16 October 2020 07:08 BST

Novacyt

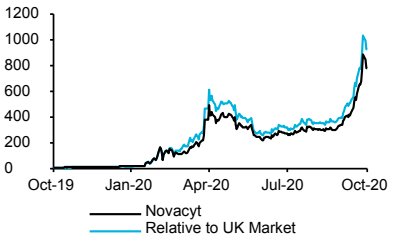
Initiating Coverage

BUY

Current Share Price	835p
Target Price	1,365p
Market Capitalisation	£590m
Shares In Issue	71m
RIC/BLBG	NCYT.L/NCYT LN
Avg. Daily Volume (3M)	983,095
Broker	Yes

Current share price(s) timed at 4:30pm on 15/10/20

Share Price



Performance (%)	1M	3M	12M
Absolute	151	220	12,344
Relative	160	237	14,939

Source: Datastream (relative to UK-DS Market index)

A new diagnostics leader emerges

With COVID-19 driving exponential demand for diagnostics and PCR the testing gold standard, PCR specialist Novacyt had strong competitive advantages in place to benefit, but the company's execution is where it has truly distinguished itself in 2020. It responded quickly to capture first mover advantage and has delivered multiple C-19 products to market at scale, driving an inflection in its revenues and significant growing cash flow. The rise in strategic importance of diagnostics is set to continue, and Novacyt has set out a credible, deliverable strategy to emerge as a long-term winner. We initiate with a Buy recommendation and initial 1,365p scenario-based target, with our blue-sky scenario of a sustained step-up in revenues into the long term seeing value north of £30. Buy.

- **First C-19 mover delivers transformational H1**: Novacyt distinguished itself from the beginning of the COVID-19 outbreak, reacting rapidly with its first SARS-CoV-2 test launched at end January, becoming Europe's first company to launch a CE-Marked test by mid-February. After this it continued to execute superbly, achieving multiple approvals/endorsements (FDA, PHE, WHO etc), bringing on eight manufacturing sites to expand its supply capacity over 100-fold, scaling up direct sales, adding major distributors, innovating rapidly with range of multiple new C-19 products. It won contracts to supply significant volume in the UK, with its global customer base expanding considerably. Its financials were transformed, with H1 2020 revs up 10-fold to €72m, EBITDA €49m and balance sheet €20m net cash after pay down of all debt.

- **Outlook even stronger into H2 and 2021:** Novacyt management had guided to 2020 revs of over €150m and EBITDA over €100m prior to a major new contract to supply its C-19 near-patient testing (NPT) system into the NHS that will drive further revs of £150m+ near term. With many variables at play we set out several forecast scenarios, with our initial base case forecasts looking for 2020 revs of over €300m. With testing demand at a multiple of current capacity and infections set to grow through the winter, we see 2021 revs exceeding 2020, at €380m (base) to over €600m (bull).

- **Opportunity to emerge as long-term diagnostics winner:** Novacyt has set out a credible three-pillar strategy of organic, R&D and accretive acquisitive growth, building around its existing respiratory and transplant, bacterial and viral diagnostics franchises. Its cash puts it in the driving seat to drive a significant industry consolidation opportunity. The bolt-on this week of IT-IS is a sensible first step that reduces execution risk, giving Novacyt end-to-end control of its NPT system, which is a key driver of potential upgrades through its rollout into various decentralised settings (e.g. NHS, care homes).

- **Valuation yet to reflect longer-term potential**: We value Novacyt at 1,365p using a scenario-based DCF approach weighted evenly (40:40) between our base (£9.5) and bull case forecasts (£15), with a 10% weighting to our bear (2020 peak, revert back to breakeven, £4.5) and blue-sky (peak €1bn revs, €100m EBITDA sustained with long-term recurring revs into NHS, £34) scenarios.

Analysts

Stefan Hamill
Tel: +44 (0)20 7260 1367
s.hamill@numis.com

Paul Cuddon
Tel: +44 (0)20 7260 1299
p.cuddon@numis.com

Specialist Sales
Ceri Morgan
Tel: +44 (0)20 7260 1304
c.morgan@numis.com

This research was prepared and approved by

Numis Securities Limited
The London Stock Exchange Building
10 Paternoster Square
London EC4M 7LT

+44 (0)20 7260 1000 | mail@numis.com
www.numis.com

Financial Summary

Valuation

Year to December	2019A	2020E	2021E	2022E
Valuation Ratios				
EV/Sales (x)	32.7	1.7	1.0	1.8
EV/EBITDA (co adj, x)	nm	2.3	1.3	3.3
EV/EBITA (x)	(344.8)	2.3	1.3	3.5
EV/NOPAT (x)	nm	2.7	1.5	4.1
Equity FCF Yield (%)	(0.3)	16.9	32.6	20.2
Dividend Yield (%)	0.0	0.0	0.0	0.0
Price/Book (x)	28.9	2.97	1.53	1.36

Source: Numis Securities Research

Financials

Year to December	2019A	2020E	2021E	2022E
Profit & loss (€m)				
Revenue	13.1	305.0	386.7	136.7
EBITDA (co adj)	0.6	229.9	282.5	72.2
EBITA (co adj)	(1.2)	228.0	280.5	70.0
Net Interest	(2.1)	(2.2)	0.2	0.4
PBT (co adj)	(3.4)	225.8	280.7	70.4
Tax Rate (co adj %)	0.0	13.0	14.0	15.0
Net Income (co adj)	(3.4)	196.6	241.4	59.8
EPS (co adj) (EUc)	(7.4)	292	326	79.6
EPS (Numis adj) (EUc)	(7.4)	292	326	79.6
Balance Sheet (€m)				
Acquired intangibles	20.2	27.4	28.4	29.5
Fxd and non-aq int assets	3.9	3.0	3.0	2.9
Net working capital	(2.0)	55.8	68.5	18.1
Capital Employed	22.2	86.2	100.0	50.5
Net Cash/(Debt)	(6.5)	93.2	313.8	451.4
Net Assets	14.6	209.1	447.0	510.7
Shareholder Funds	14.6	209.1	447.0	510.7
Cash Flow (€m)				
Operating Profit	(1.2)	228.0	280.5	70.0
Depn & non-acq amort	1.8	1.8	2.0	2.2
Chg in working capital	1.3	(94.3)	(18.2)	80.5
Other op cash flow	(0.5)	(0.7)	(0.7)	(0.7)
Operating cash flow	**0.1**	**134.9**	**263.7**	**152.0**
Capex	(0.3)	(1.0)	(2.0)	(2.0)
Tax paid	(0.1)	(29.3)	(39.3)	(10.6)
Net financing costs	(1.1)	0.3	0.3	0.3
Equity Free Cash Flow	**(1.4)**	**104.9**	**222.7**	**139.8**
Acquisitions & disposals	(1.0)	(7.2)	(1.0)	(1.0)
Financing & other	3.0	(6.4)	(1.0)	(1.0)
Chg in net cash / (debt)	**0.6**	**91.4**	**220.6**	**137.7**

Source: Numis Securities Research

Performance Metrics

Year to December	2019A	2020E	2021E	2022E
Growth Rates				
Revenue Gth (%)	(5)	2,231	27	(65)
Revenue Organic Gth (%)	(5)	2,231	27	(65)
Financials Ratios				
Operating Margin (%)	(9.5)	74.8	72.5	51.2
Net Debt/EBITDA (x)	11.4	(0.4)	(1.1)	(6.3)
ROCE (EBITA/Cap Emp, %)	(5.6)	264.6	280.5	138.4
EqFCF / adj net inc (%)	42	53	92	234

Source: Numis Securities Research

EV Calculations

Year to December	2019A	2020E	2021E	2022E
Market Cap (fd) (€m)	421.8	621.3	683.7	692.9
less Net Cash/(Debt) (€m)	(6.5)	93.2	313.8	451.4
Other EV Items	0.0	0.0	0.0	0.0
Enterprise Value (€m)	428.3	528.1	369.9	241.4
NOPAT (€m)	(1.2)	198.5	241.2	59.5

Source: Numis Securities Research

Company-specific data

Year to December	2019A	2020E	2021E	2022E
Primerdesign	6.3	300.6	381.5	130.7
- growth	1.4	4,666.6	26.9	(65.7)
- % sales	48.2	98.6	98.7	95.6
Lab21	6.8	4.4	5.2	6.0
- growth	(5.9)	(35.2)	15.0	15.0
- % sales	51.8	1.4	1.3	4.4
Total Revenues	13.1	305.0	386.7	136.7
- growth	(4.7)	2,231.4	26.8	(64.7)
Gross profit	8.4	252.8	317.6	109.5
- gross margin	64.0	82.9	82.1	80.1
R&D	(0.5)	(1.7)	(6.7)	(6.5)
- % sales	3.4	0.5	1.8	5.0
SG&A	(9.2)	(23.1)	(34.5)	(29.2)
- % sales	70.1	7.6	8.9	21.4
Adj EBIT	(1.2)	228.0	280.5	70.0
- EBIT margin	(9.5)	74.8	72.5	51.2
Adj EBITDA	0.6	229.9	282.5	72.2
- EBITDA margin	4.4	75.4	73.1	52.8

Source: Numis Securities Research

Share Price: 835p as of 15/10/20

Contents

Summary investment case

Development, manufacture & sale of clinical diagnostic testing kits

Novacyt is a diagnostics company that has built a leading position in the development, manufacture and sales of clinical diagnostic tests for disease, with specific expertise in infectious disease. It is UK domiciled but still registered and incorporated in France, and listed on both Euronext Paris (through reverse of Lab21 in 2014) and AIM (2017).

COVID-19 testing market booming

Huge near-term demand for COVID-19 tests

The COVID-19 pandemic has led to an exponential increase in demand for diagnostic tests for the SARS-CoV-2 virus (antigen tests). PCR has been a dominant testing approach for detecting viral DNA and RNA for over 30 years and is now established as the industry gold standard (for current infection) in the pandemic.

Novacyt is an infectious disease testing leader

Competitive advantages in testing for pathogens

Novacyt's Primerdesign division has one of the largest product ranges of pathogen testing kits worldwide, and a track record of rapid response to every major global viral outbreak, including Swine Flu (2009); MERS (2012), Ebola (2014); and Zika (2016). Novacyt's acquisition of Primerdesign in 2016 enabled a move up the value chain to bring its Research Use Only (RUO) tests into larger addressable markets as fully approved clinical diagnostics, starting with the CE-IVD Zika test approved in 2017. With its capabilities in rapid test development and clinical diagnostic approvals, Novacyt had strong competitive advantages in place when it became aware of the COVID-19 outbreak emerging in Wuhan, China in December 2019.

First mover with approved COVID-19 test in mid-February

First to market approved COVID-19 test in mid-February

Novacyt has distinguished itself in 2020, demonstrating its world-leading abilities to swiftly design, develop and gain approval for clinical diagnostics tests through the rapid launch of its COVID-19 test on 31 January: initially an RUO test, with regulatory approvals following quickly when it became Europe's first company to launch a CE-Mark COVID-19 test on 17 February. Since then, its test has been endorsed by various bodies, including Public Health England, WHO, UN and CNR (France) and approved in multiple countries, including an emergency approval in the US (FDA EUA).

Ten-fold rise in H1 revenues and transformed balance sheet

Revenues up 10-fold to €72m in H1, with EBITDA of €49m

Novacyt continued to move rapidly after its approvals, investing significant working capital and putting in place a network of eight manufacturing sites, increasing its supply capacity over 100-fold to >10m tests/month by end June, scaling up its UK direct sales and signing global distributors (Bruker for Europe and a major US partner). In April, Novacyt was appointed alongside AZ/GSK to set up/supply the Cambridge "Lighthouse" high-throughput testing lab and also to supply c.290k tests/week to the NHS. With the global customer base expanding alongside these two large customers, Novacyt's revenues were transformed, with H1 2020 revenues up 10-fold to €72.4m, gross margins c.20% to 83%, driving EBITDA to €49.4m. This transformed the balance sheet to €19.7m net cash after pay down of all debt and €28.8m in working capital investment.

Balance sheet transformed

FY2020 revenues forecast to be over €300m

£150m+ near-patient testing contract a potential game changer

With so many variables in play, we see a wide range in potential financial outcomes for Novacyt over 2020-21, with our initial base case forecast a mid-range estimate of how we see factors like testing demand and the vaccine programs playing out, with our bull case the realistic upside and our bear case attempting to capture the minimum outcome at this stage. At H1 results, management guided to H2 revenues increasing on H1, with guidance for the full year to exceed €150m, with EBITDA over €100m. This was prior to Novacyt's recent £150m+ contract win with the UK Department of Health & Social Care

Several avenues for upgrades, with supply not a constraint

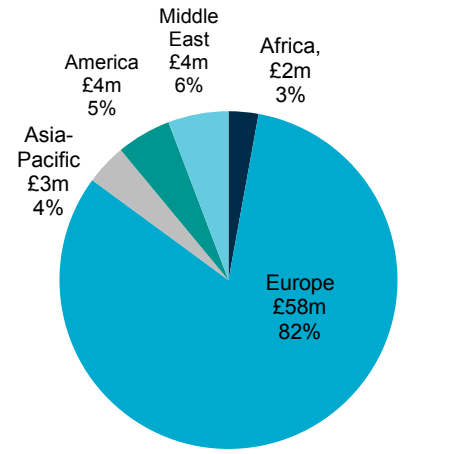
(DHSC) to supply its innovative end-to-end near-patient testing (NPT) system into the NHS this winter. This is additive and further transformational. With revenues of £150m for the next 14 weeks (for first phase of 300 instruments), we see a minimum of €305m in revenues for the full year (base and bear case), with our bull case forecast €355m.

2021 set for further growth, in our view

Further increase in UK testing volumes expected in H1 2021

At its H1 results, Novacyt management had visibility of the rate of financial performance expected in H2 2020 extending into at least H1 2021. Our initial base case forecasts see 2021 growing on 2020 given the prospect of a further step-up in UK testing volumes, and similar trends expected worldwide. Current UK capacity of c.300,000 tests a day remains too low and is limiting the pace at which the economy can reopen, with the Government's goal to nearly double capacity to 500,000 a day by November, with two more "Lighthouse" diagnostic labs to be set up to address additional PCR testing demand. We see €380m in 2021 revenues as a realistic scenario, driven by testing demand growing during the peak flu months in H1, with a bull case of €600m if the second phase of the DHSC NPT contract (for further up to 700 instruments) is triggered, up to a potential blue-sky €1bn+ if this hits its potential maximum and/or Novacyt's new product introductions deliver further. Several of these have significant revenue potential, including: Novacyt's NPT system, which addresses many settings that have high demand for such testing, with a care home trial underway with significant potential; its two gene test, which opens up large markets such as France; and its Winterplex panel, which addresses the need for testing to differentiate flu (A & B), RSV and SARS-CoV-2 as the flu season picks up. If rapid tests and vaccines do kill PCR demand and the DHSC contract does not grow at all, we model a minimum bear case of c.€200m.

Figure 1: Revs by geography H1 2020



Source: Company data

Longer-term opportunity to emerge as a UK diagnostics champion

A step-change for diagnostics industry

We see the rise in importance of diagnostics continuing for the long term, with companies such as Novacyt quickly becoming strategic to the UK during COVID-19 and, with a recognition now that further viral outbreaks are inevitable, to its pandemic responsiveness in the future. Amid this favourable backdrop, Novacyt has set out a strategy to emerge from COVID-19 as a UK diagnostics winner through a three-pillar strategy of organic, R&D and accretive acquisitive growth, building around its existing higher margin respiratory and transplant, bacterial and viral diagnostics franchises.

