

NOVACYT

Limited company with registered capital of 4,708,416.54 euros
Registered office: 13 avenue Morane Saulnier – 78140 Vélizy-Villacoublay
491 062 527 Versailles Trade and Companies Register

(hereinafter the “Company” or “Novacyt”)

ACTIVITY OF THE COMPANY AND ITS SUBSIDIARIES AND BUSINESS TRENDS DURING THE YEAR ENDED 31 DECEMBER 2019

COMBINED GENERAL MEETING DATED SEPTEMBER 29, 2020

1.1 Overview of Novacyt’s activity

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.

The following companies make up the Novacyt Group:

Biotec laboratories Ltd
Lab21 Healthcare Ltd
Microgen Bioproducts Ltd
Novacyt SA
Novacyt SA UK
Novacyt Asia Ltd
Novacyt China Ltd
Novacyt UK Holdings Ltd
Primerdesign Ltd

1.2 Situation and activity / Analysis of business trends

- Due to the extraordinary position the Company finds itself in today, the financial highlights for 2019 do not have a material bearing on the current business, however, are presented below for the record.
- As previously announced, Novacyt continued to experience increasing demand for its products during the year, however, this growth was moderated by working capital constraints, which impacted the Group’s full year revenue and profit performance.
- Adjusted EBITDA of €0.2 million in 2019 compared with €0.6 million in 2018
- Third consecutive year of positive EBITDA for the Group
- Reduction in adjusted EBITDA reflects reduced sales in 2019 due to working capital constraints during the year
- Group consolidated revenue decreased by 5% (6% at CER) to €13.1m (£11.5m) in 2019 compared with €13.7m (£12.1m) in 2018
- Excluding the Clinical Lab, which was sold in July 2019, Group revenue reduced by 2% (3% CER)
- Primerdesign grew 1% year-on-year to €6.3m in 2019 compared with €6.2m in 2018

- American sales were up 13% year-on-year driven by increased sales through Primerdesign's key US customers
- Group gross margin continued to improve and increased to 64% in 2019 from 63% in 2018
- Continues a trend of increased gross margin every year since 2014
- Improvement due to the exit from the lower margin Clinical Lab business and Primerdesign increasing its share of Group revenue to 48% (2018: 45%)
- Primerdesign's strong gross margin increased to 85% (2018: 84%)
- Successfully sold NOVAprep® and the Clinical Lab during 2019, each realising a total consideration of €0.4m
- Refinancing of borrowings in November 2019 through a €5m bond with Harbert European Growth Capital
- Cash at year end of €1.8m (£1.5m) compared with €1.1m (£1.0m) in 2018

1.3 Results, progress achieved and difficulties encountered

- 2019 was a year of consolidation as we completed the refinancing and restructure of the business, positioning Novacyt to resume its three-pillar growth strategy of organic, R&D and acquisitive growth.

Highlights

Divisional revenues

- Primerdesign sales increased to €6.3m (£5.5m), up 1% in 2019
 - Core business reagent revenues increased 8% year-on-year or €0.4m compared to 2018
 - Achieved international reagent revenue growth of 12% despite restricted q16 instrument sales due to lack of inventory
- Lab21 revenues €6.8m (£5.9m), down 10% from 2018 (-5% excluding the Clinical Lab)
 - Microgen Bioproducts, part of Lab21, saw year-on-year growth in UK and Ireland of 13% and 8% in Asia Pacific despite stock shortages
- The discontinued NOVAprep® operation achieved sales of €1.3m, which are excluded from Group consolidated revenue and do not impact the growth metrics stated above. These sales were generated before the sale of the business in December 2019 and represent 37% growth compared to the prior year

Operational highlights

- Launched next generation genesig® q32 qPCR molecular testing instrument, to complement the already revenue generating genesig® q16 instrument
- Developed and launched a new molecular multiplex test to identify 37 respiratory pathogens for the US market
- Expansion of assay development contract with Immunexpress

Harbert European Growth Capital "HEGC" financing (November 2019)

