NOVACYT

Half-yearly Activity Report

2023

Half-year financial statements ended 30 June

ACTIVITY REPORT

2023 BIANNUAL

HALF-YEARLY ACCOUNTS CLOSED ON 30 JUNE 2023

Novacyt Group

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. Its registered office is located at 13 Avenue Morane Saulnier, 78140 Vélizy Villacoublay.

Financial highlights

- Group revenue for H1 2023 of £3.3m of which £0.5m relates to COVID-19 (H1 2022: £16.5m of which £13.0m relates to COVID-19).
    - Revenue for the non-COVID-19 portfolio totalled £2.8m representing 85% of total revenue (H1 2022: £3.5m). As previously signalled, H1 2022 is a high comparator particularly in instrumentation, where sales were linked to COVID-19 sales.
    - Non-COVID-19 revenue continues to build with Q2 2023 showing 3% growth over Q1 2023 and 10% growth vs Q4 2022.
- Group gross margin increased to 50% (£1.7m) in H1 2023 (H1 2022: 24% (£4.0m)), due to lower stock write offs, but is still impacted by further stock provisions as a result of lower than anticipated COVID-19 sales.
- Group operating costs fell by £4.1m to £7.0m in H1 2023 compared with £11.1m in H1 2022.
- Group EBITDA loss before exceptionals reduced to £5.4m in H1 2023 (H1 2022: £7.1m loss).
- Loss after tax reduced to £8.3m in H1 2023 (H1 2022: £8.7m).
- Cash position at 30 June 2023 was £81.7m (FY 2022: £87.0m) and the Company remains debt free.
- Acquired the entire share capital of Yourgene on 8 September 2023 for £16.7m, settled in cash.

Operational highlights (including post-period end)

- Completed the strategic acquisition of Yourgene Health plc ("Yourgene"), significantly enhancing Novacyt's global diagnostics business, adding scale and diversification to accelerate long-term growth.

- Successfully developed nine multiplex RUO (research use only) assays in key infectious disease areas.
- IVD certification process: initiated verification and validation activities for two of the Company's developed multiplex products, with the aim of certifying them as *in vitro* diagnostics (IVD) under the UKCA mark, expected to complete during Q4 2023.
- Instrument sales recovery: Following the market saturation during the COVID-19 pandemic, the Group's instrument sales are returning to normal levels with Q2 2023 sales up by 66% vs Q1 2023.
- Recently launched Co-Prep extraction system for research use and CE marked both q16 and q32 instruments.
- On track to complete IVDR clinical trial for winter respiratory panel, genesig™ Real-time PCR SARS-CoV-2 Winterplex, in early 2024.
- Exclusive development agreement with Eluceda Ltd to develop novel biosensor technology in the fields of human and animal *in vitro* diagnostics, life science research and animal speciation.

Chief Executive's review

During the first six months of 2023 we have continued to make good progress expanding our instrumentation and RUO product portfolio and enhancing our workflow to diversify the business away from COVID-19. The recent acquisition of Yourgene was a significant strategic milestone that has significantly enhanced our global diagnostics business. This acquisition not only adds scale but also diversifies our portfolio, reinforcing our position for long-term growth.

Portfolio development

Product development

The increase in the incidence of infectious diseases is driving a growing global demand for multiplex diagnostic products that can rapidly and simultaneously detect multiple pathogens in a single test. During the period, the Company successfully developed nine new multiplex RUO assays in key infectious disease areas of respiratory virus, atypical pneumonia, viral and bacterial meningitis, eye infection, joint infection, gastrointestinal viruses and insect-borne viruses.

This expanded portfolio strengthens our diagnostic capabilities, particularly in the gastrointestinal, respiratory, and meningitis markets, as well as other high-growth disease areas. These assays have been specifically designed to seamlessly integrate with our existing instrumentation, including the recently launched Co-Prep extraction system and our q16 and q32 instruments. The Company expects these products to begin seeing commercial traction in Q4 2023.

