IT-IS is a very logical marrying up of the reagent supplier and the instrument supplier.

This enables us to develop reagents alongside the instruments, securing key instrumentation IP that expands our capabilities and product offerings.
Therefore, IT-IS is a really nice fit. The company has also done a great job integrating the acquisition into the broader company within a matter of months.

13. Does Novacyt plan to move into providing a testing service like other manufacturers?

With COVID-19 testing, there have been a significant number of new service providers popping up all over the world, not just in the UK. Novacyt is a developer and manufacturer of diagnostic products and we have no intention of expanding the business into testing services as well.

The main reason for this is we are a pure-play manufacturer, which means that we can be agnostic with a large number of direct customers that we engage with. If we had our own service, in addition to the manufacturing, then we would be direct competitors with the very customers that we’re trying to sign deals with, which would create a huge conflict of interest.

Some will be aware of the origins of the Lab21 model, which was all-around testing services. Therefore, this is a very conscious decision that the Board and the management have taken about the business today.

14. Can Novacyt tell their shareholders what patents they have applied for in the last six months and what these patents are for?

We have filed over 20 patents for our proprietary assays, the q16 and q32 PCR systems and work-flow innovations. This helps protect the culture and practice of developing novel and cutting-edge diagnostic technology, which underpins the Group’s continued growth.

15. Can you inform shareholders of when David Allmond commences employment at Novacyt which may be different to when he becomes CEO?

David Allmond will commence employment with Novacyt as CEO and a member of the Board of Directors effective from 18 October 2021.

16. What is the Group’s perspective on the lead time to secure deals and procurement cycles?

This varies from customer type, market segment, and regions. Public healthcare and NGO-driven purchases typically have a longer lead-time than our distributor or growing private healthcare segment.

Another factor which influences lead times is if an opportunity is with an existing or a new customer.

17. What are the key regulatory barriers which are preventing further revenue growth today?

Regulatory process is a key element in IVD product launches in the diagnostic market. In the last 18 months, in several places around a globe, we saw a much faster regulatory process due to the COVID-19 pandemic, including the use of emergency authorisation approvals.

Going forward, and depending on the type of products that are being launched and their risk categories, it may take between six and 18 months or longer, depending on the country being targeted.

18. What part of the business and sector do you see the most potential?

The area we see the biggest potential for future growth in is the near-patient segment. The trend towards decentralisation we have seen in the last two years, specifically towards point-of-care or near-patient testing, has been accelerated because of the COVID-19 pandemic and the increased patient awareness and interest in testing needs.

19. Given the prolonged need for PCR and LFT testing, why has the company not brought LFT manufacturing capability in-house?

Given the policy of free LFTs in the UK market, the company has taken the strategic decision to focus on PCR manufacturing in the short term and outsource the manufacturing of its existing LFT PathFLOW product lines. This will continue to be reviewed.

20. Can we now say with some certainty that COVID-19 testing at a relatively high level is likely to persist into at least your 2023 financial year?
The company believes that there will be a continued level of COVID-19 testing for some years, which will be driven by the spread of infection levels across the globe and the likely ongoing mutation of the virus leading to a need for new testing products.

21. It was noted that Novacyt has no executive employees in mainland Europe; can the team give more insight on how it plans to develop its manufacturing and sales operational push into the region.

As part of our global expansion strategy, we are identifying the key markets in mainland Europe where we want to establish ourselves and build up our direct presence.

We are also identifying the best talent and defining the right structural set up in these countries. As shown in the presentation, a direct presence is essential to increase our market access and therefore increase our future market share and growth plans.

22. Is it still the company’s aspiration to become a mid-cap company and how do you intend to achieve this?

Novacyt has established a reputation for delivering best-in-class products and is now generating significant revenues from across the world, is building a global brand, and has a strong balance sheet, all of which will support the company’s growth trajectory as we continue deliver against our stated strategy.