NOVACYT

Half-yearly Activity Report

2022

Half-year financial statements ended 30 June

ACTIVITY REPORT

2022 BIANNUAL

HALF-YEARLY ACCOUNTS CLOSED ON 30 JUNE 2022

Novacyt Group

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 Group supplies an extensive range of high-quality assays, reagents and instruments worldwide. The Group directly serves microbiology, haematology and serology markets as do its global partners, which include major corporates. Its registered office is located at 13 Avenue Morane Saulnier, 78140 Vélizy Villacoublay.

Financial highlights

- Group revenue of £16.5m in H1 2022 (H1 2021: £52.2m), predominantly driven by the expected decline in COVID-19 related sales
- Revenue derived from COVID-19 products totalled £13.0m, or 79% of total H1 revenue in 2022 (H1 2021: £47.6m (91%))
- Revenue for the non-COVID-19 portfolio was £3.5m (H1 2021: £4.6m). As previously indicated, this decline was predominantly driven by lower instrument sales compared to a strong H1 2021 which benefited from COVID-19 demand
- Group gross profit improved to £4.0m (24%) in H1 2022 (H1 2021: £1.2m (2%)). The latter was impacted by the one-off exceptional costs relating to the DHSC dispute. H1 2022 gross profit was reduced as a result of significant stock provision based on lower forecast 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 adjusted EBITDA loss of £7.1m in H1 2022 before exceptionals (H1 2021: £23.6m profit)
- Discontinued operations loss of £3.7m in H1 2022 (H1 2021: £0.6m)
- Loss after tax decreased to £8.7m in H1 2022 (H1 2021: £12.7m)
- Filed a defence of the DHSC claim issued against Primerdesign Ltd and Novacyt S.A. for £134.6m in relation to the contract dispute, as previously announced, and filed a counterclaim of £81.5m against the DHSC
- Cash position at 30 June 2022 was £99.6m (FY 2021: £101.7m) and the Company remains debt free
- Predicted Q3 2022 revenue of circa £2.0m, with similar levels expected in Q4 2022, resulting in an anticipated EBITDA loss for the full year of circa £13.5m.

Operational highlights

Portfolio development – clinical diagnostics in human health and instrumentation

- Completed a comprehensive market study to direct organic development of the post-COVID-19 diagnostics portfolio, resulting in high growth target infectious disease areas including respiratory, gastro-intestinal infections, transplant, and insect-borne pathogens

- Launched an automated liquid handling system (CO-Prep) and validating a nucleic acid extraction system to enhance post-COVID-19 integrated sample-to-result molecular workflow solution
- Advanced the design of two new direct-to-PCR assay panels for gastro-intestinal bacterial and viral infections to run on q32 instruments
    - Panels will include high-sensitivity direct-to-PCR testing chemistry for use with faecal specimens, developed during the period, expanding PROmate® product chemistry compatibility beyond anterior nasal swab samples
- Developed two single analyte transplant viral assay panels for the Epstein-Barr virus and BK virus for use on open instrument platforms
- Launched new lateral flow test (LFT) reader for use in conjunction with a broad range of assays within Novacyt's Pathflow® product portfolio, consisting of 18 non-COVID-19 products for patient screening across sexually transmitted, gastrointestinal, respiratory and insect-borne infections

Global first responder

- Three additional UK CTDA approvals during the period, taking the total number of Novacyt products approved by the CTDA to five (including one post-period approval), the most of any UK-based company
- Key patent granted in relation to ORF1a/b, which will lead to a corporation tax credit against future profits and is back dated to the original patent submission date in October 2020
- Developed Monkeypox and Adenovirus F41 research-use-only (RUO) assays to support infection monitoring
- Developed and secured CE mark for two lyophilised PROmate® products enabling deployment of near-patient COVID-19 diagnostic solution without the need for cold-chain shipping
- CE mark for 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

Post-period highlights

- Significantly expanded the clinical portfolio, adding 40 CE IVD assays, through a distribution agreement with Clonit srl, an Italian-based molecular diagnostic developer and manufacturer, to drive near-term growth
- Re-launched RUO portfolio globally with initial orders of over £100k in aggregate, including testing infectious salmon anaemia virus and bacterial kidney disease in salmon in Canada and testing salmonella in chickens in Poland, with the expectation of repeat business
- UK CTDA approval of exsig™ COVID-19 Direct Real-Time PCR assay
- Strategic decision to discontinue Microgen Bioproducts and Lab21 Healthcare businesses following a strategic review during the period
- Delivered an additional reduction in operating costs of £2.4m, in line with expectations, funded by a one-off cash restructuring charge of circa £0.8m.