As previously announced, the Company is prioritising UK Conformity Assessed (UKCA) marking for its clinical tests, which is replacing the CE mark for all *in vitro* diagnostic (IVD) products sold in the UK. Under UKCA, IVD manufacturers can continue to self-certify their

products, which typically takes six to nine months compared to the 18-24 months to achieve a CE mark under the new European In Vitro Diagnostic Regulation (IVDR). We have initiated verification and validation activities for two of our developed multiplex products, with the aim of certifying them as *in vitro* diagnostics (IVD) under the UKCA mark:

a. **genesig™PLEX Respiratory Virus Real-Time PCR Multiplex Kit II,** which complements our existing respiratory portfolio, such as the SARS-CoV-2 Winterplex, and meets the growing demand for decentralised diagnostic solutions within the UK's expanding network of Acute Respiratory Infection Hubs and Community Diagnostic Centres. The validation process for this product is expected to conclude in Q4 2023.
b. **genesig™PLEX Insect-Borne Real-Time PCR Multiplex Kit:** We have experienced strong customer demand for our existing RUO product, which targets Dengue, Chikungunya, and Zika viruses. The rise in climate change has led to an increase in the incidence of insect-borne infections and as a result there is a growing market demand for an expanded version of this product, which can detect multiple diseases. Our new multiplex product has additional target detection profiles, including West Nile, Tick-Borne Encephalitis, and Yellow Fever viruses. Validation for this product is also expected to be completed in Q4 2023.

We expect both tests to be available for clinical use in the UK during the first half of 2024.

Novacyt is also progressing the clinical trial for its winter respiratory panel, genesig™ Real-time PCR SARS-CoV-2 Winterplex, towards IVDR submission in early 2024.

Commercial progress

During H1 the Company has been focused on reestablishing its RUO and instrumentation businesses to drive growth in the non-COVID portfolio. Although overall growth has been modest, we have started to gain traction in building customer solutions in specific areas, which we believe will drive future growth. Successes in this area include our continuing development of aqua testing to enable more efficient management of fish stocks for both North America and more recently the UK, livestock testing in Latin America and progress with Dengue tenders for emerging markets.

We are currently live with a Winterplex promotional campaign with some promising early opportunities for product validation UK clinical settings.

Instrumentation & workflow
We have seen good growth in instrument sales, with Q2 2023 increasing 66% vs Q1 2023 as the market returns to normal following the saturation that was seen during the COVID-19 pandemic.

During the period we launched our new Co-Prep extraction system for RUO, which is already gaining traction with a number of customers. This is now available alongside our Co-Prep

automated liquid handling system as part of our integrated sample-to-result molecular workflow solution, which provides an end-to-end, fast scalable solution capable of processing over 1,000 tests per day.

Business Development

Acquisition of Yourgene

On 8 September 2023, we completed the acquisition of Yourgene, creating a stronger global diagnostics company with an expanded geographic commercial footprint, a broader product portfolio and deeper expertise. Yourgene brings a complementary international genomics technology and services business, focussed on delivering accurate molecular diagnostic and screening solutions, across reproductive health and precision medicine. Its portfolio of *in vitro* diagnostic products includes non-invasive prenatal tests (NIPT) for Down's Syndrome and other genetic disorders, Cystic Fibrosis screening tests, invasive rapid aneuploidy tests and DPYD test to predict patients' toxicity reactions to some chemotherapies. Yourgene's Ranger® Technology offers next generation size selection with a range of sample preparation platforms for dynamic target enrichment and can be utilised to improve workflows and performance in multiple applications including NIPT, oncology, infectious disease testing and gene synthesis.

As part of the acquisition, Yourgene's former Chair, Dr John Brown CBE, and Lyn Rees, Yourgene's former CEO, will join the Novacyt Board, as non-executive and executive director respectively, first as non-voting members, then as full members, subject to shareholder ratification at the next AGM.

Partnerships

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.

Current trading and outlook

Yourgene's financial year runs from 1 April to 31 March, which is different to the calendar year approach followed by Novacyt. It is our intention to align the accounting periods for the current fiscal year, which would result in a nine-month trading period for Yourgene consolidated with a full 12 months of Novacyt.

Unaudited revenue for Yourgene for the period 1 January to 30 June 2023 totalled £9.1m (including £0.5m of COVID-19 sales), which would give the Group a proforma revenue for H1 of £12.4m (including £1.0m of COVID-19 sales).