Expanded customer base, R&D and direct sales to drive growth

At the moment, our model sees COVID-19 testing volumes peaking in 2021, with 2022 revenues coming down, though we see longevity of demand for testing at a lower level, with Novacyt well placed, particularly in the UK. Organically, COVID-19 has driven a significant expansion in Novacyt's global customer base and improved its brand recognition, which should drive a step-up in revenue potential. The company is no longer constrained to build its platform into the right shape, with R&D investment set to rise to drive the top-line through new product introductions, and an intention to establish direct sales capability in key markets in the US and Europe, enabling it to drive the top-line and increase product margins.

Selective and accretive acquisitions

We see Novacyt ending 2020 with c.€90m+ in cash, with selective and accretive acquisitions likely to accelerate the buildout of the business around its core franchises. Novacyt's track record is strong here, with the 2016 c.€16m acquisition of Primerdesign – a good deal even without COVID – the key highlight so far.

Valuation yet to reflect long-term potential

Target price 1,365p weighted to base and bull case forecasts

We value Novacyt at 1,365p using a scenario-based DCF approach weighted evenly (40:40) between our base and bull case forecasts, which we fade after a 2021 peak to a terminal EBITDA of €22m/€33m by year 5, with a 10% weighting to our bear (2020 peak) and blue-sky (peak sales >€1bn, €100m sustainable EBITDA) scenarios.

Company background

UK-domiciled diagnostics Group originally incorporated in France

Novacyt Group is a UK-based diagnostics business that specialises in the design, development, manufacturing and commercial sale of clinical diagnostic testing kits into healthcare, life sciences, food and industrial end markets globally. It began life as three diagnostics companies: Lab21 and Primerdesign, both founded in 2005, and Novacyt, founded in France in 2006. Novacyt floated on Euronext in 2012 and, in 2014, Lab21 reversed into it in a 46:54 transaction, with its CEO Graham Mullis becoming CEO of the combined Group. Novacyt then acquired Primerdesign in 2016, before dual-listing on AIM in 2017. The Group has executed other small bolt-on transactions to bring in additional products over the years, and over 2018-19, rationalised the Group structure, divesting the NOVAprep cytology business that formed the basis of the original Novacyt, and restructuring its operations in France. This leaves the Group as essentially a UK-domiciled company that was originally incorporated and is still registered in France. The company remains dual-listed in France. The Group currently operates as two divisions:

Dual-listed on AIM in 2017

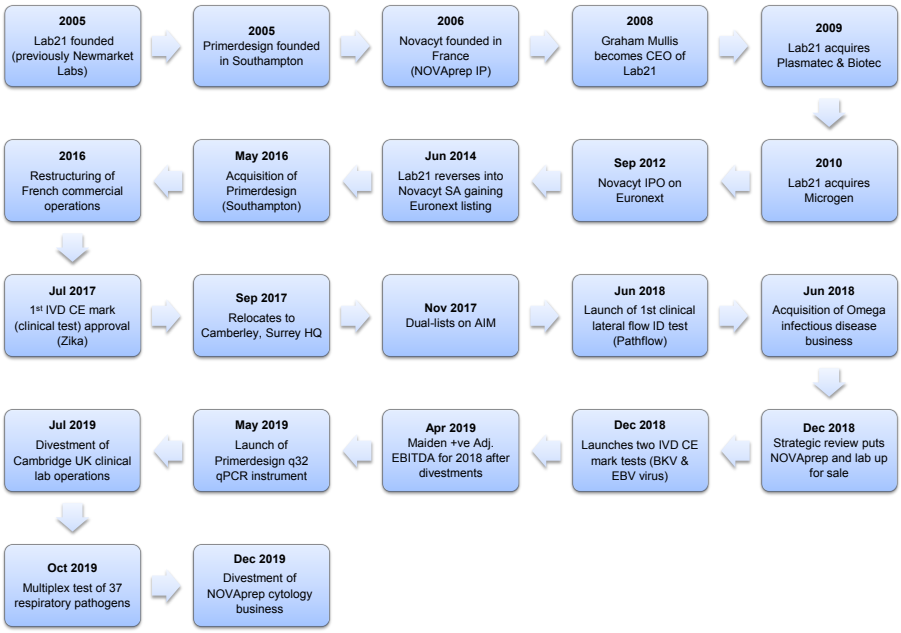
Primerdesign: DNA tests for infectious diseases at high margin

- **Primerdesign** (c.48% 2019, c.98% of H1 2020 sales) has leading expertise in the development, manufacture and commercial supply of real-time PCR diagnostic kits ("DNA tests") and reagents, mostly for use on other manufacturers' platforms together with its own instruments, provided to customers in industries such as healthcare, academia, research, food and animal health, in over 100 countries. Similar to other key high value tools, such as antibodies, its products attract high 80%+ gross margins. It occupies a c.8,500 sq.ft. facility in Southampton, Hampshire.

Lab21: protein-based IVD tests, under several brands

- **Lab21** (c.52% 2019, c.2% of H1 2020 sales) is a developer, manufacturer and distributor of largely manual protein-based *in vitro* diagnostic (IVD) tests, under brands Lab21 (serology/haematology), Microgen (microbiology), Biotec (blood grouping) and Plasmatec (CE marked IVDs). Its products are more mature, with gross margins currently 44% (with scope for these to rise on increased investment). It is based in a c.15,000 sq.ft. facility in Camberley, Surrey that was opened in 2017.

Figure 2: Summary of Novacyt history to end 2019



Source: Company & Numis Securities Research

Competitive advantages in place prior to COVID-19 outbreak

High value/margin consumables for all major diagnostic platforms

Novacyt's Primerdesign division has, over the years since its foundation in 2005, established itself as a world-leader in the development and manufacture of real-time PCR ("DNA test") testing reagents and kits for use on a wide range of diagnostic instrument platforms: essentially providing the specialised, high-value, high-margin consumables to enable tests to be performed. The company sells a range of over 500 tests across a range of diseases and has a particularly strong offering across infectious disease.

Track record of rapid response to every major global viral outbreak

Primerdesign has a history of responding to new disease outbreaks, and had developed a strong track record in this area prior to the COVID-19 outbreak this year. It was one of the first diagnostic manufacturers to introduce an H1N1 detection kit during the swine flu pandemic in 2009, as well as during the Ebola virus outbreak in 2014. Primerdesign again responded rapidly in early 2016, launching one of the world's first Zika virus tests, just prior to its acquisition by Novacyt in May of that year.

Novacyt acquisition in 2016 enabled a move up the value chain

A key element of Novacyt's strategy after its acquisition of Primerdesign in 2016 was to drive revenue synergies from the deal by moving Primerdesign up the value chain to bring a number of its research use only (RUO) tests through to full approval as clinical *in vitro* diagnostics (IVDs), leveraging the greater financial strength and regulatory capability of the enlarged Group to target a much larger overall addressable market where the tests are used in the healthcare system. This strategy unfolded over the next few years, with the first Primerdesign CE-IVD accredited assay for Zika approved in July 2017, followed by further tests in 2018.

Strong platform capabilities in place prior to COVID-19 outbreak

With its strong capabilities in rapid test development and clinical diagnostic approvals, a growing track record of delivery amongst its 1,000+ strong customer base (in over 100 countries), Novacyt had strong competitive advantages in place towards the end of 2019 as the SARS-CoV-2 virus emerged in Wuhan, China, that were enhanced from the time of the original Primerdesign deal in 2016

Emerges as COVID-19 testing leader in 2020

First European CE-mark approval a remarkable achievement

Novacyt has really distinguished itself in 2020, demonstrating its world-leading abilities to swiftly design, develop and gain approval for clinical diagnostics tests through the rapid launch of its COVID-19 test on 31 January: initially as an RUO test. Then, on 17 February, it was the first European company to launch a CE-Mark IVD test. This was a remarkable achievement that, for us, provided a **strong signal of the inherent competitive advantages of the company** and its development and regulatory platforms, and its ability to continue to introduce new products to serve unmet needs as the COVID-19 pandemic escalated.

Followed by a series of approvals by major regulatory bodies

The initial approval of Novacyt's test was followed by a rapid flurry of announcements over the February to March period where, as the situation escalated, regulators and public health bodies responded rapidly, removing the normal friction seen in the diagnostics approval, evaluation and reimbursement process to a matter of weeks. The Novacyt IVD test was rapidly endorsed by various bodies, including Public Health England, who published a formal evaluation that supported its use in the NHS, with approvals in multiple countries, including in the US (FDA Emergency Use Authorization) and the WHO (Emergency Use Listing – the first of two tests alongside Roche, with Novacyt the first open system test approved), as well as other key countries such as France (CNR approval, Institut Pasteur).

Figure 3: Summary of Novacyt's transformational progress in 2020

Source: Company & Numis Securities Research

Strong execution/scale-up drives transformational H1 results

Revenues up 10-fold to €72m in H1, with EBITDA of €49m

Novacyt continued to move rapidly after its initial CE-mark approval in February, investing significant working capital and putting in place a network of eight manufacturing sites (including key named partners Biofortuna and Biopharma Process Services), which eventually increased its supply capacity over 100-fold to over 10m tests/month by end June. It scaled up its direct sales team in the UK and signed several distribution agreements with major distributors globally, including a named agreement with Bruker for Europe and an unnamed major US partner.

Balance sheet transformed

In April, there were two key customer announcements, with Novacyt appointed alongside AZ/GSK to set up and supply the Cambridge "Lighthouse" high-throughput testing lab, part of Pillar 2 (community testing) of the five-pillar testing regime that has been put in place in the UK; then a significant agreement to supply (at least) c.290k tests/week to the NHS as part of Pillar 1 (testing in the healthcare system).

With Novacyt's global customer base also expanding considerably alongside these two large UK customers, its revenues were transformed, with H1 2020 sales up 10-fold to €72.4m, gross margins up c.20% to 83%, driving Group EBITDA to €49.4m (68% margin). This transformed the balance sheet to €19.7m net cash after pay down of all debt and €28.8m in working capital investment in the period.

Background on the technology & business model

Two main approaches test for presence/past exposure to virus

Detecting viral RNA specifically tests for presence of virus

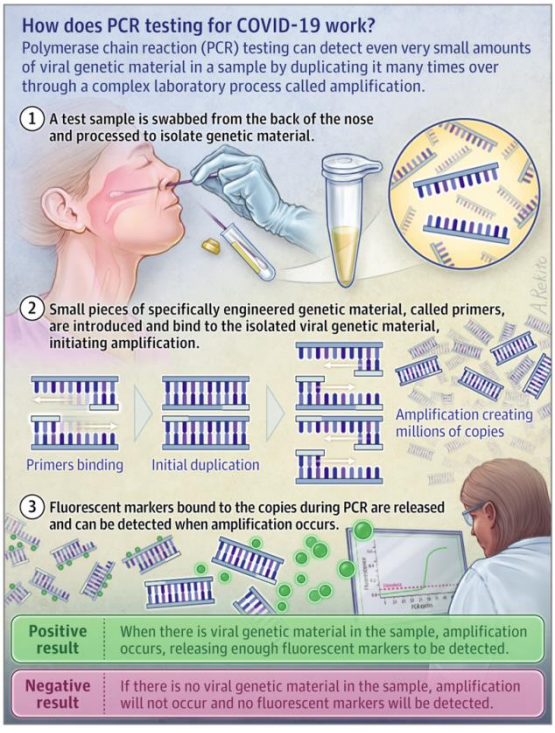
The COVID-19 pandemic has led to very significant demand for diagnostic tests for the infection, with several types of test available. The most rapid to emerge were tests for the presence of virus, known as "antigen tests" (see Glossary on page 45 for explanation of technical terms), with testing for the presence of immunity to the virus ("antibody tests") following after. The industry standard for testing current infection is to detect presence of the viral genetic material in a patient sample, which, in the case of coronaviruses, is the unique RNA sequence of the virus. This provides a unique, very specific signature of the presence of the virus in a patient sample.

PCR the industry standard for detecting current infection

PCR the industry standard COVID-19 testing approach

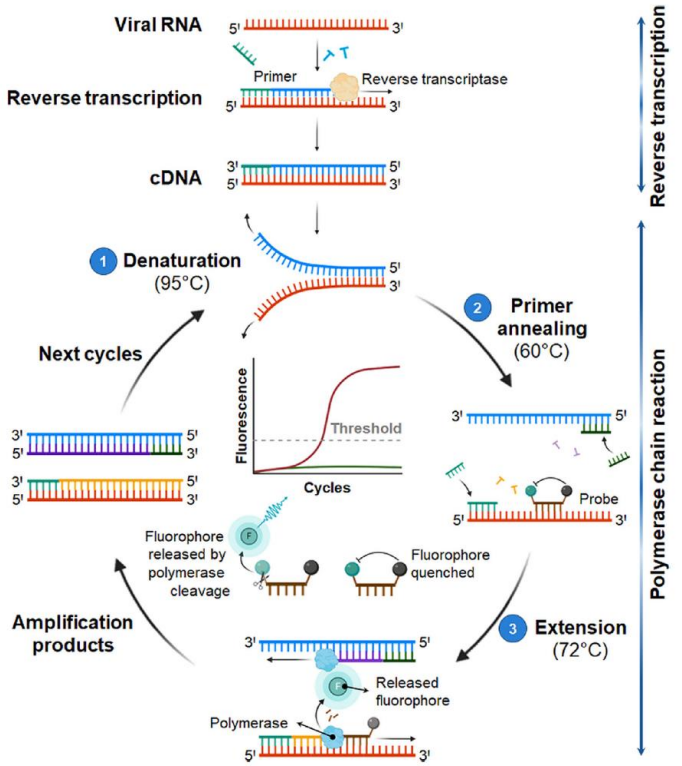
Real-time PCR or the Polymerase Chain Reaction has been the dominant testing approach for detecting specific DNA and RNA sequences for over 30 years. The technique tests a sample taken from the back of the mouth and/or nose likely to have virus. The RNA in the sample is copied to DNA, which is amplified using two PCR "primers" – small stretches of specific DNA binding sequences that are only found in the virus – with the region in between the two primers repeatedly copied to amplify up the amount of DNA so that it is detectable. Amplification is performed using an enzyme called a polymerase that has been engineered from thermostable bacteria so that it is stable at high temperature. A PCR instrument uses heat to separate the two strands of DNA in the sample, the primers bind the viral gene, and these are then copied by the polymerase as the temperature cools, doubling the amount of DNA for this specific region between the primers only. The process is repeated many times and each time doubles the number of copies, so that eventually millions of copies of the viral gene are created, which can be detected.

Figure 4: Simplified schematic of COVID-19 PCR testing



Source: JAMA

Figure 5: Schematic of real-time RT PCR



Source: A. Afzal (2020) J.Adv.Res. (doi.org/10.1016/j.jare.2020.08.002)

Real-time qPCR testing platforms consume PCR reagents and kits

Real-time qPCR uses fluorescent labelling to link the amplification of DNA to the generation of a fluorescent signal, which grows with each cycle and is detectable by the PCR instrument, which quantifies the amount of signal.

Two types of products are required in order to perform PCR diagnostic tests:

Large instruments in central labs, smaller in near-to-patient setting

- **The real-time PCR instrument**: these are either large instruments provided by large-cap diagnostics companies such as Roche and Applied Biosystems (part of Thermo Fisher), which can process hundreds of samples at once and are generally only found in large centralised labs; or smaller instruments from providers like Novacyt (Primerdesign) whose q32 instrument can process up to 32 samples at once, quickly. Here the run-time can be an hour or less due to rapid cycling, where the small size of the instrument is an advantage. Smaller instruments are suited to near-to-patient settings, where they can typically process several hundred samples a day.

Variety of consumables required for each instrument test run

- **Real-time PCR reagents and kits**: these are the consumables that are required to run each diagnostic test, which include the sample prep (nucleic acid extraction), primers specific to the virus, fluorescent probes, control reagents, polymerase enzyme and nucleotides and various buffers.

