

# R&D Update

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Novacyt S.A.

27 July 2020

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("Novacyt", the "Company" or the "Group")

R&D Update

Significant new opportunities for growth

Paris, France and Camberley, UK - 27 July 2020 - Novacyt (EURONEXT GROWTH: ALNOV; AIM: NCYT), an international specialist in clinical diagnostics, announces an R&D update.

R&D highlights

- Launch of near-patient (mobile) testing, which comprises Novacyt's COVID-19 test, direct-to-PCR RNA extraction kit (Exsig™ Direct), and q16 and q32 instruments
- Launch of a saliva sampling type to support ease of patient sampling, lower levels of discomfort and demonstrate more reproducible data
- Development of a respiratory testing panel to diagnose and distinguish between influenza A&B, RSV and COVID-19. Launch expected during September 2020 for the 2020/21 flu season in the Northern hemisphere
- Development of a two-gene test to address markets employing this testing approach. Launch expected no later than September 2020
- Development, together with a partner, of a serology (antibody) test to detect past infection of COVID-19. Launch expected in Q4 2020

The Company's COVID-19 polymerase chain reaction (PCR) test was one of the first to be developed and registered under the CE-IVD Directive, establishing Novacyt as a pioneer and a leader in COVID-19 diagnostics. The success of the product has been built around robust design principles and the selection of a gene target that has so far demonstrated exceedingly low levels of genetic mutation and variation. To date, the target has been analysed against 42,655 individual COVID-19 viral sequences and demonstrated 100% detection.

Novacyt remains committed to building on this innovative position for COVID-19 testing, and more broadly for respiratory disease testing, and investing to address unmet needs in the market. The Company has already launched three new innovative products, Exsig™ Direct, Exsig™ Mag and COVID-HT, to support laboratories testing for COVID-19 through improving workflow efficiency and helping to address the reported shortfall in global manufacturing and supply of extraction reagents.

Scientists at the Company continue to innovate and detailed below is an update on the current development activities, which are expected to drive incremental revenue for the Company once launched. Novacyt continues to build on its patent portfolio through new filings to protect its products and market leading position in COVID-19 testing.

#### Launch of near-patient (mobile) testing

Further to the Company announcement on 22 July 2020, Novacyt confirms the launch of its near-patient testing (NPT) system for COVID-19. Validation of the NPT system includes analysis of over 400 patient samples carried out by a leading, accredited clinical laboratory. The reported sensitivity and specificity are both greater than 99%.

A number of NHS hospitals are already using Novacyt's NPT system in hospital departments. Pilot programmes are underway in surgical, cancer and imaging departments where rapid, accurate testing is a pre-requisite to the patient receiving care. In addition, the NPT system is being used in the private sector, such as professional sport and mining industries. The Company is currently evaluating other markets where the NPT system could be used for rapid and frequent COVID-19 testing.

#### Launch of new sample type

The Company's COVID-19 test was developed for use with sample types initially preferred by testing authorities and key opinion leaders, which include oropharyngeal (throat) and nasopharyngeal (nasal) swabs, and sputum. To support ease of patient sampling, lower levels of discomfort and demonstrate more reproducible data, other less invasive and easier to collect sample types have been discussed by various authorities.

Recent studies<sup>1</sup> have demonstrated that saliva often has far higher numbers of viral particles compared with nasopharyngeal swabs. An independent study carried out by the Liverpool School of Hygiene and Tropical Medicine using Novacyt's COVID-19 test concluded that "SARS-Cov-2 can be detected with greater sensitivity in saliva samples compared to nasal swabs"<sup>2</sup>. Further to completing its own validation of the saliva sampling type, Novacyt confirms this sample type can be used with its COVID-19 test.

In addition, as detailed in the Company's announcement on 22 July 2020, a 2,000 patient clinical trial led Queen Mary University of London using Novacyt's near-patient testing system, is evaluating the effectiveness of mid-nose nasal swabs compared to invasive nasopharyngeal swabs as a further sampling type.