Chief Executive's review

Novacyt continues to invest in R&D and commercial resources, which represents circa £10.0m of projected opex spend in 2022, to execute on the vision and strategy announced earlier in the year to develop and commercialise its non-COVID-19 portfolio. The Company has made substantial early progress delivering against this strategy in 2022 to-date.

Portfolio development

Clinical diagnostics in human health and instrumentation

Novacyt has made considerable progress enhancing its post-COVID-19 integrated sample-to-result molecular workflow solution. We are validating a nucleic acid extraction system and we have launched an automated liquid handling system (CO-Prep™) for assay set up that complements our proprietary q16 and q32 instruments and user friendly direct-to-PCR assays to deliver an end-to-end 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 currently decentralised sample-to-result solutions are not easily scalable, slow, and costly.

Through our business development efforts, we have expanded our testing menu offering by entering into a global distribution agreement with Clonit srl, an Italian-based molecular diagnostic developer and manufacturer, to deliver near-term growth to underpin the base business and supplement the Company's internal R&D efforts. The agreement provides Novacyt with immediate access to over 40 CE marked assays (detailed below) aligned to the Company's therapeutic areas of focus identified following the comprehensive market study completed at the beginning of the period to direct organic development of the post-COVID-19 diagnostics portfolio. These areas include:

- 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)
- Transplantation (e.g., CMV, JCV, HHV-7, in addition to our internally developed EBV and BKV in vitro diagnostic transplantation assays)
- Insect-borne infections (e.g., Dengue, West Nile virus, Malaria)

All products are immediately available and designed for use on open instrument testing systems. In addition, the STI assay panel has been validated for use with Novacyt's instrumentation and the RI assay panels are expected to be validated by the end of Q1 2023, meaning the Company will be able to offer fully integrated diagnostic solutions for these two priority therapeutic areas.

These products and enhanced workflow will be targeted where there is a need for cost effective, rapid 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 offer this to customers worldwide.

In our internal R&D pipeline, we have completed principal development of a high-sensitivity direct-to-PCR testing chemistry for use with faecal specimens. This new sample type expands PROmate® product chemistry compatibility beyond anterior nasal swab samples and will be deployed as part of our two new direct-to-PCR assay panels for gastro-intestinal bacterial and viral infections to run on our q32 instruments. In addition, we developed two single analyte transplant viral assay panels for the Epstein-Barr virus and BK virus for use on open instrument platforms during the period.

Our molecular portfolio is complemented by an extensive range of lateral flow (LFT) diagnostic tests for clinical use. The range aligns with a compliments the target disease areas covered by the molecular portfolio and has been further enhanced with the launch of a new LFT reader for use in conjunction with a number of key assays within Novacyt's Pathflow® product portfolio. The small, lightweight reader is 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.

Global first responder and research-use-only (RUO) diagnostics

In addition to the clinical diagnostics and instrument portfolio, Novacyt has an extensive and established life sciences portfolio of RUO products. In 2021 and early 2022, the Company refreshed and refined the portfolio to ensure the primers and probes were up to date to reliably target current pathogens. The portfolio was subsequently relaunched globally as planned in July 2022 to deliver near-term growth to underpin the base business. This portfolio is intended to act as an innovation engine for future IVD products for use in human health.

We are encouraged by early success following the relaunch of our RUO portfolio, with initial orders of over £100k in aggregate. In addition to launching assays for both monkeypox and adenovirus F41, as announced during the period, we developed rapid solutions for testing infectious salmon anaemia virus and bacterial kidney disease in salmon in Canada. We also deployed our salmonella assays to test chickens farmed in Poland which could also be a significant market opportunity, based on initial interest.

The Company has also signed a contract with a leading global non-governmental organisation (NGO) to support the detection of arboviruses, including dengue, Zika and Chikungunya, with the total value of the first order approximately £220,000.

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.