Revenue guidance for Novacyt for the full year is in the range of £10m to £13m (including £0.6m of COVID-19 sales), and covers 12 months trading for Novacyt and approximately four

months trading for Yourgene post-acquisition. At this early stage we need to do further work on the combined businesses to determine financial/EBITDA expectations for FY 2023.

The disposal of the Taiwan laboratory announced by Yourgene on 13 June 2023 is still progressing subject to regulatory approval from the Taiwanese Government and is now expected to complete by the end of the financial year.

The Company remains focused on building on the strength of its core business to deliver long-term sustainable growth and create a leading global clinical diagnostics company focused on unmet needs in infectious diseases. Over the next six months the Company will be focussed on the integration of Yourgene and will be evaluating the best ways to leverage our combined capabilities to accelerate growth and drive efficiencies and synergies where appropriate. We intend to provide an update to the market on the integration progress at the next trading update in January 2024.

FINANCIAL REVIEW

Overview

Novacyt's H1 2023 performance delivered sales of £3.3m, an EBITDA loss of £5.4m and a loss after tax of £8.3m. Novacyt continued to execute on right sizing its cost base by reducing its opex spend by over £1.0m compared with H2 2022, and will continue to make cost savings where necessary.

Cash at 30 June 2023 was £81.7m, providing the Group with a solid foundation on which to build and execute its future strategy. This allowed the Group to acquire Yourgene on 8 September 2023 for £16.7m, settled in full in cash.

Revenue

Revenue for H1 2023 fell to £3.3m compared with £16.5m in H1 2022, predominantly driven by reduced demand for COVID-19 testing as we emerge from the pandemic. Primer Design delivered sales totalling £2.8m, whilst IT-IS International delivered sales of £0.5m for H1 2023.

Gross profit

The business delivered a gross profit of £1.7m (50%), compared with £4.0m (24%) in H1 2022. The margin has improved significantly due to lower stock write offs but is still impacted by further stock provisions as a result of lower than anticipated COVID-19 sales.

Operating expenditure

Group operating costs fell by £4.1m to £7.0m in H1 2023 compared with £11.1m in H1 2022. Savings are mainly due to lower staff costs, as headcount for continuing operations fell from circa 210 in June 2022 to approximately 120 in June 2023 as a result of the Group-wide restructuring programme. In addition, non-labour savings have been made in commercial insurance, advertising and marketing, recruitment and facilities.

The business continued to invest heavily in research and development, spending over £1.2m in H1 2023, around 17% of opex costs, to support bringing a number of new products to the market.

EBITDA

The Group reported an EBITDA loss of £5.4m for H1 2023 compared with a loss of £7.1m in H1 2022. The loss has decreased by £1.8m in the first half of 2023 driven by a reduced gross profit contribution of £2.3m as a result of lower sales, offset by a £4.1m fall in operating expenditure.

Operating loss

The Group reduced its operating loss to £8.4m compared with a H1 2022 loss of £8.7m. Year-on-year, depreciation and amortisation charges have increased by £0.2m to £1.2m due to accelerating depreciation on a number of fixed assets.

Other operating expenses have increased from £0.5m to £1.9m in H1 2023. The main items making up the H1 2023 charge are i) £0.8m acquisition related expenses, ii) £0.6m costs in relation to the ongoing DHSC contract dispute and iii) £0.5m restructuring expenses as we continue to lower our cost base.

Loss after tax from continuing operations

The Group reported a loss after tax from continuing operations of £8.1m, compared with a loss of £5.0m in H1 2022. Other financial income and expenses netted to a £0.1m income compared with a £1.6m income in H1 2022. The two key items making up the balance are i) a £1.2m net financial foreign exchange loss, mainly resulting from revaluations of bank and intercompany accounts held in foreign currencies (H1 2022: £1.4m net gain) and ii) offset by £1.5m interest received on deposits held in bank accounts (H1 2022: £0.1m), reflecting rising interest rates. The £0.2m taxation credit is made up of the movement in the current and deferred tax position.

Loss from discontinued operations

In accordance with IFRS 5, the net result of the Lab21 Products business has been reported on a separate line "Loss from discontinued operations" in the consolidated income statements for H1 2023 and H1 2022.

