

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 2023

COMBINED GENERAL MEETING DATED 26 JUNE 2024

1.1 Overview of Novacyt’s activity

Novacyt is an international molecular diagnostics company providing a broad portfolio of integrated technologies and services, primarily focused on the delivery of genomic medicine. The Company develops, manufactures and commercialises a range of molecular assays and instrumentation to deliver workflows and services that enable seamless end-to-end solutions from sample to result across multiple sectors including human health, animal health and environmental. Its registered office is located at 13 Avenue Morane Saulnier, 78140 Vélizy Villacoublay.

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

Yourgene Health Ltd

Yourgene Health UK Ltd

Yourgene Genomic Services Ltd

Yourgene Health SASU

Yourgene Health Inc

Yourgene Health GmbH

Yourgene Health Canada Holdings Ltd
Yourgene Health Canada Investments Ltd
Yourgene Health Canada Inc
Yourgene Health (Singapore) Pte. Ltd
Yourgene Health (Taiwan) Co. Ltd
Elucigene Ltd
Delta Diagnostics Ltd

1.2 Situation and activity / Analysis of business trends

- Acquired the AIM listed company Yourgene Health Ltd (formerly PLC) and its subsidiaries for an all-cash consideration of £16.7m on 8 September 2023.
- Group statutory revenue for FY2023 was £11.6m, in line with guidance, of which £0.6m relates to COVID-19 (FY 2022*: £21.0m, of which £14.7m related to COVID-19).
- Group statutory revenue for the non-COVID-19 portfolio of £11.0m represents circa 95% of total revenues (FY 2022*: £6.3m).
- Group gross profit totalled £3.7m (32%) in FY2023 (FY2022: £5.7m (27%)). The FY2023 gross profit was reduced predominantly as a result of providing for all remaining COVID-19 associated stock, 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 FY2023 totalled £13.7m before exceptional items (FY2022: £13.5m loss).
- Loss after tax increased to £28.3m in FY2023 (FY2022: £25.7m loss).
- Cash position at 31 December 2023 was £44.1m (2022: £87.0m), reflecting the cash consideration and associated costs of the acquisition of Yourgene. The Group remains debt free.

*excludes any Yourgene revenue as pre-acquisition

1.3 Results, progress achieved and difficulties encountered

Overview

2023 represented a transitional year for Novacyt, as we continued to diversify the business away from COVID-19. In September 2023, the Group completed the acquisition of Yourgene Health Limited (formerly Yourgene Health plc), which represented a significant milestone that enhanced and diversified our portfolio. We are now working as one integrated global diagnostics business, benefitting from initial synergies between the combined entities, and are focused on investing to further leverage these and achieve long-term, sustainable growth for the Group.

Operational highlights

- *Completed the strategic acquisition of Yourgene, significantly enhancing Novacyt's global diagnostics business, adding scale and diversification to accelerate long-term growth (September 2023).*
- *Lyn Rees and John Brown CBE joined the Novacyt Board as Executive and Non-Executive Director respectively (October 2023).*
- *IVD certification: received first IVDR accreditation for the Yourgene DPYD genotyping assay for chemotoxicity in chemotherapy patients (November 2023); submitted application for Cystic Fibrosis quantitative fluorescence PCR (QF-PCR) test (December 2023).*
- *Yourgene became a compatible partner of PacBio, a leading global developer of sequencing technology, supporting the use of the LightBench™ instrument (Ranger® Technology) to its global customer base (November 2023).*
- *Yourgene launched MagBench™ automated DNA extraction platform for NIPT workflows in Asia-Pacific and the Middle East (September 2023).*

- *Launch of the Primerdesign Co-Prep ES instrument, providing automated DNA and RNA extraction using Primer Design assays , for use in multiple applications. (Jan 2023)*

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

Yourgene acquisition and integration

In September 2023, Novacyt completed the strategic acquisition of Yourgene, significantly enhancing our global diagnostics capabilities, adding scale and diversification to accelerate the long-term growth of the Company. The Group now has a broader technology portfolio, with a stronger end-to-end customer offering, enhanced routes to market in Europe, Asia and the Americas, expanded skills and expertise in our R&D and commercial teams, and a rationalised, high quality distribution network to drive growth and maximise efficiencies.

We have successfully completed the integration of all key operational departments including R&D and sales, combining complementary skills in molecular biology and instrumentation and our commercial teams have full access to the wider product portfolio to address customer needs. We have also streamlined support functions, such as finance, regulatory and other back-office activities to remove duplicate corporate functions.

As part of this process, the Group has been reorganised into three business segments: Clinical, Instrumentation and Research Use Only ("RUO"). This has transferred the development and commercialisation of all clinical products to Yourgene, enabling Primer Design to focus on its core flagship offering of developing RUO assays. The IT-IS business is continuing its focus on real-time quantitative PCR instrumentation and is adding complementary technical and engineering expertise to support growth in the Ranger® Technology products.