Novacyt provides reagents & kits on an instrument-agnostic basis

Novacyt provides a wide product range of PCR tests

Novacyt provides a range of modular consumables kit products for PCR testing, covering sample prep, all of the generic components required, as well as 550+ different kits for specific tests and assays. Its **genesig COVID-19 CE-IVD** tests are provided in multiple test kit format, each including seven different components, with the key PCR reagents freeze dried, allowing shipping and storage at room temperature without the need for cold chain storage. The kits provide the components required to resuspend, and positive and negative controls to QC each run.

Shift towards open systems during the pandemic

Some diagnostics instrument platforms are sold as closed systems where users are required to purchase specific consumables to run tests, with the razor and razor-blade model often being used to finance the high upfront instrument cost. While Novacyt does offer such a model for its own instruments, the bulk of its revenues come from consumable products that can be used on a wide range of major platforms on an instrument-agnostic open basis.

During the COVID-19 outbreak, healthcare systems have generally struggled to source reagents and kits for testing, especially in the early stages of the pandemic, with closed systems in particular causing problems, and there has been a shift away from this approach to one embracing open platforms, which has been beneficial for Novacyt.

Primerdesign's rapid, effective primer design a key differentiator

PCR quickly emerged as most reliable testing approach

PCR was the first testing approach to emerge as the COVID-19 outbreak escalated, following the publication of the initial sequence of the virus on 7 January 2020, and is now well established as the industry standard (for current infection) testing approach in the pandemic, with most of this testing taking place in large centralised labs.

"*primer design is still somewhat of an art*". Prof Keith Jerome, Head of virology University of Washington.

A number of different manufacturers have emerged to provide PCR tests for COVID-19, with the main area of differentiation in the selection of the gene or genes to target and design of the key PCR primers to amplify up the desired sequence, which is the key driver of test performance. This is where past experience and know-how came into play, with Primerdesign's name the biggest clue to this being an area of significant expertise and differentiation for Novacyt.

Followed its own path during early outbreak, amid initial confusion

Experience in developing 550+ PCR tests

With the benefit of hindsight, the single biggest drivers of Novacyt's success looking back was its ability to develop a test quickly, alongside its execution on scale-up. However, this design phase was not so straightforward back in January to February 2020, when organisations such as the WHO and CDC were issuing initially confusing and conflicting advice around the best testing approach. During this period, Primerdesign was able to quickly follow its own path to developing an effective test, based on its experience of developing one of the world's broadest testing portfolios, of 550+ tests.

Revolution in genomics backdrop since SARS outbreak in 2002-4

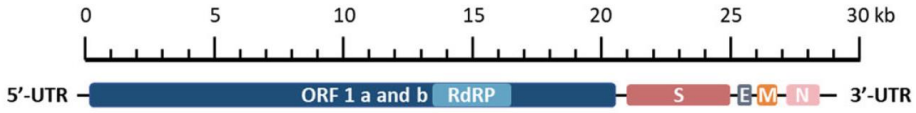
In the US, the CDC initially held up progress on testing for COVID-19 by insisting on use of its own test, which had some design issues[1] before eventually opening up to commercial providers in late February. The WHO initially recommended testing for three genes[2] to diagnose COVID-19, which was based on a view of the situation forged during the first SARS outbreak in the early 2000s, where there was limited sequence information on the virus at the time, with a two- or three-gene approach seen as a way to mitigate against genomic instability, eventually causing mutations that a single gene test could miss. However, this view predates the next generation sequencing revolution (driven by innovation out of Cambridge UK and Solexa, later acquired by Illumina) that has happened since the SARS-CoV-1 outbreak, which has transformed the pace at which genomic information now becomes available on viral outbreaks. Ten months into the SARS-CoV-2 outbreak, there are over 90,000 viral samples sequenced, allowing exquisite near real-time information on how the virus is evolving on a global basis.

Single gene approach, combined with extensive daily surveillance

Conviction to purse a single gene approach

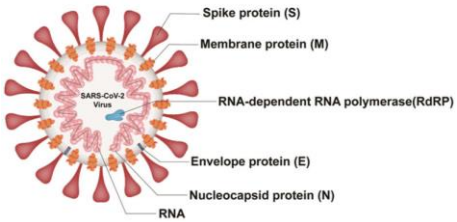
Primerdesign's test design was based on an analysis of all of the virus sequences emerging in early January, where sequence information was accumulating more rapidly than seen during SARS, with over a dozen virus sequences available relatively quickly following the initial one on 7 January. During this period, despite initially conflicting advice from the WHO and CDC on testing two or three genes (including a generic coronavirus target), the company had conviction that the best testing approach would be to maximise the quality of a single gene test target, which would simplify testing workflow, reduce setup times and reagent requirements and simplify interpretation of test results, and potentially reduce the number of false positives from cross-reaction with generic coronaviruses also.

Figure 6: Schematic of SARS-CoV-2 genome



Source: Park et al. (2020) doi.org/10.1038/s12276-020-0452-7

Figure 7: SARS-CoV-2 structure



Source: Park et al. (2020) doi.org/10.1038/s12276-020-0452-7

[1] The initial CDC N1 gene test primer formed a hairpin, negatively impacting test performance.
[2] The WHO eventually acknowledged a high-quality single gene approach as valid in mid-March.

RdRP gene with very low mutation rate selected as target

Novacyt eventually settled on the RdRP (RNA dependent RNA polymerase) gene as its preferred target, based on its in-house bioinformatics expertise and past test development experience. This gene codes for the enzyme the virus uses to replicate its RNA. This is a gene that was previously used to test for SARS, but where there is no cross reactivity of the test for the SARS-CoV-2 version of the gene with SARS or any of the other coronaviruses in general circulation in humans[3] that have been sequenced so far. The gene selected is sufficiently different to other coronaviruses, but also thought to be a region with a **very low mutation rate**, which may prove to be a more stable conserved region, less prone to changes in its sequence that might lead to eventual PCR test primer mismatch as the virus naturally mutates.

100% specificity maintained in >90,000 viral sequences to date

To ensure its COVID-19 test primers remain specific to detect SARS-CoV-2, Primerdesign's bioinformaticians have put in place an extensive daily surveillance system that reviews all of the SARS-CoV-2 sequence submissions uploaded to the public GISAID EpiCoV database every day. These are now accumulating at around 800 sequences a day submitted from all over the world, with Primerdesign publishing its surveillance update to customers once a week. As of its last update on 12 October, its analysis confirms that its test has maintained 100% detection of all 90,644 sequences published throughout the ten months of the pandemic so far. Were a mutation in the target gene to start to take hold somewhere in the world, it would likely show up quickly within this global surveillance program and Primerdesign could issue an update to its test primers to continue to catch all positive infections.

Stacks up well in performance evaluations

High specificity and sensitivity down to low viral loads

Novacyt's formal regulatory approvals for its CE-mark and FDA EUA had various *in vitro* and clinical analyses of the performance of its test, including an evaluation of 50 positive and 50 negative clinical samples (contrived, not real patient samples), with the results showing 100% specificity in all 50 negative samples (no false positives), and successful detection of virus in 48 of 50 positive samples (2 false negatives, 96% sensitivity). Some false negatives are inevitable in this type of sensitivity testing, which was explicitly designed to identify the limit of detection (LoD) of the test: the lowest concentration at which false negatives start to emerge. The LoD for the Novacyt test was 0.33 virus copies/µl, with 36/38 samples tested at this range detected, which ranks amongst the best test LoDs available, where 1-10 RNA copies per test is the current gold standard.

Validated by external evaluations

There have been several external evaluations of the Novacyt COVID-19 test, with the Public Health England and NHS evaluations coming first, in February/March. Both of these focused mainly on specificity (ruling out false positives):

- Swabs from 57 patients were evaluated by Hampshire Hospitals NHS Trust in February/early March, with four of these positives (actual validated patient positive samples were in very short supply early on) and 53 negative controls. Novacyt's CE-IVD test detected all the true positives (4) and true negatives (53) confirming 100% specificity for SARS-CoV-2.
- Public Health England's National Infection Service evaluated 195 actual negative specimens in March, including upper or lower respiratory clinical specimens, with all of these correctly identified, with no false positives in any of the negative samples tested (100% experimental specificity, which was formally deemed ≥98% specificity by PHE once the powering/number of samples of the evaluation was factored in).

[3] The only cross-reactivity observed was with two bat and pangolin coronaviruses, with enough mismatches to suggest that even these animal viruses would not be detected by the test.

A study by Kasteren *et al*. (doi.org/10.1016/j.jcv.2020.104412) estimated sensitivity of ≥96% using a study of actual patient clinical samples, including several at very low viral loads beyond the limit of detection, while Novacyt's WHO Emergency Use Listing (EUL) approval filing – the first open system approval it granted – defined the sensitivity at 98% with an LoD of 0.58 virus copies/µl.

100% sensitivity and specificity in largest test evaluation so far

Perhaps the most comprehensive evaluation that has been conducted in the field of PCR testing for COVID-19 is that by the Foundation for Innovative New Diagnostics (FIND), which invited over 200 COVID-19 IVD submissions for evaluation, which were scored according to various criteria, with 40 of the most suitable tests from 21 manufacturers selected for further evaluation using validated patient samples (50 positive, 100 negative) at the University Hospitals of Geneva (HUG). The FIND study[4] found the Novacyt test correctly identified all the samples tested, giving 100% sensitivity (50/50 samples correctly identified as positive) and 100% specificity (100/100 samples correctly identified as negative), with a low LoD (1-10 RNA copies/test). Only 12 of the 40 tests analysed achieved a similar performance, with only four of the single gene tests performing as well and Novacyt's test the only single gene RdRP test to do so (RdRP tests summarised below).

Table 1: Results of FIND evaluation of various SARS-CoV-2 tests

Company	Product	Gene targets	LoD copies/ reaction	Average Ct	Clinical sensitivity n=50 (95% CI)	Clinical specificity n=100 (95% CI)
bioMérieux	Argene	N, RdRP	10-50	32.44	96% (87-99%)	100% (96-100%)
Bioneer	AccuPower	E, RdRP	10-50	36.18	100% (93-100%)	100% (96-100%)
Boditech	ExAmplar	E, RdRP	50-100	33.46	90% (79-96%)	100% (96-100%)
KH Medical	RADI	S, RdRP	10-50	36.74	100% (93-100%)	100% (96-100%)
Primerdesign	Genesig	RdRP	1-10	36.7	100% (93-100%)	100% (96-100%)
Seegene	Allplex	E, N, RdRP	1-10	34.73	100% (93-100%)	100% (96-100%)
Vela Diagnostics	ViroKey	RdRP, ORF1	10-50	30.95	94% (84-98%)	100% (96-100%)

Source: Foundation for Innovative New Diagnostics (FIND), finddx.org/covid-19/sarscov2-eval-molecular

Broad COVID-19 product range continuing to expand

Rapid expansion of product range since initial launch in Jan 2020

Since launching its initial RUO test in late January, Novacyt has rapidly expanded its offering of COVID-19 products, offering tests in many different formats, and quickly bringing novel sample preparation products to market to speed up testing workflows in a variety of settings. Combined with its real-time PCR instrument offerings, and confidence in its supply chain, this represents a **strong product portfolio for COVID-19 testing** in a variety of settings, allowing Novacyt to access much of the addressable market (see summary table below).

[4] https://www.finddx.org/covid-19/sarscov2-eval-molecular

Table 2: Summary of Novacyt COVID-19 product range

Product	Description
genesig® 2019-nCoV (RUO)	Research use only (RUO) COVID-19 real-time PCR test to detect SARS-CoV-2 virus (in swabs) launched 31 January 2020
genesig® COVID-19-CE (CE-IVD)	CE-marked COVID-19 real-time PCR clinical diagnostic launched on 17 February 2020
genesig q16 Real-Time PCR Instrument	Fast, small footprint real-time qPCR instrument that allows analysis of up to 16 samples in under an hour
genesig q32 Real-Time PCR Instrument	Fast, small footprint real-time qPCR instrument that allows analysis of up to 32 samples in under an hour
genesig® 2019-nCoV-Easy (RUO)	Primerdesign's Easy range of test kits are designed for use on its own q16/q32 rapid real-time qPCR instruments
genesig® 2019-nCoV-std (RUO)	RUO COVID-19 multi-test kit designed for use on other real-time PCR instrument platforms
genesig® COVID-19 (US Only)	US approved (FDA EUA) version of COVID-19 test kits suitable for use in accredited US CLIA labs
genesig® COVID-19-HT (CE-IVD)	CE-marked COVID-19 test kits optimised (premixed reagents and appropriate packaging) for high throughput lab workflows
exsig™ COVID-19 direct (CE IVD)	CE-marked COVID-19 workflow solution, including rapid direct-to-PCR RNA extraction sample prep to improve turnaround
exsig™ Mag	RNA extraction kit designed to run on automated magnetic bead systems used in combination with COVID-19 tests/kits
Near-patient testing (NPT) system	Combines Novacyt's COVID-19 & direct-to-PCR exsig kits, & q16/32 instruments for complete rapid/frequent test solution
genesig® SARS-CoV-2 Winterplex (CE IVD)	CE-marked multiplex PCR test to differentiate two types of flu (A & B), RSV and SARS-CoV-2, through winter flu season
genesig® COVID-19 2G (CE IVD)	CE-marked PCR test for two viral genes (RdRP & S), for use in countries that mandate 2-gene approach (e.g. France)
Microgen Bioproducts® SARS-CoV-2 IgG EIA	CE-marked serology (antibody) ELISA (lab) test for detection of IgG antibodies to SARS-CoV-2 in blood.

Source: Company & Numis Securities Research

Complete near to patient testing (NPT) solution now in place

Novacyt's reagents serve a wide range of instrument platforms

Novacyt's broad COVID-19 product portfolio covers the full range of reagent workflows, taking samples all the way from swab to result, with a number of reagent offerings that speed up the process, and a variety of formats available, with the majority of its testing reagents to date sold for use on large open testing platforms, such as the Roche LightCycler, which are the mainstay platforms in large centralised high-throughput labs. Novacyt also has its own range of real-time qPCR instruments – the genesig q16 and q32 – for which it provides its own "Easy" range of over 550 different test kits. These are well suited to lower volume testing in smaller labs. They are attractive instruments for this setting given their small benchtop footprint. Particularly their short run times of under 1 hour, which is made possible by their very rapid temperature cycling. The short run times of the Novacyt instruments are particularly critical in the near to patient setting, where time to result is more critical and where sending tests away to longer turnaround central labs causes potential treatment delays and expense.

Its own q16 and q32 instruments are well suited to small labs

Figure 8: genesig q16 instrument

Source: Company data

Figure 9: genesig q32 instrument

Source: Company data

Clinically validated system from swab to result in under 60 minutes

In July, Novacyt announced the launch of its near-patient testing (NPT) system for COVID-19, which covers the whole testing workflow in this setting. This brings together its exsig COVID-19 Direct product, which itself is a combination of the genesig COVID-19 and exsig direct-to-PCR sample prep products, which are pre-coated into ready-to-use sample testing tubes, together with its own q16 or q32 instrument platforms. The combined system offers a simplified protocol that is easy to follow with fewer variables to introduce potential errors, easier sample handling, a simplified process for RNA extraction, with a proven workflow that delivers from swab to result in under 60 minutes. The NPT solution was validated by a leading accredited clinical lab, which showed sensitivity and specificity of over 99% using over 400 patient samples.

