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 2022

COMBINED GENERAL MEETING DATED 15 JUNE 2023

1.1 Overview of Novacyt's activity

Novacyt is an international diagnostics business delivering a broad portfolio of in vitro and molecular diagnostic tests for a wide range of infectious diseases, enabling faster, more accurate, accessible testing to improve healthcare outcomes. The Company provides customers with a seamless sample-to-result workflow using its integrated and scalable instrumentation/solutions. The Company specialises in the design, manufacture, and supply of real-time PCR kits, reagents and a full range of laboratory and qPCR instrumentation for molecular biology research and clinical use. Novacyt offers one of the world's most varied and comprehensive range of qPCR assays, covering human, veterinary, biodefence, environmental, agriculture and food testing.

The following companies make up the Novacyt Group:

Biotec Laboratories Ltd
IT-IS International Ltd
Lab21 Healthcare Ltd
Novacyt US Inc
Novacyt Inc
Microgen Bioproducts Ltd
Novacyt SA
Novacyt Asia Ltd
Novacyt China Ltd
Novacyt UK Holdings Ltd
Primer Design Ltd

1.2 Situation and activity / Analysis of business trends

- Group revenue for FY2022 was £21.0m, in line with guidance, (FY2021: £92.6m), due to the expected decline in COVID-19 related sales,
- Revenue from COVID-19 products in 2022 totalled £14.7m (FY2021: £84.0m),
- Revenue for the non-COVID-19 portfolio in 2022 totalled £6.3m (FY2021: £8.6m). This decline was predominantly driven by lower instrument sales compared to FY2021 which benefited from COVID-19 demand,
- Group gross profit totalled £5.7m (27%) in FY2022 (FY2021: £28.2m (30%)). The FY2022 gross profit was reduced as a result of significant stock provisions based on lower forecasted COVID-19 sales in addition to writing-off stock that had not been provided for previously. Excluding the impact of these items, the margin would be in excess of 60%,

- Group EBITDA loss in FY2022 is £13.5m before exceptional items (FY2021: £3.1m profit) as a result of the expected decline in revenue and in line with guidance,
- Discontinued operations loss of £3.5m in FY2022 (FY2021: £3.7m loss),
- Loss after tax increased to £25.7m in FY2022 (FY2021: £9.7m loss),
- Cash position at 31 December 2022 was £87.0m (2021: £101.7m) and the Company remains debt free.

1.3 Results, progress achieved and difficulties encountered

Overview

Novacyt's 2022 performance was impacted by a faster than anticipated decline in COVID-19 related sales, and as such is reporting a loss for the year. During the second half of 2022 the Group made good progress on i) transitioning from its reliance on COVID-19 revenue and ii) right sizing its cost base. During the year the Group carried out a large restructuring exercise to reduce its opex cost base, which saw over 100 employees leave the Group.

Operational highlights

Non-COVID-19 assay development

- Completed the development of genesig®PLEX, a multiplex gastrointestinal bacterial assay, available as a research-use-only test (RUO),
- Developed and relaunched two single analyte transplant viral assay panels for the Epstein-Barr virus and BK virus for use on open instrument platforms,
- Augmented product portfolio with the addition of over 40 CE marked *in vitro* diagnostic (IVD) assays, through a third-party distribution agreement with Clonit srl,
- International launch and UK Coronavirus Test Device Approvals (CTDA) approval of genesig® Real-time PCR SARS-CoV-2 genesig™ Winterplex® panel covering RSV, Flu A&B and COVID-19,
- Relaunched RUO portfolio globally and developed Monkeypox and Adenovirus F41 RUO assays to support infectious disease monitoring ,

COVID-19 assay development

- Six UK CTDA approvals in the year (including genesig™ Winterplex® multiplex panel), taking the total number of Novacyt products approved by the CTDA to seven, the most of any UK-based company,
- CE marked two lyophilised PROmate® products, enabling deployment of near-patient COVID-19 diagnostic solution without the need for cold-chain shipping,
- CE marked PathFlow® COVID-19 Rapid Antigen Self-Test received, one of the first saliva-based COVID-19 assays to be launched in the EEA and providing diagnosis of symptomatic and asymptomatic individuals in approximately 15 minutes,

