

Half-yearly Activity Report

2020

Half-year financial statements ended June 30, 2020

ACTIVITY REPORT

2020 BIENNIAL

HALF-YEARLY ACCOUNTS CLOSED ON 30 JUNE 2020

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 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.

Financial highlights:

- Group consolidated unaudited revenue increased over 900% to €72.4m (H1 2019: €7.2m)
- Primerdesign revenue increased over 2,000% to €70.6m (H1 2019: €3.3m) due to the success of the COVID-19 product portfolio
- Group gross margin strengthened to 83%, delivering a gross profit of €60.3m, an increase of 20% from H1 2019 (63%)
- Primerdesign maintained its strong gross margin, delivering 85% in H1 2020 (H1 2019: 86%), demonstrating strong control of margins as the business is scaled
- Group EBITDA of €49.4m (H1 2019: €0.2m)
- Operating profit of €48.3m compared to a loss of €0.7m in H1 2019, driven by the growth in sales in molecular products business
- Profit after tax of €40.2m compared to a loss of €1.2m in H1 2019
- Cash at 30 June 2020 of €19.7m after paying down all long-term debt and significant working capital investment made into stock to ensure the continuity of supply to meet the demand for COVID-19 tests

Operational highlights:

- Rapid development of new products to support laboratories and clinicians in the fight against the spread of COVID-19
 - Developed one of the first molecular tests for COVID-19, subsequently received CE Mark accreditation and Emergency Use Authorisation from most major regulatory authorities, including the US Food and Drug Administration and the World Health Organization
 - Launch of three new innovative products (Exsig™ Direct, Exsig™ Mag and COVID-HT) to support laboratories through improving workflow efficiency and helping to address the reported shortfall in global manufacturing and supply of extraction reagents
 - Launch of a saliva sampling type to support ease of patient sampling, lower levels of discomfort and demonstrate more reproducible data than other sampling types
 - Developing, together with a partner, a serology (antibody) test to detect past infection of COVID-19, with launch expected in Q4 2020
- Significant scale-up of the organisation, including increasing manufacturing and supply chain capacity and commercial support with the addition of a number of new hires
- Collaboration with AstraZeneca, GSK and University of Cambridge to support the UK COVID-19 testing effort

- Secured a supply contract with the UK Department of Health and Social Care for the Company's COVID-19 test
- Signed a number of new and significant strategic partnerships, including a distribution agreement in the US
- Surveillance programme of the Company's COVID-19 test to assess different SARS-CoV-2 viral sequences continues to demonstrate 100% detection of more than 64,000 sequences

Post-period highlights:

- Initiation of a 2,000-patient clinical trial by Queen Mary University of London using the Group's innovative near-patient testing system
- Launch of respiratory test panel (Winterplex™) to diagnose and distinguish between influenza A&B, RSV and COVID-19
- Launch of a two-gene target test for COVID-19 to address markets employing this testing approach

Strategy update highlights:

- New strategy to focus on organic, R&D and acquisitive growth in the respiratory and transplant bacterial and viral diagnostic markets
- Investment in R&D and commercial infrastructure to deliver new products and establish a direct sales force in key markets in the US and across Europe
- Selective product/technology and company acquisitions to generate additional revenues and profits to offset potential future reductions in COVID-19 revenues and enhance the Group's trajectory towards becoming a market leader in respiratory and transplant clinical diagnostics
- Acquisition of specific assets to enable Novacyt to expand its core capabilities whilst maintaining attractive margins
- Investment in developing new IP portfolio to enhance and secure future value

Operational review:

The COVID-19 pandemic has highlighted Novacyt's intrinsic ability to design, develop and rapidly scale-up market leading molecular in vitro diagnostic (IVD) tests which enable it to compete successfully at a global level. The Company has significantly increased its customer base, has built a recognised reputation for the performance of its products, formed multiple new and significant strategic partnerships and established an influential position in UK diagnostic testing. This solid foundation, combined with a transformational financial performance during H1 2020 as a direct result of the continuing success of the Company's COVID-19 product portfolio, has enabled Novacyt to eliminate all long-term debt and greatly enhance and accelerate its strategy for delivering long-term value to shareholders, further detail of which is provided in this report.

Molecular diagnostics:

During H1 2020, Novacyt's molecular diagnostics division, Primerdesign, delivered revenue growth of over 2,000% to €70.6m compared to H1 2019 revenue of €3.3m. This growth reflects the successful launch of a number of diagnostics products for COVID-19, including one of the first polymerase chain reaction (PCR) tests to combat the outbreak.

