

## 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 2020

COMBINED GENERAL MEETING DATED SEPTEMBER 29, 2021

#### 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  
IT-IS International Ltd  
Lab21 Healthcare Ltd  
Microgen Bioproducts Ltd  
Novacyt SA  
Novacyt Asia Ltd  
Novacyt China Ltd  
Novacyt UK Holdings Ltd  
Primerdesign Ltd

#### 1.2 Situation and activity / Analysis of business trends

- Group consolidated revenue increased by over 2,300% to £277.2m in 2020 compared with £11.5m in 2019.
  - Primerdesign grew more than 4,800% year-on-year to £272.8m in 2020 compared with £5.5m in 2019.
  - All key territories saw year-on-year growth, with the UK market seeing sales increase by over £217m, to £219.4m, largely driven by contracts won in support of the UK testing response to the COVID-19 pandemic. Sales to Europe (excluding the UK) were up over 1,000%, or £29m, to £32.0m driven by increased distributor sales of our range of COVID-19 tests. American sales were up 340% year-on-year to £10.3m.
- Group gross margin continued to improve increasing to 76.3% in 2020 from 64.0% in 2019.
- The Group delivered a gross profit of £211.5m in 2020 compared with £7.3m in 2019
  - This continues the trend of increasing the gross margin percentage every year since 2014.
  - The improvement is due to Primerdesign’s share of Group revenue increasing from 48% in 2019 to 98% in 2020.

- Primerdesign's gross margin decreased to 76.5% in 2020 compared with 85% in 2019, as a result of increasing the product warranty provision by £19.8m.
- Group EBITDA increased to £176.1m in 2020 compared with £0.2m in 2019.
  - EBITDA margin increased to 64% in 2020 compared with 2% in 2019.
  - This continues the trend of positive EBITDA for the Group.
- Operating profit of £167.4m in 2020 compared to a loss of £1.6m in 2019, driven by the growth in sales in the Primerdesign business.
- Profit after tax of £132.4m in 2020 compared to a loss of £5.7m in 2019.
- Cash at year-end of £91.8m compared with £1.5m in 2019, driven by the strong 2020 performance.
- The Group exits 2020 debt free after all debt was repaid during the first half of 2020.
- IT-IS International Limited, a profitable diagnostic instrument development and manufacturing company, was acquired on 15th October 2020. The net consideration for the acquisition after earnouts is £8.7m.

### 1.3 Results, progress achieved and difficulties encountered

2020 was a year of transformation and growth as the company helped support the worldwide COVID-19 pandemic response with its gold standard qPCR diagnostic tests.

#### Highlights

##### Divisional revenues

- Primerdesign sales increased to £272.8m, up 4,833% in 2020.
  - UK and Ireland NHS accounts represented £191.2m (70%) of total sales, reflecting the Company's response and contribution to the UK government testing strategy.
  - Core distributor and reseller business across UK and international markets represented £49.5m (18%) of total sales, with sales to over 85 countries.
  - Private Sector testing market represented £32.1m (12%) of total sales.
- Lab21 Products revenue of £5.2m (before intercompany eliminations), is down 14% from 2019.
  - The core business was impacted by customers diverting their testing laboratories and procedures from veterinary and food testing to COVID-19 testing, to support the global pandemic efforts.
  - The Asia Pacific region within Microgen Bioproducts grew 6% year-on-year.
- IT-IS International delivered post acquisition revenues of £6.9m (before intercompany eliminations).

#### Operational highlights

- Rapid development and launch of 10 new products to support laboratories and clinicians testing for COVID-19
  - Developed one of the first molecular tests for COVID-19, receiving CE Mark accreditation and Emergency Use Authorisation from regulatory authorities around the world
  - Launch of a number of innovative PCR products, including Exsig™, PROMate™, COVID-HT and Winterplex™, to improve workflow efficiency and address testing needs in both central and near-patient settings
- Significant organisational scale-up, including a manufacturing capacity increase of over 100x, an increase in supply chain capacity, and a significant investment in commercial infrastructure to support growth
- Strategic collaboration with AstraZeneca, GSK and University of Cambridge to support COVID-19 testing in the UK
- Secured significant contracts with national governments, including the UK DHSC, and national non-government organisations for the supply of COVID-19 products
- Acquisition and successful integration of IT-IS International Ltd in line with strategy, securing key IP and expanding core capabilities and product offering
- Development of VersaLab™ to improve near-patient PCR testing in the emerging private sector testing market

- Expertise in bioinformatics surveillance used to assess ongoing accuracy of COVID-19 tests and monitor new viral sequences of SARS-CoV-2

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

The Company expects to see significant new growth from the launch of new products during the second half including an expansion of its lateral flow antigen testing portfolio.

In the UK, we are continuing to expand our installed base at NHS hospitals with approximately 40 sites now running q16 or q32 instruments with the new PROMate™ test. Demand for COVID-19 testing through these hospitals is low at present based on low infection / testing rates but we believe this installed base will be a key long-term asset moving forwards and an opportunity for Novacyt to expand its test menu for additional diseases.