Lab21 Products reported a loss after tax of £0.2m in H1 2023 versus a loss of £3.7m in H1 2022. The H1 2023 result relates to clearing balance sheet items and interest on intercompany balances.

The H1 2022 loss includes closure costs totalling circa £1.8m made up of i) a £1.0m impairment charge on right-of-use assets (Camberley facility lease), ii) £0.6m impairment charge on remaining property, plant and equipment and iii) £0.2m redundancy costs. These costs are not repeated in 2023 as the operations of the business were closed during 2022.

Earnings per share

The H1 2023 loss per share was £0.12 (H1 2022: £0.12 loss).

Non-current assets

Property, plant and equipment has fallen by £0.6m from £2.8m at 31 December 2022 to £2.2m at 30 June 2023, driven by two main factors, i) £0.8m depreciation costs, and ii) offset by capital purchases of £0.2m.

Other non-current assets have fallen by £0.4m to £2.7m at 30 June 2023, driven by the amortisation of intangible assets.

Current assets

Inventories and work in progress has fallen from £3.0m at 31 December 2022 to £2.5m at 30 June 2023, as stock built up during the COVID-19 pandemic is wound down to reflect a more normalised expected run-rate.

Trade and other receivables has fallen by £0.4m to £33.3m at 30 June 2023 in line with a decline in sales. The trade receivables balance includes a £24.0m unpaid DHSC invoice raised in December 2020, in respect of products delivered during 2020 that remains unpaid at the date of publishing the accounts. Recovery of the invoice is dependent on the outcome of the contract dispute. Also included in trade and other receivables is a £8.2m VAT receivable balance (December 2022: £8.3m), that mainly relates to UK VAT paid on sales invoices in dispute with the DHSC. As these sales have not been recognised in accordance with IFRS 15, the revenue, trade receivable and VAT element of the transactions have been reversed, resulting in a VAT debtor balance.

Tax receivables has fallen by £0.5m to £0.6m at 30 June 2023, predominantly due to the Group receiving cash from HMRC covering the carry back of tax losses and research and development tax claims. The current balance relates to 2021 losses that can be carried back for relief against 2020 taxable profits totalling £0.1m and research and development tax claim accruals covering 2022 and 2023 totalling £0.5m.

Other current assets have fallen by £0.6m to £1.8m at 30 June 2023, due to a £0.5m fall in prepayments, predominantly driven by unwinding the annual commercial insurance charge, and a £0.1m reduction in short-term deposits driven by the repayment of a rent deposit in connection with settling the Watchmoor facility lease. Prepayments at 30 June 2023 include Group commercial insurance, rent, rates, prepaid support costs and stock that had been paid for but not delivered at the reporting date.

Current liabilities

Short-term provisions fell slightly from £20.3m to £20.0m at 30 June 2023, as a result of unwinding the dilapidations provision associated with the now closed Watchmoor facility. A

£19.8m product warranty provision booked in 2020 to cover Management's view of the maximum cost of replacing products in relation to the ongoing commercial dispute with the DHSC remains unchanged at 30 June 2023.

Trade and other liabilities increased from £2.8m to £3.0m at 30 June 2023, largely due to the impact of accruing acquisition costs in late June.

Non-current liabilities

Non-current liabilities fell by £0.1m to £1.3m at 30 June 2023, mainly due to a reduction in the deferred tax liability.

Cash flow

Cash held at 30 June 2023 totalled £81.7m compared with £87.0m at 31 December 2022. Net cash used in operating activities was £5.7m for H1 2023, made up of a working capital outflow of £0.3m and an EBITDA loss of £5.4m, compared with a cash outflow of £1.7m in H1 2022.

Net cash from investing activities has swung from a £0.2m outflow for H1 2022 to a £1.0m inflow in H1 2023, with the Group benefiting from continued interest rate rises, generating £1.1m interest from its cash balances. Capital expenditure remained broadly flat year-on-year with H1 2023 totalling £0.2m compared with £0.3m in H1 2022.

Net cash used in financing activities in H1 2023 totalled £0.5m compared with £0.3m in H1 2022, with the main cash outflow continuing to be lease payments.

The Group remains debt free at 30 June 2023.