Workflow and instrumentation development

- Launched and CE marked CO-Prep™ Automated Liquid Handling System Completed validation of a nucleic acid extraction system to enhance post-COVID-19 integrated sample-to-result molecular workflow solution,
- Launched two new lateral flow test (LFT) readers for use in conjunction with a broad range of assays within Novacyt's Pathflow® product portfolio, consisting of 18 non-COVID-19 products across sexually transmitted, gastrointestinal, respiratory and insect-borne infections,

Commercialisation

- Partnered with a global fisheries company to develop solutions for testing infectious salmon anaemia virus and bacterial kidney disease,
- Signed a contract with a leading global non-governmental organisation (NGO) to support the detection of arboviruses, including dengue, Zika and Chikungunya,

- Partnered with leading healthcare company in India to develop and supply both reagents and instrumentation.

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

Strategy highlights

During the period, Novacyt has focused on deploying talent in key geographies and optimising its global distributor network to ensure optimal commercial coverage for its recently relaunched RUO portfolio and its growing clinical offering. Through this work, coverage has been increased across EMEA and the Company has begun conducting distributor training on its full portfolio, including its expanded clinical portfolio and workflow.

- Commercialised Winterplex® panel with sales to hospitals in both the UK and Europe.
- Partnered with a global fisheries company in the development of tests and workflow for more efficient management of fish stocks; initial sales have been focused on their North American subsidiary and we are now engaging with other global sites to identify their testing needs.
- As the APAC region begins to open up post-COVID, we are re-engaging with new and existing distributors across the region with the RUO reagent and instrument products.
- Signed a contract with a leading global non-governmental organisation (NGO) to support the detection of arboviruses, including dengue, Zika and Chikungunya. This has now been extended to include West Nile fever, hepatitis A & E and haemorrhagic fever, with further orders received. We also anticipate sales of our RSV test to come in the near term and they are currently evaluating our Winterplex® ® product for deployment across Africa.
- Partnered with a leading healthcare company in India to supply both reagents and instrumentation.

The Company expects to launch an updated customer website in Q3, that will replace and consolidate former legacy sites. All commerce activity will be conducted from this single site, which will include webshop functionality, as well as a customer portal offering instrument registration and software upgrades.

Business development

In addition to the internal development of the new portfolio, the Company continues to assess strategic M&A, partnership and licencing opportunities as a priority to add scale and diversification to support the long-term growth of the business.

In January 2023 Novacyt entered into an exclusive development agreement with Eluceda Ltd, a specialist developer of electrochemical sensors, to develop novel biosensor technology in the fields of human and animal in vitro diagnostics, life science research and animal speciation. Development of two products has started and the first product is expected to launch early in 2024.

1.5 Business activity in the year ended 31 December 2022

Amounts in £'000	Primer Design	IT-IS International	Total
Geographical area			
United Kingdom	10,051	72	10,123
Europe (excluding UK)	3,372	477	3,849
America	4,134	347	4,481
Asia-Pacific	1,373	479	1,852
Middle East	347	30	377
Africa	357	1	358
Total revenue	**19,634**	**1,406**	**21,040**

1.6 Research and development activity

Product development

In July 2022 the Company relaunched its extensive and established research use only (RUO) portfolio, ensuring our primers and probes were best-in-class to reliably target current pathogens. By year-end, the team had optimised and verified the redesigns of 25 RUO products, and also developed new RUO assays for Monkeypox and Adenovirus F41.

As the product development pathway for clinical products has been significantly extended under IVDR, the Company will now develop RUO versions for its target therapeutic areas as a first step. This activity is well underway targeting the development of up to ten new multiplex products in 2023 in the areas of gastrointestinal, respiratory and insect-borne infections.

