NOVACYT

Half-yearly Activity Report

2024

Half-year financial statements ended 30 June

ACTIVITY REPORT

2024 BIANNUAL

HALF-YEARLY ACCOUNTS CLOSED ON 30 JUNE 2024

Novacyt Group

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.

Financial highlights

- Group revenue for H1 2024 of £10.3m, of which £7.8m relates to Yourgene Health ("Yourgene"), (H1 2023*: £3.3m, of which £0.5m relates to COVID-19)
- H1 2023 proforma revenue, excluding COVID-19 sales: £11.4m
- Encouraging growth in Reproductive Health (34% YoY increase on a proforma basis) and Non-Invasive Prenatal Testing ("NIPT") (5% YoY increase on a proforma basis)
- Group gross profit increased to £26.5m in H1 2024 (H1 2023*: £1.7m) due to the reversal of a £19.8m product warranty provision following the settlement with the Department of Health and Social Care ("DHSC")
- Underlying gross margin of the business increased to 65%
- Group operating costs increased to £32.1m in H1 2024 due to booking a £20m bad debt write-off following the settlement with the DHSC (H1 2023*: £7.0m)
- Underlying opex cost of £12.1m compared with a proforma H1 2023 opex cost of circa £14.7m, reflecting £5.0m annualised cost savings made following acquisition of Yourgene
- Group EBITDA loss before exceptionals of £5.6m in H1 2024, of which £0.2m is as a result of the DHSC settlement (H1 2023*: £5.4m)
- Exceptional costs totalling £8.1m include the £5.0m settlement to the DHSC (paid in July post period), resulting in the loss after tax increasing to £17.7m in H1 2024 (H1 2023*: £8.3m)
- Cash position at 30 June 2024 was £32.9m (31 December 2023: £44.1m) and the Company remains debt free

*excludes any Yourgene results as pre-acquisition

Operational highlights (including post-period end)

- Lyn Rees appointed Chief Executive Officer following a six-year tenure as CEO of Yourgene Health plc, bringing over 28 years' global healthcare leadership and commercial experience
- Steve Gibson appointed CFO, and joined the Board along with Dr Jo Mason, CSO
- John Brown CBE appointed Chairman of the Board (as announced today)
- Settled dispute with the DHSC, and successfully reclaimed £12.2m in VAT from HMRC relating to unpaid DHSC invoices resulting in cash position at 30 August of £36.6m
- IVDR certification: submitted application for Yourgene Cystic Fibrosis Base, our Amplification Refractory Mutation System PCR (ARMS-PCR) test. Submitted application for Yourgene QST*R Base Rapid Aneuploidy Analysis test using quantitative fluorescence PCR (QF-PCR)
- Launched real-time PCR workflow for rapid onsite detection of norovirus in oysters
- Completed disposal of Taiwanese laboratory business

Chief Executive's review

The first half of 2024 showed continued progress for the Group, with our efforts focused towards working as a single business, reducing our cost base and delivering growth; we saw encouraging growth in areas such as Reproductive Health and NIPT Technologies. The Group settled its dispute with DHSC in June and subsequently reclaimed associated VAT payments, improving our cash position by net of £7.2m. The Group is now in a stronger position with solid foundations in place to drive the future growth of the business.

Clinical

Reproductive Health
During the period the Reproductive Health business grew 34% on a proforma basis. As previously announced, this was largely driven by the continued strong growth of our cystic fibrosis portfolio in Australia following implementation of the government's nationwide reimbursement pathway.

Our Non-invasive prenatal testing ("NIPT") technology portfolio had a strong start and year to date we have seen double digit growth. This was driven by strong growth in India and Europe and a number of former Genomic Services NIPT customers establishing in-house laboratories and becoming higher margin technology customers to the Group.