2,000-patient NPT clinical trial in care home setting underway

Led by Prof Jo Martin, one of the UK's leading pathologists

In July, Novacyt announced the initiation of a 2,000-patient clinical trial by Queen Mary University of London using the Group's NPT system to investigate whether its use can reduce infection rates, morbidity and potentially mortality in a high-risk care home setting. The randomised clinical trial will recruit up to 2,000 residents in 50 care homes across east London and is being led by Professor Jo Martin (President of the Royal College of Pathologists, and former head of clinical pathology within NHS England). The trial will see half of the care homes adopting Novacyt's NPT system to regularly test residents, staff and visitors, while the other half will receive standard of care central lab testing once a week. If successful, this could open up the significant care home testing market for Novacyt's NPT offering.

First £150m+ NPT contract a signal of significant potential

Provision of near-to-patient testing in the NHS through the winter

In late September, Novacyt announced a new supply contract with the UK Department of Health and Social Care (DHSC) for its NTP COVID-19 testing solution, the second major contract it has been awarded from DHSC following the test supply agreement in April. The new contract is for the provision of instruments (both q16 and q32) and complete workflow reagents (exsig COVID-19 Direct), as well as its Winterplex panel test products to differentiate flu (A and B), RSV and SARS-CoV2. The intention of the contract is for Novacyt to support urgent COVID-19 testing of patients in the healthcare setting to ensure the NHS can continue to function and provide services to patients through the winter period as the flu season picks up steam, which will increase demand for testing. Novacyt will also provide training and maintenance services for the q16 and q32 instrument platforms.

Minimum of c.£150m in revenue, with significant upside potential

The contract has two phases and covers a period of up to six months. Phase one covers the first 14 weeks, with a potential extension of 10 weeks. The first phase will see the immediate deployment of 300 of Novacyt's qPCR instruments and related test consumables, with a minimum value of £150m for this 14-week period (incremental to existing contracts and prior €150m revenue guidance for 2020), with the second 10-week period potentially bringing a further £100m in consumables revenues. The second phase is optional by the DHSC and could see the provision of up to 700 additional PCR instruments, and, depending on the uptake, could be larger than the first phase. Novacyt confirmed it has the capacity to meet demand in both phases of the contract, as well as to continue building its international ex-UK sales.

Wide range of potential use cases for NPT system

This is the first significant NPT contract for Novacyt and provides a signal of the significant potential of its offering in a number of settings throughout health and social care, including:

- A&E departments – for urgent patients and to protect healthcare workers
- Imaging suites (including cancer imaging) – to help regular healthcare services to return to normal

- Transplant centres – one of the most time sensitive areas of medicine
- Respiratory clinics – to differentiate the various viruses circulating as the winter flu season picks up, impacting vulnerable patients
- Care homes – on either a centralised or dedicated on-site basis to support residents and care workers
- GP surgeries – to speed up potential long turnaround times for centralised testing, which could be useful in more remote areas
- Potential travel, office, industry and military applications

Antibody test approved in time for potential arrival of vaccines

Antibody tests to detect if infected with SARS-CoV-2 in the past

Other than antigen testing, the other main type of COVID-19 testing of broad interest is detection of the presence of immunity to the virus, known as serology or antibody testing. This approach generally uses a unique part of the virus (e.g. the S or spike protein) as an antigen, or "fishing hook" to fish out the presence of any antibodies in the blood that are specific and bind to the virus antigen. It takes up to 2 weeks to fully develop antibodies, with IgM antibodies appearing first, then the more specific, longer lasting IgG antibodies. Novacyt indicated in July that, following extensive investigation of various serological methods, it was working with a partner (unidentified) to develop an IgG antibody test.

Confidence in supply of at least 3m tests/month

Novacyt's CE-marked antibody test was launched in late September as part of the Microgen Bioproducts range within its protein diagnostics division Lab21. Novacyt validated the test in a study using over 1,600 patient samples, where it demonstrated 100% sensitivity after 14 days, and 99.4% specificity. The test is in the ELISA format, which is designed for use in a central lab, and which quantifies the amount of antibody in the sample (in contrast to yes-no lateral flow tests). Novacyt indicated it has sufficient manufacturing capacity to deliver over 3m tests per month initially, and is working with its partner to ensure this can be scaled up further according to demand.

Table 3: Microgen SARS-CoV-2 IgG test clinical performance characteristics

Category	Specification	Value
Diagnostic sensitivity	<7 days after PCR diagnosis	38.1% (8/21)
	7-14 days after PCR diagnosis	84% (21/25)
	>14 days after PCR diagnosis	100% (66/66)
Diagnostic specificity	SARS-CoV-2 [-]	99.4% (1543/1561)

Source: Company data

"Game changer" antibody test volumes never materialised

In the early stages of the COVID-19 pandemic, antibody tests were described by UK Prime Minister Boris Johnson as a "total game changer", with the indication at one point that millions of such tests would be ordered in order to provide the population with a potential "immunity passport" on prior exposure to the virus. However, such testing never materialised, as it became clear that antibody tests were a measure of prior exposure, but not of protection, as they do not test for the virus neutralising ability of the antibodies. Antibody-mediated immunity to SARS-CoV-2 is not well enough understood, yet, to provide confidence of protection against re-infection.

May see increased demand once vaccines start to roll out

This whole question around antibody levels and the protection they provide is essentially one for the vaccine industry, and the relationship between antibody levels and protection should become clearer as these studies start to report protection data in the next few months. As the vaccination programs start to roll out sometime in 2021, there will be more interest in assessing levels of antibodies in the population, which may eventually serve as a proxy for protection, driving potential increased demand for such testing next year.

Novacyt well-placed in both molecular and protein testing

Thus, in having its test ready at the start of Q4 2020, Novacyt is well placed for the timing of potential vaccine rollouts. The ability to provide confidence in supply of a significant volume of antibody tests per month may differentiate Novacyt from some other providers, particularly for the UK market, and any traction here would serve to potentially rebalance the business between its molecular (Primerdesign) and protein-testing (Lab21) divisions.

Market outlook and competition

Addressing PCR testing controversies

PCR the gold standard but not devoid of issues

PCR testing, while now well-established as the gold standard for COVID-19 testing, is not a perfect approach and there has been some criticism in the medical community and press of the heavy reliance being placed on it, with some of the key issues being raised as follows:

Real world sensitivity lower than from contrived samples

- The official sensitivity statistics of companies marketing PCR tests refer to *in vitro* tests performed in ideal standardised conditions. Estimated real-world sensitivity (successfully picking up positives) has been estimated in the 70%-95% range once the variability of fluid sampling is taken into account, with the initial swabbing the most variable and unreliable step in the process, while real-world specificity (avoiding false positives) is generally over 95%. This means that the real-world weight of a positive test result (specificity of PCR particularly reliable) is greater than a negative result, which may be caused by lower real-world sensitivity. In dealing with individual patients, symptomatic assessment is important and patients with multiple symptoms of COVID-19 are still advised to self-isolate until symptoms such as fever subside, even if they receive a negative test result.

Increased testing inevitably drives increased false positives

- The issue that the predictive value of testing can be low, even with a highly sensitive and specific test, due to the low prevalence[5] of a disease. In other words, the number of false positives can exceed actual positives, even with highly accurate tests, with test specificity the key driver of this.

PCR can test non-infectious patients as positives

- Issues around the number of PCR amplification cycles being performed, known as the cycle threshold (Ct), which if too high can pick up a very small level of irrelevant viral genome fragments from a prior infection, and report post infectious subjects as positives. There has been a push to set Ct thresholds for testing to reduce these.

…and miss infected patients in the early stages

- PCR measures viral load at one point in time for a particular patient, rather than infectiousness or prior exposure (where antibody tests more useful). So, patients with actual COVID-19 can still test negative in the very early stages of their infection, then positive during period of high viral load and infectiousness, but then still positive again once no longer infectious, then eventually negative again as the immune system completely eradicates the virus (see figure below right).

Demand for testing orders of magnitude above current volumes

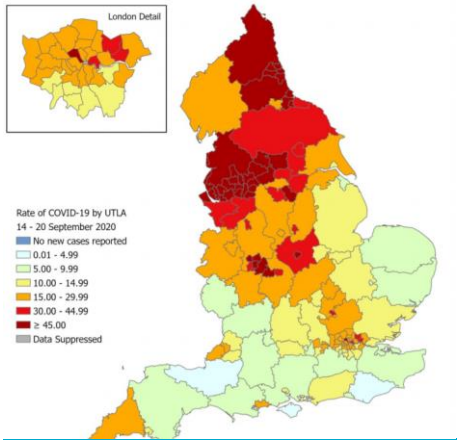
Relative trends revealed and increasing granularity desirable

Despite the testing controversies that have been seen, we see the implicit demand for testing for COVID-19 currently at **orders of magnitude above current testing volumes**. We expect to see a continued rise in volumes of centralised and decentralised testing in healthcare (UK Pillar 1 testing) and the community (UK Pillar 2) to provide essential information in managing the COVID-19 pandemic as it progresses. While the absolute statistics provided are subject to noise and uncertainty, more data is still desirable and an improvement on no data. This was very much the status back in March, where the real levels of infection are thought to have been many orders of magnitude higher than suggested during a period where testing capacity was very low.

[5] Note prevalence in this context refers to the proportion of those being tested that are actually positives (infected), a higher figure than overall population prevalence of infection – see https://www.bmj.com/content/369/bmj.m1808/rr-22 for a good explanation.

Trends in test positivity and localised granularity very useful

Figure 10: Weekly COVID-19 cases

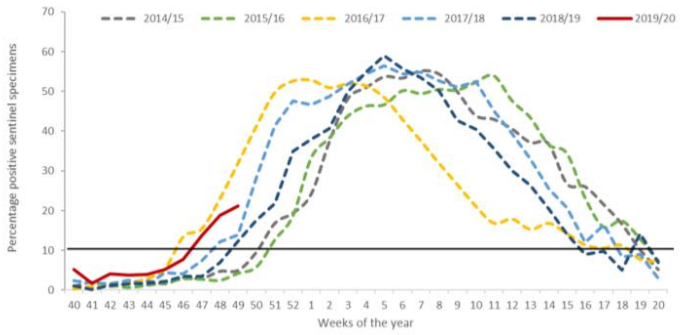


Source: Public Health England

Statistical uncertainty is now factored in to testing regimes and it is generally the relative trends and increasing granularity that more testing data provides that is valuable. For example, despite a significant number of positive tests known to be false positives, the *trend* in positive test results adjusted for the number of tests being performed (test positivity) is useful information around the trend of the actual virus, and is a predictive leading indicator for more serious issues, of hospitalisation, serious illness and deaths. The latter are perhaps the best indicators of the true status of infection in the population, but are, by their very nature, very lagging indicators, with actual levels of infection many orders of magnitude higher once these start to rise significantly.

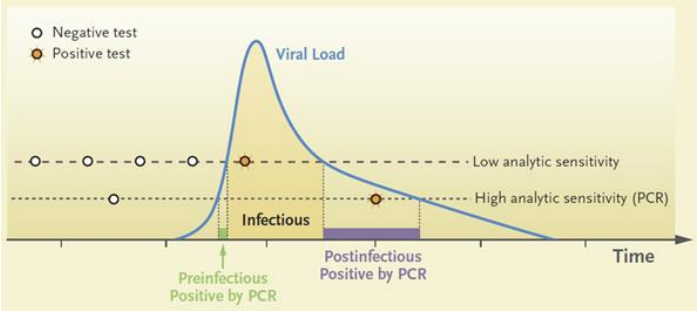
Despite the controversies in testing, performing more tests more regularly, in more settings, is welcome, as it provides higher resolution information, such as info on regional segmentation and potential localised outbreak clusters that can be spotted quickly. This information is now being used to direct the new three-tier Local Covid Alert Levels system being introduced in England and Wales in the UK. We see a significant runway for more such information as new testing technologies start to come through, which we see as being additive to PCR.

Figure 11: On average, Flu peaks in February in Europe



Source: ECDC, WHO

Figure 12: Schematic of low + high sensitivity testing regime



Source: Mina et al. (2020) doi.org/10.1056/NEJMp2025631)

"we view antigen testing as quite complementary"… "there's so much confirmatory testing that you're likely to see and so much medical-based testing around COVID. We would expect that PCR is going to continue to have robust demand for the foreseeable future." **Marc Casper, CEO, Thermo Fisher, Sep 2020**

Figure 13: Abbott BinaxNOW test

Source: Abbott

Lower sensitivity, higher volume tests to come

With demand for testing still significantly above capacity globally, there is a recognised need for novel testing technologies to come through to help the world to live with the SARS-CoV-2 virus more effectively, particularly prior to the wide availability of vaccines. Some of the most promising technologies coming through to serve this demand include:

- **Rapid, cheap antigen testing**: There is a recognised need for more regular COVID-19 surveillance to be performed in a variety of settings that, while outside the core healthcare/social care system, are causing havoc in key areas of the economy, such as the travel and entertainment sectors. The most appropriate testing approach for this is seen to be rapid disposable lateral flow antigen tests costing as little as $5 that can be deployed at scale. A number of companies are pursuing such tests[6], with the first available in significant volume the Abbott BinaxNOW. While such tests are of lower accuracy than PCR (LoD c.100-fold lower, sensitivity 97.1%, specificity 98.5%), the potential is for these to be used more regularly in population surveillance regimens (see Figure above right) to identify subjects with high viral loads and infectiousness, to help limit outbreaks. We see the implicit demand for such tests as very high – essentially **weekly testing of much of the population** at the upper end – with these tests complementing clinical diagnostics, which will remain the gold

[6] These include UK-listed biotech company Avacta, which is targeting the commercial launch of its Affimer-based lateral flow tests, being developed in collaboration with Cytiva, in 2021.

standard approach to testing in health and social care settings, as well as to confirm many of the positive results identified by these programs.

Oxford Nanopore LamPORE approved and wins DHSC contract

- **Scalable NGS-driven testing**: While PCR testing is the gold standard to identify the presence of a specific gene in a sample, DNA sequencing offers an alternative, orthogonal approach that also provides more information on the virus, with each virus sequence acting as a mutational fingerprint of where the infection came from. With pressure on PCR capacity, sequencing approaches to testing are emerging to potentially provide additional capacity. Oxford Nanopore (UK) has achieved a European CE-mark exploring a novel scalable LAMP-based sequencing approach (LamPORE), while the FDA has granted Emergency Use Approval for such testing based on Illumina short-read sequencing, with Oxford Nanopore now pursuing this for LamPORE also. These techniques bring many patient samples together into one sequencing run, using molecular bar-coding to follow each individual patient sample. The workflow is more complicated than for PCR, but the potential scalability is significant. For example, Oxford Nanopore's LamPORE has been shown to handle as many as 1,152 different patient samples in one MinION flowcell, and over 5,000 on one benchtop GridION instrument (5 flowcells) in around 5 hours. In a recent evaluation study, the Universities of Oxford/Sheffield, Public Health England and Sheffield NHS showed sensitivity of 99.1% and specificity of 99.6% in 507 validated patient samples using LamPORE. Following this, Oxford Nanopore has won a c.£113m contract with DHSC to scale-up the use of this testing technology to potentially millions of tests per month to further increase UK capacity. Again, we see this as additive to PCR testing, which remains the gold standard.
- **Antibody testing**: (see page 17 above).