Geographic expansion

During the period, Novacyt has focused on deploying talent in key geographies and optimising its global distributor network to build coverage in new markets to ensure optimal coverage for its recently relaunched RUO portfolio and its growing clinical offering. Through this work, coverage has been added for 18 new countries across EMEA and the Company has begun conducting distributor training on its full portfolio, including its expanded clinical portfolio and workflow.

Business development

In addition to the internal development of the new portfolio, the Company continues to progress the M&A strategy as a priority to support the inorganic growth of the business through scale and diversification.

DHSC dispute

On 25 April 2022, the Company was notified that the DHSC had issued a claim against Primerdesign Ltd and Novacyt S.A. for £134.6m in relation to the contract dispute announced by the Company on 9 April 2021 regarding its second supply contract with the DHSC, announced on 29 September 2020. On 15 June 2022, the Company filed a defence of the claim received on 25 April 2022 and a counterclaim of £81.5m against the DHSC. The value of the counterclaim is broadly in line with the amounts previously announced by the Company in its full year 2020 results, plus related interest.

The Company continues to believe it has strong grounds to defend the claim and assert its contractual rights, including recovering outstanding sums due from the DHSC under the counterclaim.

Unfortunately, the Company is unable to provide further comment at this time but will provide further updates as appropriate and to the extent permitted to do so.

Current trading and outlook

Group revenue for Q3 2022 is expected to be circa £2.0m bringing the year-to-date revenue to £18.5m at the end of September 2022. The Company does not expect demand for its COVID-19 products to pick up in Q4 2022 as previously anticipated, therefore, the Board expects Q4 2022 revenue to be similar to Q3 2022 resulting in an anticipated EBITDA loss for the full year of circa £13.5m.

Financial review

Overview

As announced in the Company's July trading update, Novacyt's H1 2022 performance was impacted by a faster than anticipated decline in COVID-19 related sales and, as such, is reporting a loss for the first half of the year. Following a strategic review, Novacyt is taking steps to rationalise its cost base and a restructuring project is underway to reduce operating expenditure to drive profitability.

Discontinued operations

In early 2022, Novacyt carried out a strategic review of the Lab21 Healthcare and Microgen Bioproducts businesses to consider the merits of maintaining multiple company entities/names under the Novacyt Group umbrella versus a simplified business model and brand, which the Directors believed could be more impactful. Novacyt announced its intention to discontinue both businesses in April 2022, and they had ceased day to day trading at the end of June 2022.

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 statement for H1 2021 and 2022.

Revenue

Unaudited revenue for the first half of 2022 fell to £16.5m compared with £52.2m in H1 2021, driven by reduced demand for COVID-19 testing as we emerge from the pandemic.

Gross profit

The business delivered a gross profit of £4.0m (24%), compared with £1.2m (2%) in H1 2021. The margin, at 24%, is significantly below the Group's historic margin (60%+) predominantly driven by the impact of stock in the form of i) booking a higher stock provision than normal as a result of lower forecast COVID-19 sales and ii) writing-off stock that had not been provided for previously. Excluding the impact of these items, the margin would be in excess of 60%. The H1 2021 gross profit was impacted by the £35.8m one-time cost of sales exceptional charge relating to the DHSC dispute.

Operating expenditure

Group operating costs fell by £2.2m to £11.1m in the first half of 2022 compared with £13.3m in H1 2021. Savings are mainly due to lower staff costs as i) headcount for the continuing operations has fallen from circa 235 staff in June 2021 to circa 210 in June 2022 and ii) a reduced pay-out in relation to the LTIP scheme. Further savings have been made in legal and professional fees, lower commercial insurance as the business contracts, and savings in facilities costs.

These cost reductions allowed the business to continue to invest in research and development, which saw a year-on-year increase in expenditure that supported bringing a number of new products to the market.

EBITDA

The Group reported a H1 2022 EBITDA loss of £7.1m compared with a loss of £12.1m in H1 2021. The H1 2022 EBITDA loss was predominantly driven by providing for stock at risk of not being sold in the future as demand for COVID-19 products fell and related stock write-offs. The £5.0m year-on-year EBITDA improvement is driven by a higher gross profit contribution of £2.8m mainly due to not repeating the H1 2021 one-off DHSC related cost of sales entries, with the remaining £2.2m being due to a fall in operating expenditure.