We have strengthened our competitive position in the NIPT market with the commenced roll out of upgrades of the IONA Nx NIPT workflow, which now has the capability to run twice the samples in one run than previously possible. We have a number of customer demonstration events planned for Q4'24, to drive further awareness of our capabilities. We also installed our first NIPT workflow in Colombia and have been working closely with our partner there to support, the upcoming launch of their NIPT service offering to clinics in the region.

The Group continues to focus on obtaining certification for its clinical products under the new EU requirements of the *In Vitro* Diagnostic Regulation ("IVDR"). In June 2024, we submitted IVDR certification for our Yourgene® Cystic Fibrosis Base ARMS-PCR test for both newborn screening and carrier screening in adults.

Later in June 2024, the Company submitted the application for IVDR for its rapid prenatal aneuploidy analysis Yourgene® QST*R Base, our QF-PCR test. Aneuploidies are genetic disorders where there is a variation in the number of chromosomes, such as Down's syndrome, Edwards' syndrome and Patau's syndrome.

We have also developed additional analysis capabilities, initially as a research use only ("RUO") tool, to expand our NIPT offering, including copy number variation ("CNV") analysis for our IONA Nx NIPT Workflow, in order to meet the changing market needs of some of our European lab customers. The RUO tool version is expected to be released later this month with a planned IVDR submission next year.

Precision Medicine

We saw sales of our dihydropyrimidine dehydrogenase ("DPYD") product under pressure as new competitors and technologies entered the market. We were encouraged by a report from the Association for Molecular Pathology released in July 2024, providing recommendations to help standardise the design and validation of clinical DPYD genotyping assays, demonstrating the continued global adoption of and need for DPYD testing.

We are working on upgrading our DPYD assay and have partnered with key opinion leaders around the world to ensure that the next version of the product meets the needs of the international market as clinical guidelines are being updated.

Infectious Disease

As previously announced, we will monitor the clinical demand for our genesig™ Real-time PCR SARS-CoV-2 Winterplex respiratory panel, over the winter period to evaluate the opportunity and investment required to progress the test through IVDR.

The recent surge of Mpox in Central Africa is an important health issue and has received much media attention, though the full extent of the commercial opportunity for our products is still unknown. Our RUO existing genesig® Complete Kits for Mpox 2G generated some revenue in July and August but this was not material at Group level. The market is more saturated compared to early in the COVID-19 pandemic, with an available vaccine and several competitors in the market. We are currently updating the assay based on customer feedback around the clade 1b strain and will monitor the situation to assess whether there is sufficient demand to progress the test for clinical use.

Instrumentation

We continue to evaluate new opportunities across new human and non-human applications for Ranger® Technology ("Ranger"), our automated DNA sample preparation and target enrichment technology, and continue to collaborate closely with PacBio to access more potential customers. Following customer feedback, we have commenced work on adding additional functionality to Ranger for long-read sequencing users.

Post-period we have seen the first sale of NIMBUS Select, our high throughput Ranger Technology platform to a customer in Europe who will be using it in the field of synthetic biology and the Group expects to see further LightBench evaluations and demonstration projects to mature throughout the remainder of the year.

Research use only (RUO)

Primer Design continues to see demand for its research only assays. In June, we launched a real-time PCR workflow for rapid onsite detection of norovirus in oysters, which is a serious and growing threat to oyster farmers. Testing season starts in winter and we expect to see further demand for the workflow in the coming months, as customers prepare. We have also been developing a number of additional aquaculture and veterinary products, which are expected to launch before the year end.

We have also signed a contract with a diagnostics company to develop an extraction kit for use in a clinical trial assessing the early detection of colorectal and bowel cancer. The extraction kit will initially be an RUO product but could be developed further depending on the results of the trial, which is expected to start later this year.

Genomics Services

The Group continues to see steady growth in new NIPT clinical customers across the UK. Our pharmaceutical research services has been steady and continues to offer whole genome sequencing ("WGS"), whole exome sequencing ("WES") and other specialist laboratory testing services to pharma, biotech and central laboratories for clinical studies and assay validation, as well as biomarker discovery services.