Table 4: Summary of leading COVID-19 vaccine programs (ordered by start of Phase 3 trial)

Company	Vaccine	Platform	Stage	Comments
AstraZeneca / Uni of Oxford (Jenner) / Vaccitech	AZD1222 (ChAdOx1)	Non-replicating adenoviral vector	Phase 3	Prior MERS Ph1 trial made it instant front runner. Large C-19 data-set published showing tolerable safety and over 90% pts developing neutralising Abs from 1 dose, by day 14, peaking at day 28, with T-cell responses also induced in all participants from day 7. Phase 3 trials underway in >50k pts in UK, Brazil, SA, US (on hold investigating 2 CNS SAEs). EMA has started a rolling submission for emergency approval, with AZ guiding to submitting for approval by end year.
Sinovac	CoronaVac	Inactivated virus	Phase 3	Approved for emergency use in China to vaccinate high-risk groups. Phase 2 data showed induced neutralising antibodies in >90% of participants
Sinopharm / Wuhan Institute	Inactivated vaccine	Inactivated virus	Phase 3	Approved for emergency use in China to vaccinate high-risk groups
Moderna Therapeutics	mRNA-1273	RNA	Phase 3	First to dose US patients, with Phase 1 data published showing a consistent antibody response and mild to moderate side effects. Phase 3 trial underway in Jul-20 enrolling 30,000 participants. End November seen as potential earliest EUA filing date, potentially stretching into December, with full approval seen for late Q1/early Q2 2021.
Pfizer / BioNTech	BNT162	RNA	Phase 2/3	Phase 1 data showed increases coronavirus antibodies at three doses. Phase 3 trial underway in Jul-20 enrolling 30k participants (expanded to 44k in Sep), expecting data as early as end October under best case scenario. Under political pressure to release early protection data, submit FDA EUA prior to US election. EMA started a rolling submission for emergency approval a week after starting to evaluate the AZ / Oxford vaccine.
CanSino	Ad5-nCoV	Non-replicating adenoviral vector	Phase 3	Approved for limited use in Chinese military. Phase 2 data showed a consistent antibody response that seemed to wane in older subjects
Gamaleya Institute	Sputnik-V	Non-replicating adenoviral vector	Phase 3	Approved in Russia before end of Phase 3 trials. Irrelevant to western markets.
Janssen (J&J)	Ad26.COV2.S	Non-replicating adenoviral vector	Phase 3	Janssen's Ad26 platform perhaps the best established in terms of having safety data in the most subjects (Ebola vaccine tested in >60,000 subjects). Phase 1/2 data showed single dose as effective as two in inducing immune response, giving potential single dose advantage. Phase 3 trial underway in Sep-20 enrolling 60,000 participants – recently on voluntary pause to investigate AEs.
Sanofi / GSK	SARS-CoV-2 recombinant protein vaccine	Protein subunit (same tech as flu vaccines)	Phase 1/2	Started a 400-pt Phase 1/2 trial in healthy volunteers in early Sep-20 with data expected in December. Timing guidance is Phase 3 start end 2020, with approval by end H1 2021, allowing a potential launch in H2 2021.

Source: Numis Securities Research

Testing demand to continue beyond potential vaccines

Over 100 vaccines in development

Ultimately, to generate population immunity in a safe manner, vaccines to COVID-19 will be required. The response of the global biopharma industry to the crisis has been rapid and impressive, with over 100 vaccine programs now underway across the world. Many of these have received an unprecedented level of government and regulatory support, which has allowed multiple programs to scale-up manufacturing at risk, prior to the availability of Phase 3 data, in order to bring forward their eventual rollout.

Viral vector and RNA approaches in the lead

There are several broad vaccine technologies being pursued, each with more than one shot on goal. In the lead, are companies such as AstraZeneca, Moderna and Pfizer, which are using "cut and paste" platforms to deliver the gene for the viral spike protein in RNA or DNA form. Host cells then make a harmless version of spike protein, to which an immune response develops that, in theory, protects against any real virus encountered with the spike protein on its surface. These are novel approaches that, while fast, do not yet have a track record of approval for use in humans, and it currently remains unclear how significantly they might protect against the virus. Following behind are more traditional approaches, such as Sanofi / GSK's recombinant spike protein plus adjuvant approach, an established technology that, while not expected to be available until H2 2021, could be the tortoise in the race. The China vaccines from Sinovac and Sinopharm are, in theory, well advanced on the route to market. These use a traditional inactivated virus approach and both have already achieved emergency approval in China. However, their relevance to western markets appears limited at the moment.

Sanofi / GSK's vaccine could be the tortoise in the race

AZ / Oxford vaccine may be first to market in the UK

The AstraZeneca / University of Oxford / Vaccitech vaccine emerged as an early front runner in the vaccine race, benefiting from an earlier Phase 1 trial of its platform in MERS, and was first into Phase 3. AZ recently put the Phase 3 trial on a voluntary clinical hold following a serious adverse event (SAE) in two patients who experienced transverse myelitis, a rare side effect seen in prior vaccine studies where the immune system attacks the patient's spinal cord (myelin sheath), leading to impaired movement/paralysis in serious cases. The hold was removed in the EU shortly after a review of safety data by an independent committee, but remains in place in the US. While this has delayed the AZ vaccine, particularly in the US, it is still guiding to submitting for EU approval by the end of 2020, and the EMA has started a rolling submission for emergency approval, which could see an approval early in 2021.

In April 2020, the UK Government launched its Vaccines Taskforce, which has signed agreements with the leading vaccine developers to secure UK access to vaccines. So far the program has secured access to six different programs: three of these the faster innovative platforms (AZ/Oxford, Pfizer/BioNTech, Moderna), which all expect Phase 3 data by the end of the year, with a further three more established technologies following behind (Janssen, Sanofi/GSK and Valneva).

"diversity of vaccine types is important because we do not yet know which, if any, of the different types of vaccine will prove to generate a safe and protective response to COVID-19."

"…we may never get a vaccine and if we do get one, we have to be prepared that it may not be a vaccine which prevents getting the virus, but rather one that reduces symptoms."

"What I've been anxious about is that people …think we'll have a silver bullet. That's probably not going to happen"

Kate Bingham, Chair of UK Vaccines Taskforce

As chair of the Vaccines Taskforce, Kate Bingham (of SV Health Investors) has vocally cautioned against expectations that the vaccines will provide a "*silver bullet*" of significant protection and effective sterilisation of the virus straight away. It remains to be seen how much protection the antibodies raised provide, whether they reduce infection or simply improve symptoms, and how long any protection lasts, all of which implies that significant demand for COVID-19 testing will continue.

The FDA has set a hurdle for COVID-19 vaccines to stop at least 50% of subjects getting symptomatic COVID-19. Our view is that **vaccines that provide *any* level of protection to statistical significance are likely to be approved**, given the value to society and the fact that annual flu vaccines routinely fail to reach this 50% hurdle. Again, this implies that significant demand for COVID-19 testing will continue.

PCR testing demand likely to exceed supply through H1 2021

Presuming the first vaccines are approved in early 2021, there will be little opportunity for vaccination before the coming flu season, which on average peaks in February, so **demand for PCR testing seems likely to be unaffected through H1 2021**, with volumes likely to be higher than in H2 2020, in our view. Following this, we see a significant logistical challenge in vaccine rollout in terms of both the manufacturing scale-up, and administration of vaccines, which seems likely to take at least six months.

Less than half the UK population expected to be given first vaccines

The general agreement for each of the UK Vaccine Taskforce deals has been to secure access to 60m doses. With virtually all of the leading programs requiring a two-dose regimen, the goal seems to be to vaccinate around 30m people – **or less than half of the UK population –** focusing on those that are at most risk, people aged over 50, health and care home workers and the vulnerable. Even after such a full vaccination program, which could be complete sometime in H2 2021, we see demand for COVID-19 testing to continue from those not vaccinated and those unprotected by vaccines.

Novacyt's strategy to emerge from COVID-19 as a long-term winner

Formerly an attractive subsector, with few UK-listed ways to play it

Prior to the COVID-19 pandemic, we saw molecular diagnostics as an attractive subsector within healthcare, offering investors exposure to the growth in aging consumers increasingly taking responsibility for their own health and wellness, and trends such as rising infectious and chronic disease, the measured self, technology innovation, personalised medicine and expanding healthcare access in emerging markets. However, there were relatively few ways to play the theme in the UK public market.

Now a more attractive subsector

COVID-19 has changed the landscape, leading to a step-change in the long-term attractiveness of the sector and the emergence of new sector champions ready to take advantage. We see the rise in importance of diagnostics continuing for the long term as governments invest in their diagnostics infrastructure and pandemic preparedness systems globally, supporting a new wave of innovative diagnostics companies like Novacyt.

With Novacyt effectively a new UK-listed way to play it

Novacyt has excelled in innovating rapidly during the crisis, bringing a steady stream of new products to market regularly, whilst scaling up its capacity to provide the UK Government and other customers with significant confidence in supply during this critical time. Rather than bask in its early financial success, it has continued to capitalise on its competitive advantages in infectious disease testing to further differentiate itself, bringing new solutions, such as its Winterplex panel, antibody test and an impressive end-to-end near-to-patient testing system to market to serve ongoing unmet needs, which has led to game-changing successes, such as the DHSC NPT contract, with more to come.

Three-pillar strategy to deliver continued shareholder value

Amid this favourable backdrop, the company has set out a strategy to emerge from COVID-19 as a UK diagnostics winner, having identified specific growth opportunities in diagnostics that its strong balance sheet now enables it to pursue. Its goal is to deliver continued shareholder value through a three-pillar strategy of organic, R&D and accretive acquisitive growth. The focus will be in the areas where it has existing competitive advantages within its higher margin respiratory and transplant, bacterial and viral diagnostics franchises.

No longer constrained to build on its existing competitive position

COVID-19 has driven a significant expansion in Novacyt's global customer base and improved its brand recognition, driving a permanent step-up in its revenue potential. The company is no longer constrained to build its platform into the right shape around its core competitive positions. The intention is to establish direct sales capability in key markets such as the US and Europe, enabling it to drive the top-line and capture more product margin, with particularly attractive potential for its NPT system to target large addressable markets globally, which is better driven by a direct sales effort. R&D investment can also drive growth through new product introductions across both:

- Primerdesign, where many of its existing 550+ RUO products could be taken to clinical diagnostic approvals, expanding their market potential
- Lab21, which has significant potential from across the range product revitalisation

IT-IS the first COVID bolt-on, with more M&A expected

Fragmented space, with significant consolidation potential

In a fragmented industry where many potential targets have not benefitted as strongly from COVID-19, but have attractive IP or products suited to more normal times, selective and accretive acquisitions are a core part of Novacyt's strategy going forward. Its track record is already strong here, with the 2016 acquisition of Primerdesign (for c.€13.0m upfront, around 2X sales, with €3.3m in deferred consideration) – a good deal even before COVID – the key highlight so far. Post its success in 2020, Novacyt's cash puts it in the driving seat to drive a significant industry consolidation opportunity.

£10.1m bolt-on of instrument partner IT-IS

This week, Novacyt announced its first acquisition post its balance sheet transformation in 2020, the bolt-on of IT-IS International Ltd for initial cash consideration of £10.1m. IT-IS is a private UK-based diagnostic instrument development and manufacturing business based in the North East (near Middlesbrough) that was founded in 2004. It the exclusive manufacturer of Novacyt's PCR instrument range, the q16 and q32. The deal is expected to be immediately accretive, with IT-IS delivering revenues of £3.9m in 2019, with gross margins of c.55% and £0.8m in net profits, rising to a run-rate of c.£5.0m in H1 2020 helped by increased demand in the COVID-19 pandemic, with gross margins expanding to c.58%. With c.£3.6m in cash on the balance sheet at completion, the net initial cash consideration is c.£6.5m (c.1.67X trailing 2019 sales, c.8.1X net profit), with a further £1.9m earn out payable over the next two years on achievement of certain manufacturing targets.

Reduces execution risks in area of significant potential demand

We see the bolt-on of IT-IS as a small but strategically sensible and financially disciplined first step on the acquisition front for Novacyt. It is a vertical integration that evolves Novacyt to a broader diagnostic platform instrument and reagent manufacturer. It secures Novacyt's access to the IP and manufacturing of its near-patient testing (NPT) instruments, bringing these in-house, which we see reducing potential execution risk for currently signed supply NPT contracts (mainly the DHSC). This gives Novacyt end-to-end control of its NPT system, which has significant potential to see further demand and win contracts to supply a variety of decentralised settings, in line with shifting testing policy, as described in more detail on page 16.

Forecasts

Wide range of possible revenue outcomes

Ten-fold increase in revs in H1

In its recent interim results, Novacyt reported H1 FY2020 revenues of €72.4m, driven mainly by the high margin Primerdesign division, with gross margins up c.20% to 83%, driving Group EBITDA to €49.4m (68% margin), transforming the mid-year balance sheet to €19.7m net cash after pay down of all debt and significant working capital investment (€27.7m). In terms of run-rates, around 90% of revenues in the half-year were achieved in Q2, with around €25m in revenues achieved in June. Although this was a striking 10-fold increase in revenues in the period on a relative bases, it reflects Novacyt's prior focus on infectious disease testing and strong capabilities in PCR, and was a similar uplift on an absolute basis to peers such as Diasorin (Italy) and well below that seen with the large global diagnostics companies, as summarised in the table below.

Table 5: Summary of recent molecular diagnostics COVID-19 earnings impacts

Company	Period	Impact
bioMérieux	H1 2020	+16% in H1, BIOFIRE (PCR) +64% (+€190m to €489m) inst. base +40%
Cepheid (Danaher)	Q2 2020	>100% growth (+c.$250m to >$500m) 4-fold rise in instrument placements
Diasorin	H1 2020	Molecular revs +158% with €92.2m in C-19 revs
Novacyt	H1 2020	Ten-fold rise in revs to €72.2m with c. €66m of this in Q2.
Qiagen	Q2 2020	+19% CER growth with "significant" growth (less colour due to bid sit) in C-19 consumables and relevant instrument placements up 60-100%+
Roche	Q2 2020	>100% growth in molecular diagnostics (+>500m CHF to >1bn CHF)
ThermoFisher	H1 2020	+$1.5bn in C-19 response revs in H1, with c.$4.5bn expected for 2020

Source: Company results releases & transcripts (Alphasense)

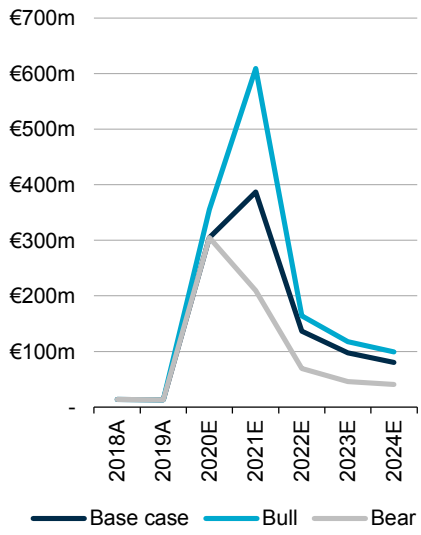
Base case, bull and bear models to capture wide uncertainty range

Looking forward over H2 2020 and 2021, there is a potentially wide range of possible outcomes for the business, depending on key factors such as:

- Novacyt's success in winning further COVID-19 contracts/tenders in the UK and other countries, and extensions of current contracts
- Progress with ex-UK sales via distributors and a potential move to direct sales in certain territories
- The severity of the flu season and anticipated second wave of COVID-19 infections
- The extent of testing performed, with Novacyt particularly dependent on the UK government's strategy and successful execution in ramping up delivery of increased testing in the coming winter season
- The longevity of testing, which depends on the potential success and protection provided by vaccine programs and subsequent pace of rollout of vaccine/vaccines in the UK and beyond.