With the strengthened expertise of the combined leadership team, we are continuing to evaluate our portfolio and product mix, identifying those that will benefit most from further investment. With the strength of our balance sheet, we are confident we will be able to accelerate growth in areas with highest potential, particularly NIPT, Ranger® Technology and Precision Medicine.

1.5 Business activity in the year ended 31 December 2023

Amounts in £'000	Primer Design	IT-IS International	Yourgene Health	Total
Geographical area				
United Kingdom	1,415	29	1,919	3,363
France	268	48	743	1,059
Europe (excluding UK and France)	628	397	815	1,840
America	1,076	163	419	1,658
Asia-Pacific	1,029	290	1,449	2,768
Middle East	211	10	222	443
Africa	360	20	68	448
Total revenue	4,987	957	5,635	11,579

1.6 Research and development activity

Portfolio update

1) Clinical

The Clinical business is focused on three key therapeutic areas Reproductive Health, Precision Medicine and Infectious Diseases, which each represent large and growing addressable market opportunities. We continue to drive sales of these products in our core markets in Europe, Asia and some key regions in Americas.

Obtaining certification for our clinical products under the new EU requirements of the *In Vitro* Diagnostic Regulation (“IVDR”) remains a key priority for the Group. We received our first IVDR certification in November 2023, with the Yourgene® DPYD genotyping assay, an important test for oncology treatment, which identifies cancer patients at risk of suffering a severe, and potentially life-threatening, reaction to common chemotherapy. In December 2023, the Company submitted the application for its Cystic Fibrosis quantitative fluorescence PCR (QF-PCR) test, which is used for newborn screening as well as carrier screening in adults during family planning.

We have continued to see strong growth in India, which is a major market for Yourgene’s Sage™ 32 and 12 NIPT workflows. To support this in September, the Company launched MagBench™ in Asia-Pacific and the Middle East. MagBench™ is an automated DNA extraction platform optimised for the Sage 32 NIPT Workflow, which enables simple, fast, and cost-efficient, bench-top robotic cell-free DNA (cfDNA) extraction.

The Group launched its CE marked winter respiratory panel, genesig™ Real-time PCR SARS-CoV-2 Winterplex, before the cold winter season in the UK and has had a steady uptake with a number of NHS customers. However, given the considerable financial and staff resource required to advance a product to IVDR, we will monitor clinical demand over the coming winter to evaluate the opportunity and the investment required to progress the test.

2) Instrumentation

Our instrumentation offering has been significantly enhanced by the addition of Ranger® Technology, Yourgene’s automated DNA sample preparation and target enrichment technology, which provides better performance and improved workflows in multiple applications including NIPT, oncology, infectious disease testing and gene synthesis. We see opportunities for Ranger® across multiple markets, as it addresses key industry problems such as sample preparation and purity, can meet high volume requirements in markets such as gene synthesis, and has proven capability with multiple gene sequencing platforms.

In Q1 2023 we saw the launch of the Primerdesign Co-Prep ES instrument, providing automated DNA and RNA extraction using Primerdesign optimised assays, which enables pathogen detection across numerous applications.

3) Research Use Only

Primer Design has maintained its position as a leader in custom assay development, having delivered over 500+ custom assays in addition to its extensive menu/catalogue, which includes over 1200 assays. Building on this expertise it has expanded its capabilities into the animal diagnostics and aquaculture sectors, developing assays for both its own portfolio as well as client-specific needs.

Based on extensive customer and market feedback, the team have launched a range of “Complete” assays, which include our market leading customised mastermixes, unique enzyme and control combinations, that are tailored to provide everything our customers need in one kit for their experiments. In addition, the mastermix reagents have been launched as a stand-alone component that can be used for any labs working with multiplex assays, giving a route into potential new customer labs.

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 after having taken into account the available information they have for the future, and especially the cash forecast prepared for the next 12 months.

In preparing this cash forecast, the Directors have considered the following assumptions:

- The business plan for the next 12 months;
- The working capital requirements of the business;
- A positive cash balance at 31 December 2023 of £44,054,000;
- The possible outcomes of the Department of Health and Social Care “DHSC” commercial dispute having a trial date set for June 2024;
- Payment of the remaining Coastal Genomics earn-out milestones;
- No additional external funding has been forecast.

If Novacyt had to pay the full value of the DHSC claim in the period up to and including May 2025, which is not the scenario that management considers to be most likely, then the Group would not have sufficient funds to settle the liability without agreeing a payment plan. This matter raises substantial doubt about the ability of the Group to continue as a going concern in the worst case scenario.

As at 31 December 2023, the Group’s 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 6 February 2024 Novacyt received formal notification from INEX Innovate Pte Ltd of its decision to terminate discussions regarding the acquisition of Yourgene Health Taiwan Co Ltd, as originally announced by Yourgene Health on 13 June 2023.

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 2023 financial year.