Integration update

Since the completion of the acquisition of Yourgene Health in September 2023, the Company has implemented actions that will deliver c.£5.0m of annualised cost savings ahead of schedule, including the refocus of the Primer Design business on the RUO market, the elimination of duplicate corporate functions and other corporate costs, as well as streamlining of management and disposing of the Taiwanese laboratory business. We are looking to implement further significant costs savings and continue to look at ways to right size the cost base of the business.

Board changes

There have also been a number of changes to the Board during the period and post-period end. I was appointed CEO in May 2024 and Steve Gibson, Chief Financial Officer and Dr Joanne Mason, Chief Scientific Officer, joined the Board in July. As announced today, John Brown CBE has been appointed Chairman, succeeding James Wakefield. John has a proven track record of successfully building life sciences companies and his wealth of knowledge in capital markets and the life sciences sector will be important as we look to execute the strategic plan of the combined business.

On behalf of the Board, I would like to thank James for his contribution and leadership to Novacyt, especially navigating the business through the pandemic and its after-effects. Under James' tenure, the business has made a series of successful acquisitions, including Primer Design and more recently Yourgene Health. James leaves the business in a strong financial position, debt free and with significant cash resources.

DHSC settlement and VAT reclaim

The £5.0m settlement with the DHSC has enabled management to focus entirely on the integration and growth of the combined business. Following the settlement, we successfully reclaimed £12.2m in VAT from HMRC relating to the unpaid DHSC invoices. This has resulted in the Group's net cash position increasing by £7.2m, with cash of £36.6m at 31 August 2024.

Taiwan disposal

In July 2024, we announced that the Group was in advanced stages of disposing of its Taiwanese laboratory business, in-line with our strategy of rationalising our offering and focusing resources on areas of higher margin and growth potential. The deal has now concluded for a nil upfront consideration, with the possibility of earnouts of up to $2m on future milestones.

Outlook

Growth has been encouraging in areas such as Reproductive Health and NIPT Technologies; with double digit growth across our NIPT portfolio year to date and we expect Group revenue for the full year to remain at a similar run-rate. During the rest of the year, our priorities remain on working as a single business, reducing our cost base and positioning the Company for long-term growth. An important process will be the continued rationalisation of our product and service offering to focus resources on those areas with the highest growth potential. As previously announced, our R&D team is also developing a pipeline of new products, which we expect to bring to market over the next three years, ensuring we have a balanced and exciting product portfolio that meets the needs of our customer base and allows us to expand into new technologies and applications.

The new management team has now been in place for five months; during that time, we have significantly derisked the business by concluding the dispute with the DHSC, made considerable progress with integration of two complex businesses and delivered considerable cost savings with a clear road map to further right size the cost base of the Group. With our robust cash position and in-house expertise, we are well placed to accelerate the growth of our product portfolio and invest in exciting new product opportunities to deliver shareholder value. We are working on a comprehensive growth strategy for the combined Group and look forward to further updating the market with more details in H1 2025.

FINANCIAL REVIEW

Overview

Novacyt's H1 2024 performance delivered sales of £10.3m, an EBITDA loss of £5.6m and a loss after tax of £17.7m following the resolution of the DHSC commercial dispute. Novacyt continued to execute on right sizing its cost base by reducing its opex spend by £2.6m compared with H1 2023, on a proforma basis, and will continue to make further cost savings where possible.

Cash at 30 June 2024 was £32.9m, providing the Group with a solid foundation on which to build and execute its future strategy. The £5.0m settlement agreed with the DHSC was paid in early July, reducing the cash position further.

Revenue

Revenue for H1 2024 increased to £10.3m compared with £3.3m in H1 2023, driven by the inclusion of Yourgene sales that were not present in H1 2023. Yourgene Health delivered sales of £7.8m, or 75% of total sales, Primer Design delivered sales totalling £2.2m, whilst IT-IS International delivered sales of £0.3m in H1 2024.