Consolidated income statement as at 30 June 2023

Amounts in £'000	(Unaudited) Six month 30 June 2023	(Unaudited) Six month 30 June 2022
Continuing Operations		
Revenue	3,339	16,508
Cost of sales	-1,674	-12,498
Gross profit	**1,665**	**4,010**
Sales, marketing and distribution expenses	-1,506	-2,887
Research and development expenses	-1,239	-3,271
General and administrative expenses	-5,579	-6,211
Governmental subsidies	125	180
Operating loss before exceptional items	**-6,534**	**-8,179**
Other operating income	-	2
Other operating expenses	-1,862	-535
Operating loss after exceptional items	**-8,396**	**-8,712**
Financial income	1,994	2,351
Financial expense	-1,911	-723
Loss before tax	**-8,313**	**-7,084**
Tax income	174	2,041
Loss after tax from continuing operations	**-8,139**	**-5,043**
Loss from discontinued operations	-209	-3,656
Loss after tax attributable to owners of the Company	**-8,348**	**-8,699**
Loss per share (£)	-0.12	-0.12
Diluted loss per share (£)	-0.12	-0.12
Loss per share from continuing operations (£)	-0.12	-0.07
Diluted loss per share from continuing operations (£)	-0.12	-0.07
Loss per share from discontinued operations (£)	-0.00	-0.05
Diluted loss per share from discontinued operations (£)	-0.00	-0.05

Breakdown of revenue by operating segment and geographic area

- At 30 June 2023

Amounts in £'000	Primer Design	IT-IS International	Total
Geographical area			
United Kingdom	796	18	814
France	159	37	196
Rest of Europe	379	205	584
America	689	75	764
Asia-Pacific	555	194	749
Africa	172	20	192
Middle East	28	12	40
Total revenue	**2,778**	**561**	**3,339**

- At 30 June 2022

Amounts in £'000	Primer Design	IT-IS International	Total
Geographical area			
United Kingdom	8,446	1	8,447
France	99	23	122
Rest of Europe	2,606	245	2,851
America	3,271	243	3,514
Asia-Pacific	853	381	1,234
Africa	201	1	202
Middle East	138	-	138
Total revenue	**15,614**	**894**	**16,508**

CONTINGENT LIABILITIES

During 2021, the Group received notification of a contract dispute between its subsidiary, Primer Design Ltd, and the DHSC related to revenue totalling £129,125,000 in respect of performance obligations satisfied during the financial year to 31 December 2020.

During 2021, a further £49,034,000 (including VAT) of products and services were delivered and invoiced to the DHSC which have subsequently been included as part of the ongoing dispute. Management made the judgement that in accordance with IFRS 15, Revenue from Contracts with Customers, it was not appropriate at that stage in the dispute to recognise as revenue, any sales invoices raised to the customer in 2021 that were in dispute. However, Management remains committed to obtaining payment for these goods and services.

Payment for £23,957,000 of invoices in respect of products delivered during 2020 remains outstanding at the date of publishing the interim accounts and recovery of the debt is dependent on the outcome of the dispute.

On 25 April 2022, legal proceedings were issued against Novacyt and Primer Design Ltd in respect of amounts paid to Primer Design Ltd totalling £134,635,000 (including VAT) by the DHSC. This refers to £132,814,000 (including VAT) of reagent sales out of a total disputed amount of £154,950,000 (£129,125,000 excluding VAT as previously reported) plus £1,821,000 (£1,517,000 excluding VAT) of q16 instruments which have been added to the dispute. This takes the total 2020 revenue in dispute to £130,642,000.

On 15 June 2022, Novacyt and Primer Design Ltd filed a defence of the claim received on 25 April 2022, and Primer Design Ltd made a counterclaim of circa £81,500,000 including interest and VAT against the DHSC.

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.

The Group remains committed to defending the case and asserting its contractual rights, including recovering outstanding sums due from the DHSC.

Management have reviewed the position at 30 June 2023 and deem this to be an appropriate reflection of the current commercial dispute.

Management and the Board of Directors have reviewed the product warranty provision totalling £19,753,000 booked in 2020 in relation to the DHSC dispute and have deemed that it remains appropriate at 30 June 2023.

SUBSEQUENT EVENTS

On 3 July 2023, Novacyt announced the proposed cash acquisition of Yourgene Health plc, which subsequently completed on 8 September 2023.