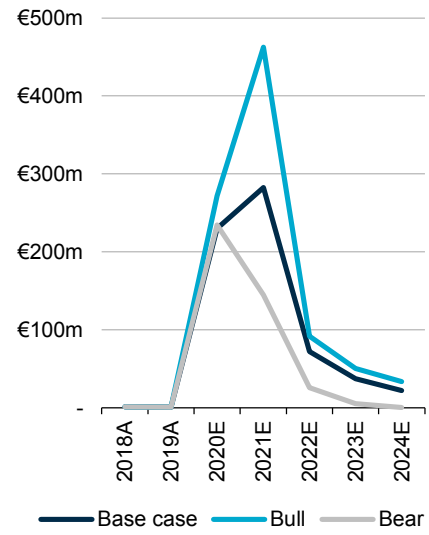
We have built an initial base case forecast based on a mid-range estimate of how we see these factors evolving over the next 18 months, together with a bull case scenario that examines potential realistic upside (note there are blue-sky scenarios possible further above this), as well as a bear case that tries to capture a minimum forecast outcome at this stage. Given the large uncertainty range involved, we use euros and sterling interchangeably at a 1:1 ratio to keep things simple for now, and we see further updates as likely as events unfold, which should narrow the uncertainty range over time.

Figure 14: Revenue scenarios



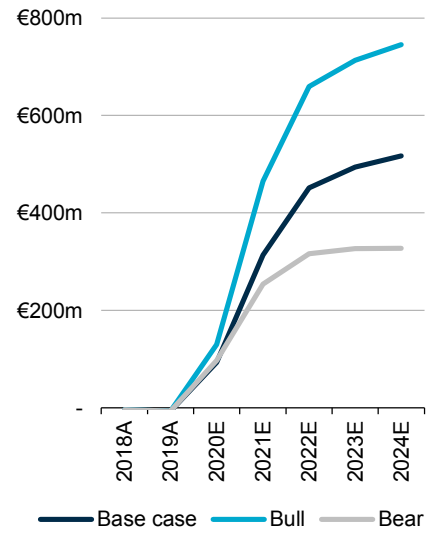
Source: Company & Numis Securities Research

Figure 15: EBITDA scenarios



Source: Company & Numis Securities Research

Figure 16: Net cash scenarios



Source: Company & Numis Securities Research

FY2020 outlook

Initial base case sees an over three-fold increase in H2 2020

At its recent H1 2020 results, Novacyt management outlined a very positive short-term outlook, guiding to stronger revenues in H2, with full-year revenues expected to exceed €150m, with EBITDA exceeding €100m in the year. With an encouraging c.€66m in Q2 and c.€25m in revenues in the month of June, we saw upside to this figure based on already signed contracts alone, as well as a high possibility of new contract wins. The recent £150m+ contract with the Department of Health & Social Care (DHSC) is set to be additive to this. This covers a period of up to six months in two phases. Phase one covers an initial fixed term of 14 weeks, which will see immediate deployment of 300 of Novacyt's PCR instruments and related test consumables, with a minimum value of £150m for this 14-week period. Assuming a c.€15m minimum run-rate per month prior to this contract, or c.€45m in Q3 revenues, we see the final quarter run-rate expanding by around €45-50m per month, driving c.€180-190m in Q4 revenues, or c.€305m for the full year.

Bull case

Bull case looks for >€275m in H2 revs, up c.4-fold on H1

In our bull case, we see the potential for either a higher underlying run-rate of c.€25m a month or an early triggering of the second phase of the recent DHSC contract to drive an additional €50m+ in H2 revenues, driving our full year forecast up c.20% to c.€355m.

Bear case

With good near-term visibility over the likely minimum for 2020, our bear case forecasts model the same revenues as the base case for the immediate short term in 2020, diverging from 2021 onwards, as the range of potential outcomes increases.

FY2021 outlook

"I see scenarios above 2020, and I see scenarios below"… There's so many variables that it's very hard to pin down the number. So **the one thing we do know is the number should be very large**, and then we'll narrow it down as it gets closer to 2021." **Marc Casper, CEO, Thermo Fisher, on the 2021 outlook**.

Even if a significant increase in community testing is achieved through the government's "moon-shot" rapid lateral flow antigen tests coming through in H1 2021, many of these will drive a requirement for confirmatory testing. Also, much of Novacyt's testing volume is performed in the clinical/healthcare setting, where the increased accuracy of PCR will remain desirable. So, we see demand for PCR testing continuing to exceed supply for at least H1 2021, where we would envisage an increased run-rate of testing on H2 2020.

H2 2021 is more difficult to call, given that there is a more realistic prospect of vaccines potentially starting to be rolled out on this timeframe. However, despite all the plans in place to do this quickly, it is likely to be a protracted process, given the logistical challenges and some population caution seems likely in advance of longer-term safety data in a sufficient number of patients.

H1 2021 likely to exceed H2 2020, in our view

Our initial base case forecasts see Novacyt's H1 2021 revenues likely to exceed those in H2 2020, given the increased exit run-rate through this period, and the fact that the flu season normally peaks in February, on average. Assuming Phase one of the recent DHSC contract is extended by a minimum of 10 weeks, this will drive around €100m in further revenue into Q1, with the potential for this to extend beyond. Our initial €380m+ base case revenue estimates assume Q1 2021 is as strong as Q4 2020, with the quarterly run rate fading back to c.€40-50m by year end given the more limited visibility on H2 at the moment.

Bull case

Bull case sees 2021 revs >€600m

In our bull case for 2021, we assume that the optional second phase of Novacyt's recent DHSC NPT contract is triggered. This provides for up to 700 additional Novacyt PCR instruments being placed into hospitals, and, depending on the uptake, could be larger than the first phase. The size of this second phase of the contract could range up to £350-600m over a similar 24-week period, versus £150-250m for the first phase, if all 700 instruments are ordered, with each instrument supporting the same consumables pull-through. At the moment, our bull case assumes an additional £250m+ in revenues from this being exercised to some extent, at a similar size to Phase one, with an extra 300 instruments, with upside to this possible as events unfold. We model c.£50m of this falling in 2020 and c.£200m+ in 2021, driving our bull case forecasts to >€600m for the year.

Blue sky

Blue sky sees 2021 revs >€1bn+

In a blue sky scenario, where the second phase of the DHSC hospital testing contract was exercised in full to its maximum, the total value of the contract could range as high as £850m, which would potentially drive our 2021 revenue forecasts above €1bn at the top end of the range. We see such a scenario as possible given the implicit demand for testing and Novacyt's track record of delivery, and factor this into our valuation with a 10% weighting.

Bear case

Bear case reflects potential bull case for society from vaccines

Our bear case forecasts assume lower demand for testing in 2021 compared to 2020, based on a more positive outcome than anticipated from rapid testing rolling out sooner than anticipated, and the vaccine programs providing higher protection than anticipated, with smooth execution on population rollout early in 2021. In such a scenario, we envisage that Phase one of the DHSC contract would likely be extended into the second 10-week phase to some extent, but phase two not exercised at all, with underlying revenues tailing off through H1 2021, into H2, though likely still at a higher run-rate than H1 2020, when Novacyt was scaling up its capacity. In this scenario, we see 2021 revenues falling by c.33% to c.€200m.

Other forecast assumptions

Gross margins fade from mid-80s to high 70s

We see Lab21 revenues recovering slightly in H2 2020 as the rest of the diagnostics industry recovers slightly post peak lockdowns, with the top-line accelerating into double-digits over the remainder of the forecast. This is driven by the positive impact of Novacyt having adequate working capital in the business, through increased investment in the sales platform and new product development, with upside potential should Novacyt see significant traction with its COVID-19 antibody test as vaccines roll out. We model Primerdesign gross margins (pre-IT-IS) remaining strong at 80%+, moderating slightly from the c.85% seen in H1 2020 on the significantly higher revenues, down to c.80% over the forecast, brought down slightly by the impact of the IT-IS acquisition (greater instrument mix). On the other hand, we see Lab21 gross margins expanding modestly over the period. On a Group basis, the divisional mix drags gross margins from the mid-80s back into the high 70s as the COVID-19 boost fades over the forecast.

Significant step-up in sales and marketing and R&D likely

Below gross profits, we see the operating cost base of the company, in its current shape, growing significantly, but dwarfed by the significant boost in gross profits coming in. We model opex rising c.25% in H2 over H1 2020, then c.50% in 2021 as the pace of organic investment steps up, with some of this cost, as the sales and marketing level likely to be variable (on fixed-term contracts) through the initial COVID-19 boost. We envisage Novacyt will increase investment in R&D to drive the underlying top-line through a permanently increased pace of new product development, with even more investment in sales and marketing, where it is likely to start building direct sales capabilities beyond the UK to support a permanently higher revenue base.

Benefits from UK patent box

We model an effective tax rate of c.13% in 2020, in line with that seen in H1, as Novacyt benefits from the UK Patent Box, with this rising gradually to c.15% over the forecast.

FY2022 and beyond

Bear case

Bear case sees Novacyt return to breakeven…

…but still generating over €300m in cash during COVID-19 period

In modelling the fade in revenues and EBITDA post the initial COVID-19 boost over 2020-21, we started with the bear case first: asking, how bad could it get post the COVID-19 peak? The most pessimistic view we could envisage was Group EBITDA fading all the way to near-breakeven, back where it started pre-COVID. We see this as too pessimistic a view, but see it as instructive, as it provides a downside DCF valuation, and low-end estimate of Novacyt's potential cash pool. Even in this scenario, we see cash of nearly €90m+ by end 2020, rising to over €300m over the forecast. In reality, this would give the company a significant cash advantage over many other small diagnostics companies during the COVID-19 outbreak, enabling it to supplement its organic investments to build a larger, sustainable diagnostics business through M&A.

Base case

2021 assumed as the peak for the moment

The most appropriate base case scenario we envisage at the moment is that 2021 is likely a peak year for COVID-19 testing, with our base assumption that the rollout of at least one vaccine program should complete over the course of the year, driving 2021 as a near-term peak year for Novacyt's near-term revenues. This is set to drive the company's cash flow significantly, giving Novacyt significant working capital available to drive all areas of its business.

Base case sees a fade to c.€22m in sustainable EBITDA…

Our base case models a fade period over 2022 to 2024, which makes a broad-brush assumption that the underlying business ex-COVID grows to c.€10m in sustainable EBITDA, helped by:

…driven by an expanded underlying non-COVID business…

- **Increased cross-selling** from a significantly expanded customer base, on a global basis, with a significantly enhanced brand and reputation coming out of the crisis.
- Improved working capital, driving increased investment in **new product development** across both Primerdesign, where more of its 550+ RUO products could be taken through to CE-marked clinical approvals, and Lab21, which has significant potential from across the range product revitalisation.
- Improved working capital, driving increased investment in **sales and marketing** across both Primerdesign and Lab21, with key markets such as the US and Europe being evaluated, while RoW markets will see further development of the distribution and partner network.

…and continued long-term demand for COVID-19 testing

On top of this, we see long-term demand for COVID-19 testing to continue within Novacyt's current customer footprint into the long term at some level, with long term UK rapid development and manufacturing capability now more strategically important. We model at a further €10m in sustainable EBITDA for now, driving our initial year 5 organic terminal EBITDA estimate to €20m, with the IT-IS bolt-on lifting this to €22m/£20m.

With M&A to drive further upside

Beyond these organic initiatives, deployment of some of the excess cash on the balance sheet is likely to be a significant strategic priority, with selected, accretive M&A of products/technologies/capabilities/assets to drive sustainable profits to above these levels. Our base case forecast sees >€300m in excess cash being generated by end 2021. If deployed into private company bolt-ons at an average multiple of c.10x EV/EBITDA, this would drive an additional €30m+ in EBITDA. If executed well, with a coherent, growing diagnostics business built out, we would see such a company having the potential to drive a **sustainable £1bn+ market cap in the future**.

Potential to build sustainable £1bn+ market cap business

Bull case

In our bull-case, we model a less aggressive fade in revenues over 2022-24, with a higher level of sustainable long-term COVID-19 testing (and other pandemic preparedness revenues) demand, driving a c.50% higher year 5 terminal EBITDA estimate of c.€33m/£30m.

Base case forecasts

Table 6: P&L Income statement

Year-end December (€m)	2018A	2019A	2020E	2021E	2022E	2023E	2024E
Primerdesign (inc. IT-IS)	6.2	6.3	301	381	131	91	73
- growth		*1%*	*4667%*	*27%*	*-66%*	*-31%*	*-20%*
- % sales	*45%*	*48%*	*99%*	*99%*	*96%*	*93%*	*90%*
Lab21	7.2	6.8	4	5	6	7	8
- growth		*-6%*	*-35%*	*15%*	*15%*	*15%*	*15%*
- % sales	*52%*	*52%*	*1%*	*1%*	*4%*	*7%*	*10%*
Lab (divested Jul-19)	0.3	-					
Total Revenues	**13.7**	**13.1**	**305**	**387**	**137**	**97**	**81**
- growth		*-5%*	*2231%*	*27%*	*-65%*	*-29%*	*-17%*
COGS	(5.1)	(4.7)	(52)	(66)	(24)	(18)	(15)
Primerdesign (inc. IT-IS) GP	5.2	5.4	251	315	107	73	58
- gross margin	*84%*	*85%*	*83%*	*83%*	*82%*	*80%*	*79%*
Lab21 gross profit	3.4	3.0	2	2	3	4	4
- gross margin	*47%*	*44%*	*44%*	*47%*	*50%*	*51%*	*52%*
Gross profit	**8.6**	**8.4**	**253**	**318**	**110**	**76**	**62**
- gross margin	*63%*	*64%*	*83%*	*82%*	*80%*	*78%*	*77%*
R&D	(0.4)	(0.5)	(2)	(7)	(6)	(7)	(8)
- % sales	*3%*	*3%*	*1%*	*1.8%*	*5%*	*8%*	*10%*
SG&A	(8.6)	(9.2)	(23.1)	(34.5)	(29.2)	(28.8)	(28.6)
- % sales	*62%*	*70%*	*8%*	*9%*	*21%*	*30%*	*36%*
Adj EBIT	**(0.4)**	**(1.2)**	**228**	**281**	**70**	**35**	**20**
- EBIT margin	*-3.1%*	*-9.5%*	*75%*	*73%*	*51%*	*36%*	*24%*
Depreciation	1.5	1.8	2	2	2	2	2
Adj EBITDA	**1.0**	**0.6**	**230**	**283**	**72**	**37**	**22**
- EBITDA margin	7.6%	4.4%	75%	73%	53%	38%	27%
Net interest	(0.7)	(2.1)	(2)	0	0	0	1
Adj PBT	**(1.1)**	**(3.4)**	**226**	**281**	**70**	**36**	**20**
Adj. Tax (NSe)	(0.0)	0.0	(29)	(39)	(11)	(5)	(3)
Adj Net profit	**(1.2)**	**(3.4)**	**197**	**241**	**60**	**30**	**17**
Ave shares - diluted (m)	37.7	45.7	67	74	75	76	77
Adj EPS (dil., EURc)	**(3.1)**	**(7.4)**	**292**	**326**	**80**	**40**	**22**
Exceptionals	(1.0)	(0.5)	(1)	-	-	-	-
Op profit	(1.4)	(1.8)	227	281	70	35	20
PBT	(2.1)	(3.9)	225	281	70	36	20
Tax	(0.0)	0.0	(29)	(39)	(11)	(5)	(3)
Net profit from continuing ops	(2.1)	(3.9)	196	241	60	30	17
EPS (basic) – continuing ops	(5.6)	(8.5)	300	330	81	40	23
EPS (dil.) - continuing ops	(5.6)	(8.5)	291	326	80	40	22