Gross profit

The business delivered an underlying gross profit (excluding the impact of the DHSC settlement) of £6.7m (65%), compared with £1.7m (50%) in H1 2023. The margin has improved significantly as there have been no major stock write offs, following impairment of all remaining COVID-19 associated stock at year-end.

Operating expenditure

Underlying Group operating costs (excluding the impact of the DHSC settlement) increased by £5.1m to £12.1m in H1 2024 compared with £7.0m in H1 2023, driven by the inclusion of Yourgene costs that were not present in H1 2023. On a proforma basis, H1 2024 opex costs are £2.6m lower than H1 2023 predominantly as a result of the integration cost savings that have been delivered so far post-acquisition.

Headcount at the end of June 2024 was around 240 which is largely consistent with the position at year end (237).

EBITDA

The Group reported an EBITDA loss of £5.6m for H1 2024, compared with a loss of £5.4m in H1 2023. The loss has increased slightly, by £0.2m, which is driven by a £5.0m increase in the

underlying gross profit, as a result of increased sales, offset by higher underlying operating expenditure of circa £5.1m.

Operating loss

The Group operating loss increased to £17.1m compared with a loss of £8.4m in H1 2023. Year-on-year, depreciation and amortisation charges have increased by £2.2m, to £3.4m, mainly due to the inclusion of charges associated with assets acquired as part of the Yourgene acquisition.

Other operating expenses have increased from £1.9m to £8.1m in H1 2024. The main items making up the H1 2024 charge are i) £5.0m DHSC settlement fee, ii) £2.4m costs in relation to the now settled DHSC contract dispute, and iii) £0.7m other costs including restructuring expenses as we continue to lower our cost base.

Loss after tax from continuing operations

The Group reported a loss after tax of £17.7m, compared with a loss of £8.1m in H1 2023. Other financial income and expenses netted to a £0.8m expense compared with a £0.1m income in H1 2023. The three key items making up the balance are i) a £1.1m net financial foreign exchange loss, mainly resulting from revaluations of bank and intercompany accounts held in foreign currencies (H1 2023: £1.2m net loss), ii) £0.4m of IFRS 16 lease interest payments (H1 2023: £nil), offset by iii) £0.7m interest income on deposits held in bank accounts (H1 2023: £1.5m), reflecting the reduced cash position year-on-year. The £0.2m taxation credit is made up of the movement in the current and deferred tax position.

Earnings per share

The H1 2024 loss per share was £0.25 (H1 2023: £0.12 loss).

Non-current assets

Right-of-use assets have decreased by £1.0m to £10.0m at 30 June 2024, predominantly as a result of depreciation charges.

Other non-current assets have decreased by £1.3m to £9.0m at 30 June 2024, driven by the amortisation of intangible assets.

Current assets

Trade and other receivables have fallen since December 2023 predominantly as a result of the DHSC settlement, whereby the December 2020 unpaid invoice for £24.0m has now been written off as it will no longer be paid.

Also included in trade and other receivables is a £13.4m VAT receivable balance (December 2023: £8.5m), that mainly relates to VAT paid in the UK on sales invoices that will not be paid by the DHSC as per the terms of the settlement agreement (circa £12.2m). This has subsequently been repaid to Novacyt in August 2024.

Tax receivables has fallen by £0.3m to £0.4m at 30 June 2024, predominantly due to the Group receiving cash from HMRC covering FY22 research and development tax claims. The current balance relates to research and development tax claim accruals covering 2023 and 2024.

Other current assets have fallen by £0.9m to £1.7m at 30 June 2024, with the key driver being the unwinding of the annual commercial insurance prepayment charge. Prepayments at 30 June 2024 include Group commercial insurance, rent, rates and prepaid support costs.

Current liabilities

Short-term provisions have fallen by £19.8m since December 2023 as a result of the DHSC settlement, whereby the product warranty provision made in relation to the dispute has been reversed.