Operating loss

The Group reported an operating loss of £8.7m compared with a H1 2021 loss of £13.0m. This improvement is predominantly driven by not repeating the one-off DHSC related cost of sales entries booked in H1 2021. Year-on-year, depreciation and amortisation charges have increased by £0.2m to £1.0m and other operating expenses have increased from £nil to £0.5m which mainly relates to the DHSC dispute. In H1 2021, £0.3m costs relating to the DHSC dispute were reported in general and administrative expenses, these were reclassified to other operating expenses in the 2021 year end accounts.

Loss after tax from continuing operations

The Group reported a loss after tax from continuing operations of £5.0m, improving its position from a £12.1m loss in H1 2021. Other financial income and expenses netted to a £1.6m income compared with a £1.4m charge in H1 2021, driven by a £1.4m net financial foreign exchange gain mainly resulting from revaluations of the 2017 to 2020 LTIP scheme liability and bank and intercompany accounts held in foreign currencies. In addition, with interest rates rising the Group received £0.1m interest on deposits held in bank accounts. Taxation at £2.0m compared with £2.3m in H1 2021 mainly represents corporation tax due in the UK and remains a credit balance due to the Group being loss making.

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 statement for H1 2021 and H1 2022.

The Lab21 Products business reported a net loss of £3.7m in H1 2022 versus a loss of £0.6m in H1 2021. The loss has increased year-on-year due to i) gross profit falling by £0.7m due to lower revenues as customers moved to COVID-19 testing and sales have not picked up to pre-COVID-19 levels, stock write offs and closure related stock provisions; ii) other closure related costs including the £1.0m impairment of right-of-use assets, the £0.6m impairment of remaining property, plant and equipment and £0.2m redundancy costs and iii) a £0.6m swing on tax, moving from a tax income to a tax expense, primarily due to the release of all deferred tax balances, as unused tax losses cannot be utilised by the Group post closure.

Non-current assets

Right of use assets has decreased from £1.8m at 31 December 2021 to £0.6m at 30 June 2022, largely as a result of fully impairing the right-of-use asset associated with the Camberley facility following the closure of the businesses that operated from that site.

Property, plant and equipment has decreased by £1.2m from the year ended 2021 to £3.4m at 30 June 2022, driven by three main factors i) the £0.6m impairment of fixed assets associated with the Lab21 Products business ii) £0.7m depreciation charges and iii) offset by capital purchases of £0.1m.

A £4.8m deferred tax asset has been recorded at 30 June 2022 compared with £3.1m at the year ended 2021. £0.9m of the balance relates to the unpaid portion of the Long-Term Incentive Plan charge that was recognised in the 2020 accounts, but that will not be deducted for taxation until the remaining payments are made in 2022. £0.3m arises from the elimination of internal profit on products and services purchased by Primerdesign from Microgen Bioproducts and IT-IS International and still held in stock at the end of June 2022. The remaining £3.6m relates to UK tax losses that can be carried forward to offset future tax liabilities.

Current assets

Inventories and work in progress has fallen significantly to £4.3m at 30 June 2022 from £11.5m at 31 December 2021, this is mainly due to i) providing for stock that is at risk of not being sold due to the fall in expected future demand for COVID-19 related products and ii) expensing stock that has expired in 2022 that was not previously provided for.

Trade and other receivables has fallen by £3.2m since the year end in line with a decline in sales resulting in a closing balance of £35.3m. 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 interim accounts. Recovery of the invoice is dependent on the outcome of the contract dispute. Also included in trade and other receivables is a £8.4m VAT receivable balance (December 2021: £8.2m), 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 £4.0m from the year end to £1.0m at 30 June, as the Group received a refund for the overpayment of 2020 corporation tax from HMRC in March 2022. The current balance relates to 2021 losses that can be offset against 2020 taxable profits totalling £0.6m and a Research and Development Expenditure Credit (RDEC) accrual covering 2021 and 2022 totalling £0.4m.

Current liabilities

Trade and other liabilities fell to £8.1m at 30 June 2022 from £17.2m at 31 December 2021, predominantly as a result of payments made in relation to the 2017 to 2020 LTIP scheme, together with a £2.0m decrease in trade payables and accrued invoices in line with reduced sales.