With the strengthened cash position of the Company, the business will continue to invest in innovation, organic expansion, and external business development, in line with its updated growth strategy. The Company also continues to evaluate M&A opportunities and will consider additional bolt-on acquisitions to add strategic assets and expand its geographical footprint.

#### 1.5 Business activity in the year ended 31 December 2020

Amounts in '000 £	Primerdesign	Lab21 Products	IT-IS International	Total
<b>Geographical area</b>				
United Kingdom	218,552	591	246	219,389
Europe (excluding UK)	30,917	1,058	56	32,031
Africa	2,896	151	6	3,053
Asia-Pacific	5,305	920	453	6,678
America	9,655	340	316	10,311
Middle East	5,492	250	-	5,742
<b>Total revenue</b>	<b>272,817</b>	<b>3,310</b>	<b>1,077</b>	<b>277,204</b>

#### 1.6 Research and development activity

2020 was a year of agile and innovative product development. One of the Company's key strengths is to innovatively address market needs with our products. We were quick to respond to COVID-19, producing one of the first tests for the virus in January 2020, and we maintained this pace throughout the year, launching new assays and workflow solutions to build a comprehensive COVID-19 product portfolio.

The continued development and expansion of our COVID-19 portfolio is a testament to our ability to match the rapid evolution of SARS-CoV-2 with real-time bioinformatics surveillance and accelerated product development. This is demonstrated post-period end by the rapid development and launch of our PCR genotyping portfolio, known as SNPsig®, to detect variants, initially focused on SARS-CoV-2 variants.

To date, Novacyt has launched over 10 new COVID-19 related products since the beginning of 2020 and has moved from one to three major molecular diagnostic product platforms. All three product platforms, detailed below, have proven to be successful and open different potential markets.

- genesig™ PCR tests for small to medium central laboratories
- PROMate™ PCR tests for near-patient testing
- High throughput genesig™ PCR tests for large laboratories

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 laboratory, HT settings that can run on many laboratory systems as well as our own q16/32 rapid-PCR systems. Our internal R&D is complemented by an expert business development function, which has developed a global network of innovate partners and has successfully in-licensed antibody, antigen and work-flow solutions to expand our product offering.

Across the COVID-19 market, testing requirements are increasing in complexity. There is a regulatory requirement for multigene assays (two and three gene assays) to exclude the (S and N) genes that are most prone to mutations and for suppliers to provide detailed bioinformatic surveillance. We are well positioned with an expert bioinformatics team and will continue to invest in this area as we develop our plans for our focus in product expansion post COVID-19.

### **Investment in IP**

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 Company's product development process, and forming a key part of protecting future value within the business. We have filed over 20 patents to protect our proprietary assays, the q16/32 PCR systems and workflow innovations. This culture and practice of developing novel and cutting-edge diagnostic technology underpins the Company's continued growth and agility. As such, the R&D team has more than doubled in size and now includes a leading bioinformatics team and the Company's clinical trial function that undertakes clinical trials in the UK, Europe, US and Latin America.

This clinical expertise is a key requirement of the new IVD-R regulation being introduced in May 2022 and as such the Company 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 Company's clinical expertise also includes over a dozen physicians, clinical and laboratory scientists that provide real-time scientific advice. This, coupled to our leading bioinformatics and surveillance functionality, enable the Group to remain at the forefront of new diagnostic innovation.

### **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 June 2022. 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 2020 of £91,765,000;
- Payment of the second tranche of the Long-Term Incentive Plan ("LTIP") that commenced in November 2017 and concluded in November 2020;
- Payment of the first earn-out milestone related to the IT-IS International acquisition; and

- Management's confidence in settling the outstanding commercial dispute.

In the event the current dispute is fully settled in favour of the counterparty, the forecast prepared by the Group shows that it is able to cover its cash needs during the financial year 2021 and until June 2022 without the raising of any banking or other financing facility.

As at 31 December 2020 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, 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 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**

After the year end, the Group received notification of a contract dispute related to revenue totalling £129,124,000 in respect of performance obligations satisfied during the financial year to 31 December 2020. £23,957,000 of invoices in respect of products delivered during the year is outstanding at the date of signing the financial statements and recovery of the invoice is dependent on the outcome of the dispute.

After the year end, a further £49,034,000 of product delivered and invoiced in 2021 is unpaid and part of the commercial discussions that are ongoing.

The Group has taken independent legal advice and a provision has been made in the financial statements in respect of management's best estimate in respect of this claim.

Management and the Board of Directors have discussed the legal advice presented to them and have formed a judgment that, in accordance with the contractual terms, it should be possible to replace the products in dispute and a product warranty provision has been made accordingly.

If a claim under the limited assurance warranty is successful then management's best estimate of the settlement cost is up to a maximum of £19,753,000, the timing of any outflow is dependent on settlement of the dispute. If no settlement is achieved and legal action is required, the timing of any possible outflow will be extended.

It is possible, but not probable, that the refund claim under the limited assurance warranty will be successful. The timing of any cash outflow is dependent upon the success of a claim and the terms negotiated for repayment.

If the settlement of the claim is materially different from management's determination of replacing the products, the financial statements with regards to revenue and the provision for product warranty could be significantly impacted.

#### **1.10 Existing branches**

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