Trade and other liabilities increased from £7.2m to £11.5m at 30 June 2024, driven by the inclusion of the £5.0m settlement due to the DHSC which was paid in July 2024, offset by a reduction in accruals and payroll related liabilities.

Non-current liabilities

Lease liabilities long-term have decreased by £0.7m, to £11.8m, driven predominantly by rental payments made in H1 2024.

Contingent consideration long-term has reduced to nil from £0.7m at December 2023, following a settlement agreement that accelerated the milestone payment in return for a reduced fee.

Cash flow

Cash held at 30 June 2024 totalled £32.9m compared with £44.1m at 31 December 2023. Net cash used in operating activities was £9.1m for H1 2024, made up of a working capital outflow of £3.5m and an EBITDA loss of £5.6m, compared with a cash outflow of £5.7m in H1 2023.

Net cash from investing activities has swung from a £1.0m inflow in H1 2023 to a £1.1m outflow in H1 2024, driven by reduced interest income as a result of a lower cash balance, the payment of outstanding contingent consideration in relation to the historic Coastal Genomics acquisition and higher capital expenditure.

Net cash used in financing activities in H1 2024 totalled £0.9m compared with £0.5m in H1 2023, with the main cash outflow continuing to be lease payments.

The Group remains debt free at 30 June 2024.

Consolidated income statement as at 30 June 2024

Amounts in £'000	(Unaudited) Six month 30 June 2024	(Unaudited) Six month 30 June 2023
Continuing Operations		
Revenue	10,322	3,339
Cost of sales	-3,595	-1,674
Cost of sales - exceptional	19,753	-
Gross profit	**26,480**	**1,665**
Sales, marketing and distribution expenses	-3,090	-1,506
Research and development expenses	-1,499	-1,239
General and administrative expenses	-10,943	-5,579
General and administrative expenses - exceptional	-19,964	-
Governmental subsidies	-	125
Operating loss before exceptional items	**-9,016**	**-6,534**
Other operating income	-	-
Other operating expenses	-8,088	-1,862
Operating loss after exceptional items	**-17,104**	**-8,396**
Financial income	2,096	1,994
Financial expense	-2,910	-1,911
Loss before tax	**-17,918**	**-8,313**
Tax income	219	174
Loss after tax from continuing operations	**-17,699**	**-8,139**
Loss from discontinued operations	-	-209
Loss after tax attributable to owners of the Company	**-17,699**	**-8,348**
Loss per share (£)	-0.25	-0.12
Diluted loss per share (£)	-0.25	-0.12
Loss per share from continuing operations (£)	-0.25	-0.12
Diluted loss per share from continuing operations (£)	-0.25	-0.12
Loss per share from discontinued operations (£)	-0.00	-0.00
Diluted loss per share from discontinued operations (£)	-0.00	-0.00

Breakdown of revenue by operating segment and geographic area

- At 30 June 2024

Amounts in £'000	Primer Design	IT-IS International	Yourgene Health	Total
Geographical area				
United Kingdom	565	25	1,698	2,288
France	127	29	1,143	1,299
Rest of Europe	391	98	1,413	1,902
America	415	94	965	1,474
Asia-Pacific	401	102	2,245	2,748
Africa	193	1	86	280
Middle East	91	-	240	331
Total revenue	**2,183**	**349**	**7,790**	**10,322**

- 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**

SUBSEQUENT EVENTS

In July 2024, Novacyt paid the DHSC £5.0m as per the terms of the settlement agreement, as communicated in the press release on 11 June 2024.

Novacyt divested Yourgene Health Taiwan on 31 July 2024 for an upfront consideration of nil dollars, with the possibility of earnouts totalling up to $2m upon hitting certain targets.

In August 2024, Novacyt successfully reclaimed £12.2m in VAT from HMRC, in relation to invoices that will no longer be paid by the DHSC as per the terms of the settlement agreement.