Cash flow

Cash held at the end of June 2022 totalled £99.6m compared with £101.7m at 31 December 2021. Net cash used in operating activities was £1.7m compared with £12.2m cash used in H1 2021, made up of a working capital inflow of £5.4m offset by an EBITDA loss of £7.1m.

Capital expenditure in H1 2022 fell to £0.3m compared with £2.0m in H1 2021, after the Group heavily invested in insourcing manufacturing during 2021.

Net cash used in financing activities in H1 2022 totalled £0.2m versus £0.4m in H1 2021, with higher interest now being received on bank balances following interest rate rises, helping to reduce the outflow.

The Group remains debt free at 30 June 2022.

Patent Box

On 30 March 2022, Novacyt (specifically Primerdesign Ltd) received confirmation that the UK Intellectual Property Office had granted the key patent (ORF1a/b), with patent number GB2593010. This means that the effective rate of tax on profits (adjusted for certain rules) derived from the sale of products incorporating this patent is close to 10% rather than the current UK corporation tax rate of 19%.

The effective tax rate is given via a tax deduction and due to the uncertainty over the precise timing of the tax relief available to the company and the complexity involved in making a claim for the first time, a tax asset has not been recognised. The asset will only be recognised when Management can reliably measure and predict the outcome of a Patent Box claim in terms of value and timing.

Management believes that if the eventual claim is successful the benefit to Novacyt will be in excess of £5.0m of future tax credits to offset against future profits.

Consolidated income statement as at 30 June 2022

Amounts in £'000 Continuing Operations	(Unaudited) Six month 30 June 2022	(Unaudited) Six month 30 June 2021 (*)
Revenue	16,508	52,201
Cost of sales	-12,498	-15,254
Cost of sales - exceptional	-	-35,770
Gross profit	**4,010**	**1,177**
Sales, marketing and distribution expenses	-2,887	-2,991
Research and development expenses	-3,271	-1,875
General and administrative expenses	-6,211	-9,477
Governmental subsidies	180	208
Operating loss before exceptional items	**-8,179**	**-12,958**
Other operating income	2	-
Other operating expenses	-535	-
Operating loss after exceptional items	**-8,712**	**-12,958**
Financial income	2,351	342
Financial expense	-723	-1,763
Loss before tax	**-7,084**	**-14,379**
Taxation	2,041	2,295
Loss after tax from continuing operations	**-5,043**	**-12,084**
Loss from discontinued operations	-3,656	-591
Loss after tax attributable to owners of the Company	**-8,699**	**-12,675**
Loss per share (£)	-0.12	-0.18
Diluted loss per share (£)	-0.12	-0.18
Loss per share from continuing operations (£)	-0.07	-0.17
Diluted loss per share from continuing operations (£)	-0.07	-0.17
Loss per share from discontinued operations (£)	-0.05	-0.01
Diluted loss per share from discontinued operations (£)	-0.05	-0.01

* The 2021 consolidated income statement is presented to reflect the impact of the application of IFRS 5 relative to discontinued operations, by stating the Lab21 Products activity on a single line “Loss from discontinued operations”.

Breakdown of revenue by operating segment and geographic area

- At 30 June 2022

Amounts in £'000	Primer Design	IT-IS International	Total
Geographical area			
United Kingdom	8,446	1	8,447
Europe (excluding UK)	2,705	268	2,973
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**

- At 30 June 2021

Amounts in £'000	Primer Design	IT-IS International	Total
Geographical area			
United Kingdom	20,899	217	21,116
Europe (excluding UK)	20,201	166	20,367
America	4,948	392	5,340
Asia-Pacific	3,650	709	4,359
Africa	700	50	750
Middle East	253	16	269
Total revenue	50,651	1,550	52,201

Revenue has decreased year on year as a result of COVID-19 sales dropping as the demand for tests has reduced.

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 by the DHSC to the Group for amounts paid to Novacyt totalling £134,635,000 (including VAT). 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 filed a defence of the claim received on 25 April 2022, and made a counterclaim of £81,500,000 including interest against the DHSC.

The Group continues to believe it has strong grounds to defend the claim and assert its contractual rights, including recovering outstanding sums due from the DHSC under the counterclaim.

Management have reviewed the position at 30 June 2022 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 2022.

SUBSEQUENT EVENTS

No significant events have taken place since the reporting date