Market leading PCR test for COVID-19

In response to the emerging COVID-19 emergency, Novacyt made the strategic decision to develop a diagnostic test for SARS-CoV-2 in early January 2020. The Company launched the test in late January 2020 and subsequently received clinical use approval from a number of leading global regulatory authorities, including CE Mark accreditation and Emergency Use Authorisation (EUA) from the US Food and Drug Administration (FDA) and the World Health Organization (WHO). This rapid development of a test for COVID-19 positioned Novacyt at the forefront of the global response to the spread of the virus.

Significant demand and capacity expansion

To meet the unprecedented demand for the test following its launch, Novacyt initiated a programme to significantly scale-up the organisation. The Company engaged Chartwell Consulting, a specialist in rapid process improvement, in early April 2020 to manage and support the planning, procurement and logistics for the capacity increase. This included increasing the Company's own production capacity at the Primerdesign site in Southampton, UK, as well as entering into contract manufacturing partnerships. The Company also needed to manage supply chain capacity, which included expanding its key raw material supplier base to develop a long-term and sustainable high volume supply of its tests.

Established an influential position in UK diagnostic testing

The COVID-19 pandemic has highlighted the importance of diagnostics as part of the treatment regime across the globe. In the UK, the government has a goal of supporting and creating a national diagnostics industry that can compete on the global stage. During H1 2020, Novacyt has been actively engaged with the UK Department of Health and Social Care (DHSC) in supporting this goal. This was demonstrated in April 2020 through a contract with the DHSC for the supply of its COVID-19 test and separately a collaboration with AstraZeneca, GSK and the University of Cambridge for high-throughput COVID-19 testing. The Company has also partnered with multiple private testing laboratories who support various industries as they try to manage and maintain their businesses.

Having established an influential position in UK diagnostic testing during the pandemic, Novacyt continues to be actively engaged with the DHSC and remains well positioned to support future national testing initiatives.

Product portfolio expansion in COVID-19 and respiratory diseases

Using Primerdesign's in-house expertise and specialisation in rapid development of molecular solutions, Novacyt continued to evolve its offering during H1 2020 with a range of new products to support the application of the Company's COVID-19 testing solution in a number of scenarios. This included various formats of the Company's first generation test to support traditional and high-throughput laboratory settings (exsig™ Mag and COVID-HT), direct-to-PCR products (exsig™ Direct) which significantly reduce the time-to-result by reducing the cumbersome pre-analytical extraction phase of testing, a two-gene test to support testing in markets that mandate a two-gene testing approach, near-patient testing solutions, and a respiratory test panel aimed at supporting testing during the winter season (Winterplex™).

In July 2020, Queen Mary University of London announced the initiation of a 2,000-patient clinical trial using Novacyt's innovative near-patient testing system, which can deliver a result within an hour. The study is investigating whether daily COVID-19 testing reduces the infection rate, morbidity and mortality in the high-risk care home population. Novacyt believes daily testing has the potential to reduce the transmission of SARS-CoV-2 in the high-risk care home population and in a wider community setting.

The Company has also been investing in its rapid testing instrumentation platforms, q16 and q32, which allow for efficient and high-performance testing in near-patient environments. By the end of the year, Novacyt expects to manufacture and install an increasing number of instruments and will have capacity for significantly more as demand builds. As part of its investment, the Company is further improving the operational workflow of its reagents with these instrument platforms, reducing cycle times significantly below 60 minutes and reducing the level of operator involvement.

Continued high-performance of products

The success of the Company's COVID-19 test has been built around robust design principles and the selection of a gene target that has so far demonstrated exceedingly low levels of genetic mutation and variation. To date, the gene target has been analysed

against over 64,000 individual COVID-19 viral sequences and demonstrated 100% detection. The Company's recently launched two-gene target test for COVID-19 has also been added to this weekly surveillance monitoring programme to demonstrate continued efficacy of the test to diagnose SARS-CoV-2.

Expansion of product portfolio in respiratory and transplant bacterial and viral diseases

As part of its renewed strategy, Novacyt plans to build its international presence with an increased portfolio of IVD products for clinical use in respiratory and transplantation markets. A new R&D pipeline of products is being developed to enable Novacyt to build upon its reputation established in COVID-19 testing. The Company will continue to seek immediate approval for IVD classification of new products, as well as developing current, specific products from Primerdesign's extensive research-use-only range to establish a portfolio of high value, clinically approved diagnostics.

Protein diagnostics:

During H1 2020, the Company's protein diagnostics business, comprising of Lab21 Healthcare and Microgen Bioproducts, was significantly influenced by the COVID-19 pandemic and saw a reduction in global demand for its products. As a result, Novacyt engaged Chartwell during the period to focus on operational efficiencies in manufacturing to improve future outputs and lower the cost of goods.

The Company has also developed a plan to expand its Pathflow® brand of products and expects to launch a number of additional tests over the next few months to expand its rapid testing portfolio for infectious diseases.