#### Development of a respiratory testing panel

There remains a challenge for healthcare providers in differentiating COVID-19 from other respiratory diseases,

particularly during a seasonal flu outbreak, due to patients presenting with similar symptoms. This is driving the requirement for the development of respiratory testing panels that are able to diagnose and distinguish the difference between types of flu and COVID-19. Novacyt has been working closely with certain key opinion leaders to determine the make-up of such panels. This has resulted in the development of a panel covering the differential diagnosis of influenza A&B, respiratory syncytial virus (RSV) and COVID-19. Novacyt expects to launch the panel as a CE Mark product in September 2020 for the 2020/21 "flu season" in the Northern hemisphere.

#### Development of a two gene test

Whilst the Company's COVID-19 test continues to demonstrate a market leading performance in terms of specificity and sensitivity, there are a number of countries legislating that a two-gene testing approach is employed. This approach is driven by concerns regarding mutation of the virus and the inability for some other PCR tests to detect positive cases.

Whilst Novacyt is able to demonstrate the superiority of its specific single gene approach, with the test having received emergency use authorisation from most major health bodies, including the US FDA and WHO, the insistence on deployment of two gene tests has impaired the Company's ability to penetrate certain markets. The Company is therefore finalising the development of its own two gene target test and expects to launch this two gene test no later than September 2020.

1Wyllie et al: medRxiv 2020.04.16.20067835; doi: <https://doi.org/10.1101/2020.04.16.20067835>

2Byrne and Adams et al: medRxiv preprint doi: <https://doi.org/10.1101/2020.07.09.20149534>; July 2020

#### Serology (antibody) testing

It has been widely documented that healthcare providers require an effective method to identify individuals who have previously been exposed to COVID-19 and who may therefore have immunity to further infection. Serological methods typically try to distinguish between IgM and IgG antibodies.

The human immune response to infection results in the body producing different types of antibodies at different stages of the infection, with IgM being produced before IgG. However, the initial antibody response is not produced immediately and may not be detectable until up to 14 days after infection. Therefore, detection of viral RNA by PCR testing is the most sensitive method of choice in early diagnosis of infection, often in patients who are showing few or no clinical symptoms. The IgM antibody response is also short lived. However, the body generates a longer lasting response with the production of IgG antibodies. It is these IgG antibodies that are indicative of past infection and which can typically impart some form of immunity against future infection.

Following extensive investigation of a number of serological methods, Novacyt is working with a partner who has developed a test for the detection of the IgG antibody to COVID-19. To date, the product has demonstrated significant levels of sensitivity and specificity for detection of IgG in patients 14 days after testing positive for

COVID-19 by a PCR test. Novacyt is now in the process of conducting its own performance evaluation to validate the serology test and will look to launch a CE Mark product during the fourth quarter of 2020.

Graham Mullis, Group CEO of Novacyt, commented:

"Novacyt has established itself as a pioneer in COVID-19 diagnostics through the rapid development and success of its PCR test for the virus. We remain committed to building on this innovative position for COVID-19 testing, and more broadly across infectious diseases, as we continue to invest in the business to address unmet needs in the diagnostics market. The immediate pipeline of new products is expected to drive incremental revenue for the Company in the near-term, but Novacyt's strengthened financial position also means we are able to redefine our R&D pipeline for the next three years, which we expect to drive significant and continued growth opportunities in the longer-term."

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) 596/2014.

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#### About Novacyt Group

The Novacyt Group is an international diagnostics business generating an increasing portfolio of in vitro and molecular diagnostic tests. Its core strengths lie in diagnostics product development, commercialisation, contract design and manufacturing. The Company's lead business units comprise of Primerdesign and Lab21 Products, supplying an extensive range of high-quality assays and reagents worldwide. The Group directly serves microbiology, haematology and serology markets as do its global partners, which include major corporates.

For more information please refer to the website: [www.novacyt.com](http://www.novacyt.com)

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