Novacyt entered into a €5.0 million secured loan in November 2019. The €5.0million HEGC secured term loan is repayable over 48 months with an initial 12 month interest-only period followed by 36 equal monthly payments of interest and capital. Key features of the loan are:

- Interest is fixed at 11% per annum throughout the four-year term
- HEGC is granted warrants over 6,017,192 ordinary shares (8.5% of the principal loan amount) with a conversion price of €0.0698 each, representing a 5% discount on the volume weighted average price ("VWAP") of the ten trading days prior to completion, exercisable for a period of 7 years from completion
- HEGC have taken a first ranking charge over the assets of the UK businesses with a pledge over Novacyt
- Novacyt may pay back the loan in full at any time during the 48 months

1.4 Foreseeable change in the Company's position and future prospects

The Primerdesign and Lab21 businesses started the year strongly, with an order book significantly higher than the beginning of 2019 and with working capital to fully restore the Group's supply chain through the first half of 2020.

In early January 2020, Novacyt commenced the development of a new test in response to the emerging novel coronavirus (COVID-19) threat emerging from China. Primerdesign launched its test in late January 2020 to become one of the world's first molecular tests for the SARS-CoV-2 virus. The test was the first to achieve CE-IVD status and was subsequently approved for emergency use by the US Food and Drug Administration, the World Health Organisation and other regulatory bodies. The Company quickly established the need to develop significant manufacturing capacity and today has eight dedicated manufacturing sites capable of producing COVID-19 tests at an output rate of more than ten million tests per month, which Novacyt expects to achieve from June 2020 onwards. Through its investment in raw materials and manufacturing, the Company is now in a position to service significant and expected growth in demand for its COVID-19 test.

Sales, orders and commitments to purchase the test since the initial launch have significantly exceeded expectations and have been transformational for the Group; all indications are that the positive financial effects of this will continue. This is additional revenue to Novacyt's other operations at Primerdesign and Lab21 Products. The Directors believe the significant demand for the Company's COVID-19 test will continue through to the end of the year, and may extend well into 2021, as the global demand for COVID-19 testing continues to increase. Further revenues are also expected from the launch of the Company's COVID-19 related products described later, which include the Exsig™ Direct extraction reagent and mobile COVID-19 testing.

In addition, the Directors believe the successful development, launch and sale of the COVID-19 test will have a positive, long-term effect on the business. As well as reinforcing the expertise within the business, the Company now has a new and significantly increased base of global customers. The Company is already experiencing increased demand for its B2B molecular design and development capabilities and the Board believes these opportunities will extend to Novacyt's extensive product portfolio.

1.5 Business activity in the year ended 31 December 2019

Amounts in '000 €	Corporate & Cytology	Corporate & Diagnostics	Molecular Products	Total
Geographical area				
Africa	-	639	356	995
Europe	-	2,809	2,676	5,485
Asia-Pacific	-	1,744	812	2,556
America	-	738	1,934	2,672
Middle East	-	845	528	1,373
Revenue	-	6,775	6,306	13,081

1.6 Research and development activity

Developments in the field of Molecular testing:

In May 2019, Primerdesign launched its next generation genesig® q32 qPCR molecular testing instrument ("q32"). As stated at the time of AIM IPO, Novacyt has utilised some of the funds to focus on product development, and the q32 is a direct result of this investment. The q32 is a larger genesig® real-time qPCR instrument, which provides customers with a faster and higher throughput solution for Novacyt's genesig® real-time PCR kits. The q32 complements the smaller, portable genesig® q16 instrument ("q16"), which is used in laboratories and the field, and provides customers with an alternative instrument when faced with multiple terrain and off-site testing challenges

The q32 provides test results within 60 minutes using genesig® kits, making it one of the fastest qPCR instruments on the market due to its rapid heating and cooling capabilities and unique lid design. Like the q16, the q32 is robust and, therefore, highly reliable. It allows the analysis of up to 32 patient samples in tube or strip format, using fluorescence detection technologies. The q32 software also allows users to experience a quick and easy operation for all genesig® kit applications with a straightforward setup process.