The Company continues to make good progress in the development and launch of a central lab-based serology test for the detection of the IgG antibody to COVID-19. To date, the product has demonstrated significant levels of sensitivity and specificity for detection of IgG in patients 14 days after testing positive for COVID-19 by a PCR test. Novacyt now expects to launch a CE Mark approved product by the end of September 2020.

Financial review:

Revenue

Unaudited revenues for the first half of 2020 were €72.4m compared to revenues for 2019 of €7.2m, representing a growth rate of over 900% predominantly driven by the strong growth from Primerdesign. This follows the successful development and launch of one of the world's first molecular tests for COVID-19 in January 2020.

Gross margin

Gross profit has shown continued positive momentum, increasing to €60.3m (83%) compared to €4.6m (63%) in the first half of last year. This margin (83%) is in line with Primerdesign's historic margin and, therefore, as Primerdesign has increased its overall share of Group revenue, it has driven up the overall Group percentage margin.

Primerdesign maintained its strong gross margin delivering 85% in H1 2020, demonstrating that gross margin can be maintained as the business is scaled.

The Lab21 Products business unit has been significantly impacted by COVID-19 as many of its customers focused their attention on COVID-19 testing resulting in a significant year-on-year revenue and margin decline. However, the business entered H2 with a strong order book and expects to see sales and margin improve towards the end of 2020.

EBITDA

The Group continued its profitability trend delivering an EBITDA of €49.4m in the first half of 2020. The underlying Primerdesign EBITDA margin has increased to over 80% from

40% in H1 2019 when management charges are excluded, demonstrating that the division can be scaled without significant additional overheads. With Primerdesign delivering approximately 98% of Group revenue in H1 2020 at 85% gross margin, its continued success contributes substantially to the Group's positive EBITDA as the effect of increasing Primerdesign revenues as a percentage of overall Group revenues has been to enhance the overall profitability of the Group.

To support the substantial growth seen by the Group in 2020, investment has been made in overheads including the hiring of new staff and additional facilities spend to maximise manufacturing output. As a percentage of revenue these incremental costs are negligible, which is reflected in the Group delivering an EBITDA margin of 68% in H1 2020.

Operating Profit

The Group delivered an operating profit of €48.3m compared with a H1 2019 loss of €0.7m. Year-on-year exceptional charges and depreciation/amortisation costs are only €0.2m higher in 2020, driven by the impairment of Omega ID acquisition intangible assets. The key driver for the movement from a loss in 2019 to a profit in 2020 is driven by the EBITDA profitability of €49.4m.

Net Profit After Tax

Net profit after tax increased to €40.2m in H1 2020 from a loss of €2m in H1 2019. Due to the settlement of all outstanding Group debt in June 2020, borrowing costs increased year-on-year by €1.7m to €2.3m. As a result of the profits delivered by the Group in H1 2020, a UK corporation tax provision of €5.9m has been made at 30 June 2020, which was subsequently paid in July 2020.

Balance Sheet:

The Group held €19.7m of cash on the balance sheet at 30 June 2020 compared to €1.8m at 31 December 2019. This large increase in cash is predominantly driven by the significant upturn in trading that has delivered substantial profits to the Group, resulting in an operating cash inflow of €24.6m. Cash outflows from financing activities totalled €5.6m, made up of a €2.9m cash inflow from the conversion of warrants and an outflow of €8.5m on settling all Group debts/borrowings. Capital expenditure in H1 2020 was minimal at €0.2m as infrastructure investment had been made in prior periods.

Inventory has increased by €13.2m to €15.6m from €2.4m at 31 December 2019. The majority of the inventory balance relates to building stock to meet the needs of the COVID-19 pandemic and allow Novacyt to fulfil customer demand immediately. The lead time for obtaining some raw materials is significant, so bulk orders have been placed to ensure there are no supply chain issues, which resulted in the higher raw materials balance at 30 June 2020.

Trade receivables have increased since the year end by €26.3m to €28.5m driven by the ramp-up in sales as the Group responded to the COVID-19 pandemic with the launch of its tests. Approximately 90% of the debtor book as at 30 June 2020 was current and related to sales in June 2020. Prepayments have increased since 31 December 2019 by €0.7m driven by upfront payments for stock (consumables and instruments) that were not received in H1 2020.

At 30 June 2020, the Company is debt free after settling all outstanding amounts, such that net debt decreased from €8.3m at 31 December 2019 to nil.

Short-term provisions have increased by €4.1m since 31 December 2019 to €4.2m at 30 June 2020, driven by an increase in the long-term incentive plan liability, as a result of the Company's share price increasing since the start of the year.