Source: Company & Numis Securities Research

Table 7: Cash flow statement

Year-end December (€m)	2018A	2019A	2020E	2021E	2022E	2023E	2024E
EBITDA	**1.0**	**0.6**	**230**	**283**	**72**	**37**	**22**
Working capital	1.2	1.3	(94)	(18)	81	14	7
Discontinued ops	(1.8)	(1.3)					
Other	(0.8)	(0.5)	(1)	(1)	(1)	(1)	(1)
Cash from ops	**(0.4)**	**0.1**	**135**	**264**	**152**	**51**	**28**
Tax	(0.2)	(0.1)	(29)	(39)	(11)	(5)	(3)
Interest	(0.7)	(1.1)	0	0	0	0	0
Net Cash from ops	**(1.2)**	**(1.1)**	**106**	**225**	**142**	**46**	**26**
Capex	(0.7)	(0.3)	(1)	(2)	(2)	(2)	(2)
- % sales	5.0%	2.6%	0	0	0	3%	3%
Operating FCF	**(1.9)**	**(1.4)**	**105**	**223**	**140**	**44**	**24**
M&A	(2.0)	(1.0)	(7)	(1)	(1)	-	-
Other	0.0	0.0	-	-	-	-	-
Investing CF	**(2.7)**	**(1.3)**	**(8)**	**(3)**	**(3)**	**(2)**	**(2)**
Share issuance	(0.0)	(0.2)	3	-	-	-	-
Debt issuance	1.4	4.2	(8)	-	-	-	-
Interest	(0.6)	(1.0)	(1)	(1)	(1)	(1)	(1)
Financing CF	**0.8**	**3.0**	**(6)**	**(1)**	**(1)**	**(1)**	**(1)**
Increase Cash	**(3.2)**	**0.6**	**91**	**221**	**138**	**43**	**23**

Source: Company & Numis Securities Research

Table 8: Balance sheet statement

Year-end December (€m)	2018A	2019A	2020E	2021E	2022E	2023E	2024E
Goodwill	16.1	15.9	23	24	25	25	25
Intangible Assets	4.9	4.3	4	4	4	4	4
Tangible Assets	1.2	3.5	3	3	2	3	2
Non-current financial assets	0.2	0.2	0	0	0	0	0
Other	-	0.2	0	0	0	0	0
Fixed Assets	**22.5**	**24.2**	**30**	**31**	**32**	**33**	**32**
Inventories	2.3	2.4	39	44	14	9	6
Debtors	3.9	2.2	73	92	33	22	17
Other	0.3	0.4	0	0	0	0	0
Cash	1.1	1.8	93	314	451	494	517
Current assets	**7.7**	**6.8**	**205**	**451**	**499**	**526**	**541**
Assets held for sale	2.3	0.1					
Total assets	**32.5**	**31.1**	**236**	**482**	**531**	**558**	**573**
ST Debt	(3.1)	(2.2)	-	-	-	-	-
Lease		(0.3)	(0)	(0)	(0)	(0)	(0)
Creditors	(4.6)	(4.6)	(17)	(24)	(15)	(14)	(13)
Tax liability			(6)	(8)	(2)	(1)	(1)
Deferred consideration	(1.6)	-	-	-	-	-	-
Provisions	(0.1)	(0.1)	(0)	(0)	(0)	(0)	(0)
Other	(0.4)	(0.6)	(1)	(1)	(1)	(1)	(1)
ST liabilities	**(9.8)**	**(7.7)**	**(24)**	**(32)**	**(18)**	**(16)**	**(15)**
Liabilities held for sale	(0.1)	-					
Net current assets	**(2.0)**	**(0.9)**	**181**	**418**	**481**	**510**	**526**
LT Debt	(2.3)	(6.1)	-	-	-	-	-
Lease		(2.4)	(2)	(2)	(2)	(2)	(2)
Provisions	(0.2)	(0.2)	(0)	(0)	(0)	(0)	(0)
Deferred tax	(0.1)	(0.0)	(0)	(0)	(0)	(0)	(0)
Other	-	-	-	-	-	-	-
LT liabilities	**(2.5)**	**(8.8)**	**(3)**	**(3)**	**(3)**	**(3)**	**(3)**
Total liabilities	**(12.4)**	**(16.5)**	**(26)**	**(35)**	**(20)**	**(18)**	**(17)**
Net Assets	**20.1**	**14.6**	**209**	**447**	**511**	**540**	**556**

Source: Company & Numis Securities Research

Bull case forecasts

Table 9: P&L Income statement

Year-end December (€m)	2018A	2019A	2020E	2021E	2022E	2023E	2024E
Primerdesign (inc. IT-IS)	6.2	6.3	351	604	158	110	90
- growth		*1%*	*5467%*	*72%*	*-74%*	*-30%*	*-18%*
- % sales	*45%*	*48%*	*99%*	*99%*	*96%*	*94%*	*91%*
Lab21	7.2	6.8	4	5	6	7	9
- growth		*-6%*	*-35%*	*20%*	*20%*	*20%*	*20%*
- % sales	*52%*	*52%*	*1%*	*1%*	*4%*	*6%*	*9%*
Lab (divested Jul-19)	0.3	-					
Total Revenues	**13.7**	**13.1**	**355**	**609**	**164**	**117**	**99**
- growth		*-5%*	*2617%*	*71%*	*-73%*	*-29%*	*-16%*
COGS	(5.1)	(4.7)	(60)	(104)	(28)	(20)	(17)
Primerdesign (inc. IT-IS) GP	5.2	5.4	293	498	130	89	73
- gross margin	*84%*	*85%*	*83%*	*83%*	*82%*	*81%*	*81%*
Lab21 gross profit	3.4	3.0	2	2	3	4	5
- gross margin	*47%*	*44%*	*44%*	*47%*	*50%*	*51%*	*52%*
Gross profit	**8.6**	**8.4**	**295**	**501**	**133**	**93**	**77**
- gross margin	*63%*	*64%*	*83%*	*82%*	*81%*	*79%*	*78%*
R&D	(0.4)	(0.5)	(2)	(8)	(8)	(9)	(9)
- % sales	*3%*	*3%*	*0%*	*1.3%*	*5%*	*8%*	*10%*
SG&A	(8.6)	(9.2)	(23.1)	(38.6)	(30.1)	(29.5)	(29.4)
- % sales	*62%*	*70%*	*7%*	*6%*	*18%*	*25%*	*30%*
Adj EBIT	**(0.4)**	**(1.2)**	**270**	**461**	**90**	**48**	**31**
- EBIT margin	*-3.1%*	*-9.5%*	*76%*	*76%*	*55%*	*41%*	*31%*
Depreciation	1.5	1.8	2	2	2	2	2
Adj EBITDA	**1.0**	**0.6**	**272**	**463**	**92**	**51**	**33**
- EBITDA margin	7.6%	4.4%	77%	76%	56%	43%	34%
Net interest	(0.7)	(2.1)	(2)	0	1	1	1
Adj PBT	**(1.1)**	**(3.4)**	**268**	**461**	**90**	**49**	**32**
Adj. Tax (NSe)	(0.0)	0.0	(35)	(65)	(14)	(7)	(5)
Adj Net profit	**(1.2)**	**(3.4)**	**233**	**396**	**77**	**42**	**27**
Ave shares - diluted (m)	37.7	45.7	67	74	75	76	77
Adj EPS (dil., EURc)	**(3.1)**	**(7.4)**	**346**	**535**	**102**	**55**	**35**
Exceptionals	(1.0)	(0.5)	(1)	-	-	-	-
Op profit	(1.4)	(1.8)	269	461	90	48	31
PBT	(2.1)	(3.9)	267	461	90	49	32
Tax	(0.0)	0.0	(35)	(65)	(14)	(7)	(5)
Net profit from continuing ops	(2.1)	(3.9)	233	396	77	42	27
EPS (basic) – continuing ops	(5.6)	(8.5)	356	542	103	55	36
EPS (dil.) - continuing ops	(5.6)	(8.5)	345	535	102	55	35

Source: Company & Numis Securities Research

Table 10: Cash flow statement

Year-end December (€m)	2018A	2019A	2020E	2021E	2022E	2023E	2024E
EBITDA	**1.0**	**0.6**	**272**	**463**	**92**	**51**	**33**
Working capital	1.2	1.3	(94)	(59)	121	15	7
Discontinued ops	(1.8)	(1.3)					
Other	(0.8)	(0.5)	(1)	(1)	(1)	(1)	(1)
Cash from ops	**(0.4)**	**0.1**	**177**	**403**	**212**	**65**	**40**
Tax	(0.2)	(0.1)	(35)	(65)	(14)	(7)	(5)
Interest	(0.7)	(1.1)	0	0	0	0	0
Net Cash from ops	**(1.2)**	**(1.1)**	**143**	**339**	**199**	**58**	**36**
Capex	(0.7)	(0.3)	(1)	(2)	(2)	(3)	(2)
- % sales	5.0%	2.6%	0	0	0	3%	3%
Operating FCF	**(1.9)**	**(1.4)**	**142**	**337**	**197**	**55**	**33**
M&A	(2.0)	(1.0)	(7)	(1)	(1)	-	-
Other	0.0	0.0	-	-	-	-	-
Investing CF	**(2.7)**	**(1.3)**	**(8)**	**(3)**	**(3)**	**(3)**	**(2)**
Share issuance	(0.0)	(0.2)	3	-	-	-	-
Debt issuance	1.4	4.2	(8)	-	-	-	-
Interest	(0.6)	(1.0)	(1)	(1)	(1)	(1)	(1)
Financing CF	**0.8**	**3.0**	**(6)**	**(1)**	**(1)**	**(1)**	**(1)**
Increase Cash	**(3.2)**	**0.6**	**128**	**335**	**195**	**54**	**32**

Source: Company & Numis Securities Research

Table 11: Balance sheet statement

Year-end December (€m)	2018A	2019A	2020E	2021E	2022E	2023E	2024E
Goodwill	16.1	15.9	23	24	25	25	25
Intangible Assets	4.9	4.3	4	4	4	4	4
Tangible Assets	1.2	3.5	3	3	2	3	3
Non-current financial assets	0.2	0.2	0	0	0	0	0
Other	-	0.2	0	0	0	0	0
Fixed Assets	**22.5**	**24.2**	**30**	**31**	**32**	**33**	**33**
Inventories	2.3	2.4	39	59	13	8	5
Debtors	3.9	2.2	73	124	34	23	18
Other	0.3	0.4	0	0	0	0	0
Cash	1.1	1.8	130	465	660	713	746
Current assets	**7.7**	**6.8**	**242**	**648**	**707**	**745**	**769**
Assets held for sale	2.3	0.1					
Total assets	**32.5**	**31.1**	**272**	**680**	**739**	**778**	**803**
ST Debt	(3.1)	(2.2)	-	-	-	-	-
Lease		(0.3)	(0)	(0)	(0)	(0)	(0)
Creditors	(4.6)	(4.6)	(17)	(30)	(15)	(14)	(14)
Tax liability			(6)	(10)	(2)	(1)	(1)
Deferred consideration	(1.6)	-	-	-	-	-	-
Provisions	(0.1)	(0.1)	(0)	(0)	(0)	(0)	(0)
Other	(0.4)	(0.6)	(1)	(1)	(1)	(1)	(1)
ST liabilities	**(9.8)**	**(7.7)**	**(24)**	**(42)**	**(18)**	**(16)**	**(15)**
Liabilities held for sale	(0.1)	-					
Net current assets	**(2.0)**	**(0.9)**	**218**	**607**	**689**	**729**	**754**
LT Debt	(2.3)	(6.1)	-	-	-	-	-
Lease		(2.4)	(2)	(2)	(2)	(2)	(2)
Provisions	(0.2)	(0.2)	(0)	(0)	(0)	(0)	(0)
Deferred tax	(0.1)	(0.0)	(0)	(0)	(0)	(0)	(0)
Other	-	-	-	-	-	-	-
LT liabilities	**(2.5)**	**(8.8)**	**(3)**	**(3)**	**(3)**	**(3)**	**(3)**
Total liabilities	**(12.4)**	**(16.5)**	**(26)**	**(44)**	**(21)**	**(19)**	**(18)**
Net Assets	**20.1**	**14.6**	**246**	**636**	**719**	**759**	**785**

Source: Company & Numis Securities Research

Bear case forecasts

Table 12: P&L Income statement

Year-end December (€m)	2018A	2019A	2020E	2021E	2022E	2023E	2024E
Primerdesign (inc. IT-IS)	6.2	6.3	301	204	64	40	35
- growth		*1%*	*4667%*	*-32%*	*-69%*	*-37%*	*-13%*
- % sales	*45%*	*48%*	*99%*	*98%*	*92%*	*88%*	*85%*
Lab21	7.2	6.8	4	5	5	6	6
- growth		*-6%*	*-35%*	*5%*	*5%*	*5%*	*5%*
- % sales	*52%*	*52%*	*1%*	*2%*	*8%*	*12%*	*15%*
Lab (divested Jul-19)	0.3	-					
Total Revenues	**13.7**	**13.1**	**305**	**210**	**69**	**46**	**41**
- growth		*-5%*	*2231%*	*-31%*	*-67%*	*-34%*	*-11%*
COGS	(5.1)	(4.7)	(47)	(32)	(11)	(7)	(6)
Primerdesign (inc. IT-IS) GP	5.2	5.4	255	174	54	34	29
- gross margin	*84%*	*85%*	*85%*	*85%*	*85%*	*85%*	*84%*
Lab21 gross profit	3.4	3.0	2	2	3	3	3
- gross margin	*47%*	*44%*	*44%*	*47%*	*50%*	*51%*	*52%*
Gross profit	**8.6**	**8.4**	**257**	**176**	**57**	**37**	**33**
- gross margin	*63%*	*64%*	*84%*	*84%*	*82%*	*81%*	*80%*
R&D	(0.4)	(0.5)	(2)	(4)	(1)	(1)	(1)
- % sales	*3%*	*3%*	*1%*	*1.8%*	*2%*	*3%*	*3%*
SG&A	(8.6)	(9.2)	(23.1)	(29.2)	(27.1)	(26.9)	(27.0)
- % sales	*62%*	*70%*	*8%*	*14%*	*39%*	*59%*	*66%*
Adj EBIT	**(0.4)**	**(1.2)**	**233**	**143**	**23**	**3**	**(2)**
- EBIT margin	*-3.1%*	*-9.5%*	*76%*	*68%*	*34%*	*6%*	*-5%*
Depreciation	1.5	1.8	2	2	2	2	2
Adj EBITDA	**1.0**	**0.6**	**234**	**145**	**26**	**5**	**0**
- EBITDA margin	7.6%	4.4%	77%	69%	37%	11%	1%
Net interest	(0.7)	(2.1)	(2)	0	0	0	0
Adj PBT	**(1.1)**	**(3.4)**	**230**	**143**	**24**	**3**	**(2)**
Adj. Tax (NSe)	(0.0)	0.0	(30)	(20)	(4)	(0)	0
Adj Net profit	**(1.2)**	**(3.4)**	**200**	**123**	**20**	**3**	**(2)**
Ave shares - diluted (m)	37.7	45.7	67	74	75	76	77
Adj EPS (dil., EURc)	**(3.1)**	**(7.4)**	**298**	**166**	**27**	**3**	**(2)**
Exceptionals	(1.0)	(0.5)	(1)	-	-	-	-
Op profit	(1.4)	(1.8)	232	143	23	3	(2)
PBT	(2.1)	(3.9)	230	143	24	3	(2)
Tax	(0.0)	0.0	(30)	(20)	(4)	(0)	0
Net profit from continuing ops	(2.1)	(3.9)	200	123	20	3	(2)
EPS (basic) – continuing ops	(5.6)	(8.5)	306	168	27	4	(2)
EPS (dil.) - continuing ops	(5.6)	(8.5)	297	166	27	3	(2)