Through a combination of internal R&D and third-party sourcing, the Company has already launched a portfolio of CE marked clinical assays in the following areas:

- A winter respiratory panel with the internally developed genesig® Real-time PCR SARS-CoV-2 Winterplex® launched in Europe and CTDA approved for UK launch in October 2022,
- Sexually transmitted infections (STI) (e.g., Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis),
- Gastrointestinal infections (e.g., Clostridium difficile, Enterovirus),
- Respiratory (RI) (e.g., Mycoplasma pneumoniae),
- Two single analyte transplant viral assay panels for the Epstein-Barr virus and BK virus for use on open instrument platforms during the period.

These products and our enhanced workflow solution will be targeted to indications where there is a need for cost-effective, rapid, accurate and highly precise diagnostic testing. Based on market research, we believe the key market for this offering is in routine testing in mid-to-low volume spoke laboratories and non-routine services in hub laboratories. As identified in April 2022 at the strategy update, we will target these markets due to our differentiated customer offering.

For Europe, which is our initial target geography with CE marked products, the Company estimates a market size of circa £470m growing at a CAGR of 10%. The mid-term goal is to expand our offering to customers worldwide.

Our molecular portfolio is complemented by an extensive range of lateral flow diagnostic tests (LFTs) for clinical use. The range aligns with the target disease areas covered by our molecular portfolio and has been further enhanced with the launch of two new LFT readers for use in conjunction with a number of key assays within Novacyt's Pathflow® product portfolio. The readers are designed to provide digital test results based on optical imaging technology, thereby removing the ambiguity of manually interpreting a reading. The result is available in a matter of seconds (~10-12 secs) in a digital form that can be exported to other systems.

Instrumentation & workflow

Novacyt has made considerable progress enhancing its post-COVID-19 integrated sample-to-result molecular workflow solution. We have validated a nucleic acid extraction system and have launched an automated liquid handling system (CO-Prep™) for assay setup that complements our proprietary q16 and q32 instruments and user friendly direct-to-PCR assays to deliver an end-to-end, fast scalable workflow solution capable of processing over 1,000 tests per day. The new workflow reduces hands-on time and risk of contamination whilst providing robust sample stewardship to reduce the chance of human error. The complete workflow platform can be used where current decentralised sample-to-result solutions are not easily scalable, slow, and costly.

COVID-19 portfolio

To ensure Novacyt remains well positioned for any future COVID-19 outbreaks in both developed and developing markets, the Company has consolidated its portfolio. To this end, Novacyt secured CE mark accreditation for its saliva-based PathFlow® COVID-19 Rapid Antigen Self-Test and an ambient version of its PROmate® COVID-19 2G assay designed for international shipping. Both tests complement the Company's established genesig® COVID-19 Real-Time PCR portfolio and PROmate® COVID-19 direct to PCR 1G and 2G assays.

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 Group 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 2024. 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 2022 of £86,973,000;
- Payment of the Long-Term cash Incentive Plan ("LTIP") that commenced in 2021 and vests at the end of 2023; and
- The DHSC commercial dispute having a trial date set for June 2024.

The forecast prepared by the Group shows that it is able to cover its cash needs during the financial year 2023 up until April 2024.

As at 31 December 2022 the Group is debt free and its main financial liabilities are trade and other payables.

Trade and other receivables, 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. The Group is mainly exposed to the Euro and US Dollar currencies as the company now reports in Great British Pounds, which is its main functional currency.

- 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.

The Group has adopted a policy of only dealing with credit worthy counterparties and obtaining sufficient collateral where appropriate, as a means of mitigating the risk of financial loss from defaults. The Group uses publicly available financial information and its own trading records to rate its major customers' risk levels. The Group's exposure and the credit ratings of its counterparties are continuously monitored and the aggregate value of transactions concluded is spread amongst approved counterparties.

The Group uses debt collection agencies and government backed schemes to collect difficult aged debts as a last resort.

- Liquidity risk

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

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

Subsequent events

On 30 January 2023, Novacyt announced that the UK High Court had directed Novacyt, that the hearing of the case between Primer Design Ltd / Novacyt SA and the DHSC has been listed to commence on 10 June 2024 and is expected to last 16 days.

1.10 Existing branches

Pursuant to the provisions of Article L. 232-1 of the French Commercial Code, we inform you that there are no branches of the Company during the 2022 financial year.