Trade and other liabilities has increased from €4.6m since 31 December 2019 to €16.3m at 30 June 2020 in line with the growth in the business. Trade payables has increased to €3.6m and accrued invoices covering predominantly third-party manufacturing costs has increased to €7.6m, from €2.1m and €0.9m, respectively. In order to meet market demand for the COVID-19 test, the Group took the early decision to outsource elements of manufacturing to allow the business to be scaled up quickly. Tax liabilities in the form of Value Added Tax (VAT) payable in the UK has increased by €4.6m to €4.7m from €0.1m at 31 December 2019.

For the first time, the Group has been able to benefit from the UK Patent Box regime, which provides a special reduced corporation tax rate to incentivise research and development by taxing patent revenues differently from other commercial revenues. Subject to a number of adjustments, the effective rate of tax on profits derived from the sale of products subject to patents is close to 10% rather than the normal UK tax rate of 19%. The Patent Box rate is normally claimed once a patent has been granted, but it is expected that the Group's products will fall within a specific exemption allowing the reduced rate to be claimed immediately. Due to the uncertainty over the details of the full calculation, for current reporting purposes a reduced corporation tax rate of 12% on profits from patented products has been assumed. As a result of the profit delivered in H1 2020, the Group booked a UK corporation tax provision of €5.9m.

Outlook

Novacyt's near-term focus is to deliver strong organic revenue growth in the core business, where the Directors believe demand for its products will continue to grow into at least H1 2021 as COVID-19 testing continues. In the medium-term, Novacyt expects to leverage its reputation, market intelligence and relationships developed during the COVID-19 response to commercialise new products, as well as expand its presence in respiratory and transplant clinical diagnostics, to meet significant unmet market needs. The Directors expect to supplement the Company's product portfolio and expand its core capabilities through executing selective and accretive M&A at the right time.

The Directors reiterate guidance announced on 13 July 2020; given the visibility of orders, extended contracts and the launch of new COVID-19 related products, revenue for the second half of the year is expected to be greater than the first half of the year and margins to be at least at a similar level. Full year revenues are expected to exceed €150 million and EBITDA profitability to exceed €100 million. The Company expects this rate of financial performance to extend into the first half of 2021. The Directors remain confident in and excited by the prospects of the business, not only for the short-term, but also for the longer-term.

TURNOVER BY OPERATIONS:

The table below shows revenue from ordinary operations:

Amounts in '000 €	(Unaudited) Six month 30 June 2020	(Unaudited) Six month 30 June 2019
Manufactured goods	72,210	6,676
Services	-	306
Traded goods	26	58
Other	138	183
Total Revenue	72,374	7,223

BREAKDOWN OF REVENUE BY OPERATING SEGMENT AND GEOGRAPHIC AREA:

○ At 30 June 2020

Amounts in '000 €	Lab21 Products	Primerdesign	Total
Geographical area			
Africa	64	2,014	2,078
Europe	943	58,040	58,983
Asia-Pacific	518	2,764	3,282
America	195	3,685	3,880
Middle East	70	4,081	4,151
Revenue	1,790	70,584	72,374

○ At 30 June 2019

Amounts in '000 €	Lab21 Products	Primerdesign	Total
Geographical area			
Africa	358	161	518
Europe	1,555	1,352	2,906
Asia-Pacific	1,097	496	1,594
America	409	980	1,390
Middle East	551	264	815
Revenue	3,970	3,253	7,223

Consolidated income statement at 30 June 2020

Amounts in '000 €	(Unaudited) Six month 30 June 2020	(Unaudited) Six month 30 June 2019
Continuing Operations		
Revenue	72,374	7,223
Cost of sales	-12,109	-2,643
Gross profit	60,265	4,580
Sales, marketing and distribution expenses	-1,966	-1,317
Research and development expenses	-593	-229
General and administrative expenses	-9,035	-3,639
Governmental subsidies	-	7
Operating profit/loss before exceptional items	48,672	-598
Other operating income	5	57
Other operating expenses	-353	-123
Operating profit/loss after exceptional items	48,324	-664
Financial income	87	36
Financial expense	-2,292	-579
Profit/loss before tax	46,120	-1,208
Tax (expense)/income	-5,924	-
Profit/loss after tax from continuing operations	40,195	-1,208
Loss from discontinued operations	-	-786
Profit/loss after tax attributable to owners of the company	40,195	-1,994
Profit/loss per share (€)	0.61	-0.05
Profit/diluted loss per share (€)	0.61	-0.05
Profit/loss per share from the continuing operations (€)	0.61	-0.03
Profit/diluted loss per share from the continuing operations (€)	0.61	-0.03
Loss per share from the discontinued operations (€)	0.00	-0.02
Diluted loss per share from the discontinued operations (€)	0.00	-0.02

The June 2019 consolidated income statement is presented to reflect the impacts of the application of IFRS 5 relative to discontinued operations, by stating the NOVAprep activity on a single line "Loss from discontinued operations".

SUBSEQUENT EVENTS :

There are no subsequent events to report.