During the year, Primerdesign also completed the design and development of the molecular respiratory panel based on a 384 well plate format for use by its North American business partner in their CLIA approved diagnostic testing laboratory network. Primerdesign designed the multiplex test to identify 37 respiratory pathogens, which makes it one of the most comprehensive respiratory panels available in the market today. In addition to identifying a large number of respiratory disease pathogens, the new diagnostic product was designed with proprietary freeze-drying technology to stabilise the product to optimise its ease of use and performance.

Primerdesign will supply this product under a five-year manufacturing agreement as its partner launches the new respiratory panel in the US market through its own clinical testing laboratories to provide a Laboratory Developed Diagnostic Test (“LDT”) result for its customers.

This development marked a significant step forward in the Group’s B2B strategy by providing our North American business partner with the opportunity to serve the significant demand for the US seasonal respiratory testing market, which typically runs from September to April. It also demonstrated the increasing capability of Novacyt’s R&D team as it broadens its product portfolio and builds the skills to develop more complex products. The rapid development of this new multiplex molecular diagnostic panel shows the power of our integrated research, development and commercialisation team.

1.7 Polluting or dangerous activities

None

1.8 Main risks and uncertainties facing the Company and management of financial risks

The directors have, at the time of approving the financial statements, a reasonable expectation that the Company has adequate resources to continue in operational existence for the foreseeable future. Thus, they adopt the going concern basis of accounting in preparing the financial statements.

The going concern model covers the period up to and including April 2021. In making this assessment the Directors have considered the following elements:

- the working capital requirements of the business;
- a positive cash balance at 31 December 2019 of €1,805,000;
- the repayment of the current bond borrowings according to the agreed repayment schedules;
- the financing cash inflow relating to the exercise of warrants in Q1 2020;
- a payment of the first tranche of the LTIP that commenced in November 2017;
- increased operating cash inflows generated by the Covid-19 pandemic;

The forecast prepared by the company shows that it is able to cover its cash needs during the financial year 2020 and until April 2021 without the raising of any further bank or other financing facility.

The Group’s main financial liabilities are loans, as well as trade and other payables. Their main purpose is to finance operating activities.

Loans, trade and other receivables, and cash and cash equivalents held by the Group are generated by operating activities.

- Currency risk

The Group has significant operations in the United Kingdom, where its main subsidiaries are located. Nevertheless, its funding is denominated primarily in euros.

- Credit risk

Credit risk is the risk of financial loss, following the failure by a third party to honour its commitment to repay a debt. The Group is exposed to credit risk due to its operating activities (mainly through trade receivables) and through deposits with banks.

The Group's exposure to credit risk is represented by the risk of counterparty default: maximum exposure is equal to the carrying amount of these instruments.

At this stage, it is not yet clear how Brexit will affect trading, corporate taxation, free movement of persons and regulatory aspects in the United Kingdom. The tax implications, depending on the outcome of ongoing negotiations between the European Union and the United Kingdom, are unknown at this stage. At the time of writing, Novacyt does not foresee any significant impact on the business. The Board of Directors continues to monitor developments in terms of impacts on market, operational, legal and financial risks, and will implement any corrective actions that may be necessary.

- Liquidity risk

Since its creation, the Group has financed its growth by successive capital increases, loans, grants and public aid for innovation, and the reimbursement of research tax credit receivables.

To overcome limits in its capacity to self-finance its growth, the Group has been required to seek other sources of funding, notably through capital increases.

The Group may fail to obtain additional capital when it needs it, or such capital may not be available on acceptable financial terms for the Group.

The occurrence of one or more of these risks could have an adverse effect on the Group's business, financial position, earnings, growth and prospects.

1.9 Significant events occurring between the reporting date and the date of this report

During January and February 2020 Novacyt's share price increased to over €2 per share, a key contributing factor being the launch of a Covid-19 diagnostic test kit by Primerdesign. This share price increase resulted in all remaining warrant holders exercising their warrants which gave rise to a net cash inflow of €2,400,000 into the business and the warrant overhang has now been removed completely.

1.10 Existing branches

Novacyt SA has a branch in the UK called Novacyt SA UK