Source: Company & Numis Securities Research

Table 13: Cash flow statement

Year-end December (€m)	2018A	2019A	2020E	2021E	2022E	2023E	2024E
EBITDA	**1.0**	**0.6**	**234**	**145**	**26**	**5**	**0**
Working capital	1.2	1.3	(94)	37	45	8	3
Discontinued ops	(1.8)	(1.3)					
Other	(0.8)	(0.5)	(1)	(1)	(1)	(1)	(1)
Cash from ops	**(0.4)**	**0.1**	**139**	**181**	**70**	**13**	**2**
Tax	(0.2)	(0.1)	(30)	(20)	(4)	(0)	0
Interest	(0.7)	(1.1)	0	0	0	0	0
Net Cash from ops	**(1.2)**	**(1.1)**	**110**	**161**	**66**	**12**	**3**
Capex	(0.7)	(0.3)	(1)	(2)	(2)	(1)	(1)
- % sales	5.0%	2.6%	0	0	0	3%	3%
Operating FCF	**(1.9)**	**(1.4)**	**109**	**159**	**64**	**11**	**2**
M&A	(2.0)	(1.0)	(7)	(1)	(1)	-	-
Other	0.0	0.0	-	-	-	-	-
Investing CF	**(2.7)**	**(1.3)**	**(8)**	**(3)**	**(3)**	**(1)**	**(1)**
Share issuance	(0.0)	(0.2)	3	-	-	-	-
Debt issuance	1.4	4.2	(8)	-	-	-	-
Interest	(0.6)	(1.0)	(1)	(1)	(1)	(1)	(1)
Financing CF	**0.8**	**3.0**	**(6)**	**(1)**	**(1)**	**(1)**	**(1)**
Increase Cash	**(3.2)**	**0.6**	**95**	**157**	**62**	**10**	**1**

Source: Company & Numis Securities Research

Table 14: Balance sheet statement

Year-end December (€m)	2018A	2019A	2020E	2021E	2022E	2023E	2024E
Goodwill	16.1	15.9	23	24	25	25	25
Intangible Assets	4.9	4.3	4	4	4	4	4
Tangible Assets	1.2	3.5	3	3	2	1	0
Non-current financial assets	0.2	0.2	0	0	0	0	0
Other	-	0.2	0	0	0	0	0
Fixed Assets	**22.5**	**24.2**	**30**	**31**	**32**	**31**	**30**
Inventories	2.3	2.4	39	24	7	4	3
Debtors	3.9	2.2	73	50	17	10	9
Other	0.3	0.4	0	0	0	0	0
Cash	1.1	1.8	97	254	316	327	327
Current assets	**7.7**	**6.8**	**209**	**328**	**340**	**342**	**340**
Assets held for sale	2.3	0.1					
Total assets	**32.5**	**31.1**	**239**	**359**	**373**	**373**	**370**
ST Debt	(3.1)	(2.2)	-	-	-	-	-
Lease		(0.3)	(0)	(0)	(0)	(0)	(0)
Creditors	(4.6)	(4.6)	(17)	(16)	(11)	(10)	(10)
Tax liability			(6)	(4)	(1)	(0)	0
Deferred consideration	(1.6)	-	-	-	-	-	-
Provisions	(0.1)	(0.1)	(0)	(0)	(0)	(0)	(0)
Other	(0.4)	(0.6)	(1)	(1)	(1)	(1)	(1)
ST liabilities	**(9.8)**	**(7.7)**	**(24)**	**(21)**	**(12)**	**(11)**	**(11)**
Liabilities held for sale	(0.1)	-					
Net current assets	**(2.0)**	**(0.9)**	**185**	**307**	**328**	**331**	**329**
LT Debt	(2.3)	(6.1)	-	-	-	-	-
Lease		(2.4)	(2)	(2)	(2)	(2)	(2)
Provisions	(0.2)	(0.2)	(0)	(0)	(0)	(0)	(0)
Deferred tax	(0.1)	(0.0)	(0)	(0)	(0)	(0)	(0)
Other	-	-	-	-	-	-	-
LT liabilities	**(2.5)**	**(8.8)**	**(3)**	**(3)**	**(3)**	**(3)**	**(3)**
Total liabilities	**(12.4)**	**(16.5)**	**(26)**	**(23)**	**(15)**	**(14)**	**(13)**
Net Assets	**20.1**	**14.6**	**213**	**336**	**358**	**360**	**357**

Source: Company & Numis Securities Research

Valuation

DCF the most appropriate approach

Peak cash flow and sustainable EBITDA the key value drivers

Given the dominance of its near-term cash flows to the Novacyt story, we see DCF as the most appropriate valuation approach for the company at the moment. The two key drivers of this value are:

- The extent of the assumed near-term peak in revenues driven by the COVID-19 testing boom, the key driver of near-term cash flows (PV FCF)
- The level of sustainable EBITDA beyond this, the key driver of terminal value (PV TV)

Scenario-based target price of 1,365p

Given the wide range in potential financial outcomes for Novacyt over 2020-21, we derive our target price using a scenario-based approach that weights each of our base, bull, bear and blue-sky scenarios according to our current conviction and visibility around what will be achieved. Our main conviction is currently weighted evenly (40:40) between our base (950p) and bull case forecasts (1,500p), with a 10% weighting to our bear (450p) and blue-sky (3,400p) scenarios, driving our scenario-based target price to 1,365p as laid out in the table below.

Table 15: Scenario-based target price

	Base	Bull	Bear	Blue-sky
Description	H1 exit run rate + first phase of DHSC NPT contract	Second phase of DHSC NPT contract doubles its size	Vaccines return life to normal driving significant reduction in testing in 2021	Maximum revs from NPT contract. Further contract wins. Sustained NHS revs into long term
Near-term peak revs	€387m (2021)	€609m (2021)	€305m (2020)	€1,001m (2021)
Terminal EBITDA	€22m	€33m	€0m	€100m
PV near-term cash flow	€510m	€732m	€337m	€1,307m
PV terminal value	€238m	€444m	€28m	€1,355m
NPV / share	**950p**	**1,500p**	**450p**	**3,400p**
Weighting	*40%*	*40%*	*10%*	*10%*
Target price	**1,365p**			

Source: Numis Securities Research

These four scenarios are each laid out in full detail below.

Base case valuation of 950p

Three-stage DCF approach

Our DCF approach is essentially a 3-stage DCF, with the first stage equivalent to our explicit near-term two-year forecasts to end 2021, which we see absorbing a meaningful amount of working capital, followed by a three-year (fast) fade period, where we see working capital being released and initially assume a terminal EBITDA of €22m (as described in more detail on page 29), followed by 0% perpetuity growth. This drives a base case valuation of 950p, as shown in the table below. We factor this into our valuation with a 40% weighting.

Table 16: Novacyt base case DCF valuation

Year end December (€m)	2020E	2021E	2022E	2023E	2024E
Revenues	**305**	**387**	**137**	**97**	**81**
- *growth*	*2231%*	*27%*	*-65%*	*-29%*	*-17%*
EBITDA	**230**	**283**	**72**	**37**	**22**
- *% sales*	*75%*	*73%*	*53%*	*38%*	*27%*
Working capital	(94)	(18)	81	14	7
Tax	(29)	(39)	(11)	(5)	(3)
Capex (inc. M&A)	(8)	(3)	(3)	(2)	(2)
Free-cash flow	**98**	**222**	**139**	**44**	**24**
PV of Cash flow	**105**	**220**	**128**	**38**	**19**
PV FCF	€510m				
PV terminal value	€238m				
Implied EV	**€748m**				
Net cash/(debt)	-€7m				
Equity value	**€741m**				
EUR per GBP	1.11				
Equity value (£m)	**£669m**				
No. shares (dil.)	71				
Value per share (p)	**950p**				

Target valuation date: Oct 2021; WACC=8%; g=0%. Source: Numis Securities Research

Implicit 15x EBITDA multiple

In our base case, we use a perpetuity growth rate of 0%, which drives a more conservative view of the terminal value of the business, with around two-thirds of the DCF value coming from the near-term cash flows and a third from the terminal value. The terminal value is the same as applying an EV/EBITDA multiple of c.15x (or EV/Sales of c.4x) to our assumed terminal EBITDA of €22m and discounting back, which is towards the lower end of peer tools and diagnostics multiples: essentially c.€320m in future equity value plus cash.

Bull case valuation of 1,500p

Implicit 19x EBITDA multiple

Our bull case DCF below assumes a terminal EBITDA a third higher than in the base case (as described in more detail on page 29), applying a higher perpetuity growth rate of 2%. This implicitly assumes a future equity value of c.€600m (18x EBITDA or 6x sales) discounted back.

Table 17: Novacyt bull case DCF valuation

Year end December (€m)	2020E	2021E	2022E	2023E	2024E
Revenues	**355**	**609**	**164**	**117**	**99**
- *growth*	*2617%*	*71%*	*-73%*	*-29%*	*-16%*
EBITDA	**272**	**463**	**92**	**51**	**33**
- *% sales*	*77%*	*76%*	*56%*	*43%*	*34%*
Working capital	(94)	(59)	121	15	7
Tax	(35)	(65)	(14)	(7)	(5)
Capex (inc. M&A)	(8)	(3)	(3)	(3)	(2)
Free-cash flow	**135**	**336**	**196**	**55**	**34**
PV of Cash flow	**144**	**334**	**180**	**47**	**26**
PV FCF	€732m				
PV terminal value	€444m				
Implied EV	**€1176m**				
Net cash/(debt)	-€7m				
Equity value	**€1169m**				
EUR per GBP	1.11				
Equity value (£m)	**£1054m**				
No. shares (dil.)	71				
Value per share (p)	**1500p**				

Target valuation date: Oct 2021; WACC=8%; g=2%. Source: Numis Securities Research

Bear case valuation of 450p

Implicit 1x Sales multiple

Our bear-case factors in no upside from the Department of Health and Social Care near patient testing (NPT) contract that Novacyt has recently been awarded, with Phase 2 of the contract not being exercised, and Novacyt winning no further significant contracts beyond this, then fading to a breakeven EBITDA business with minimal terminal value such that c.90% of the valuation is made up by near-term cash flow. With this scenario factoring in a return to breakeven profitability, the EBITDA multiple is irrelevant, while the implicit EV/sales multiple is equivalent to c.1x sales.

Table 18: Novacyt bear case DCF valuation

Year end December (€m)	2020E	2021E	2022E	2023E	2024E
Revenues	**305**	**210**	**69**	**46**	**41**
- *growth*	*2231%*	*-31%*	*-67%*	*-34%*	*-11%*
EBITDA	**234**	**145**	**26**	**5**	**0**
- *% sales*	*77%*	*69%*	*37%*	*11%*	*1%*
Working capital	(94)	37	45	8	3
Tax	(30)	(20)	(4)	(0)	0
Capex (inc. M&A)	(8)	(3)	(3)	(1)	(1)
Free-cash flow	**102**	**158**	**64**	**12**	**2**
PV of Cash flow	**109**	**157**	**59**	**10**	**2**
PV FCF	€337m				
PV terminal value	€28m				
Implied EV	**€365m**				
Net cash/(debt)	-€7m				
Equity value	**€359m**				
EUR per GBP	1.11				
Equity value (£m)	**£323m**				
No. shares (dil.)	71				
Value per share (p)	**450p**				

Target valuation date: Oct 2021; WACC=8%; g=2%. Source: Numis Securities Research

Blue sky valuation of 3,400p

What if Novacyt's profits were sustainable into the long term?

In a blue sky scenario, where the second phase of the DHSC hospital testing contract was exercised in full to its maximum, the total value of the contract could range as high as £850m, which would potentially drive our 2021 revenue forecasts above €1bn at the top end of the range. Our final scenario also asks the question: what if the level of profitability and cash flow Novacyt has delivered so far was sustainable into the long-term? This is a scenario we can envisage should Novacyt, for example, become well embedded as a strategic provider into the UK NHS for the long term. In this scenario we model a much higher sustainable EBITDA of €100m, which drives a significantly higher valuation of 3,400p, with around 50% of this derived from the terminal value (vs one-third in the base case and only c.10% in the bear case). We currently factor this into our valuation with a 10% weighting.

Table 19: Novacyt blue sky DCF valuation

Year end December (€m)	2020E	2021E	2022E	2023E	2024E
Revenues	**355**	**1,001**	**512**	**270**	**192**
- *growth*	*2617%*	*182%*	*-49%*	*-47%*	*-29%*
EBITDA	**272**	**781**	**361**	**163**	**100**
- *% sales*	*77%*	*78%*	*70%*	*61%*	*52%*
Working capital	(94)	(161)	140	67	23
Tax	(35)	(109)	(54)	(24)	(14)
Capex (inc. M&A)	(8)	(3)	(3)	(7)	(5)
Free-cash flow	**135**	**508**	**444**	**199**	**103**
PV of Cash flow	**144**	**504**	**408**	**169**	**81**
PV FCF	€1,307m				
PV terminal value	€1,357m				
Implied EV	**€2,664m**				
Net cash/(debt)	-€7m				
Equity value	**€2,657m**				
EUR per GBP	1.11				
Equity value (£m)	**£2,396m**				
No. shares (dil.)	71				
Value per share (p)	**3,400p**				

Target valuation date: Oct 2021; WACC=8%; g=2%. Source: Numis Securities Research

Porters & SWOT

Suppliers		Entrants
Bargaining power of suppliers **MEDIUM** Molecular diagnostics tests require the bringing together of multiple specialised components (-) Novacyt maintains control of the key IP in tests, such that suppliers depend on them as a route to market (+) Instrument manufacture a competitive space (+)		**Threat of new entrants** **MEDIUM** Over 100 patents and multiple recognised infectious disease testing brands and trade markets globally, with 2020 cash flow funding specific C-19 filings (+) Regulatory approvals and instrument installed bases act as entry barriers also (+) Specialised know-how and sticky customer bases (+)
	Industry Competitors **MEDIUM/HIGH** Handful of dominant global diagnostics gorillas such as Thermo and Roche dominate the industry (-) Competition intense in COVID-19 testing, with most diagnostics companies developing products (-), though significant differences in execution (+) Potential for new national UK diagnostics champions to emerge post COVID (+) Fragmented industry with a huge no. of acquisition and bolt-on opportunities to consolidate (+)	
Substitutes		**Buyers**
Threat of substitute products **LOW/MEDIUM** PCR molecular testing technology has been an industry standard for 40 years and not yet bettered (+) NGS sequencing becoming cheap enough to become realistic, but are complementary, additive approaches, not substitutes (+) Mass decentralised lateral flow antigen testing could take pressure off central labs, though those testing positive will require a PCR re-test (+)		**Bargaining powers of buyers** **MEDIUM** Governments and health systems have quickly become Novacyt's key customers (+) Confidence in ability to supply driving purchasing decisions through COVID-19 crisis (+) Favourable economics of increased testing to reopen the economy driving rapidly rising volumes (+) COVID-19 testing market still supply rather than demand-driven (+)

SWOT analysis

Strengths	Weaknesses
Market leading and proprietary testing technologies / capabilities, particularly in infectious disease	Small player in industry dominated by heavyweights (Thermo, Roche, Siemens, Abbott
Highly credible track record of rapid delivery and execution throughout COVID-19 pandemic	Lacks global brand, scale and breadth of offerings beyond molecular testing
Well connected into UK government	UK government / NHS a key customer (>50% of sales)
Strong forward visibility of demand through 2020 and into 2021	Nascent US presence
	Relatively short history of delivering double-digit EBITDA profits
Opportunities	**Threats**
Leverage COVID-19 transformation to emerge as a new UK diagnostics champion and integral part of future pandemic preparedness systems	Demand for COVID-19 related diagnostic testing may peak over winter 20-21 flu season
Continued investment to drive up supply capacity	Potential technology disruption could reduce demand for PCR tests
Further innovation and launch of new tests as epidemic progresses	Possible contract cancellations
Bolt-on further service lines to broaden offering / increase scale and sell more products to expanded customer base	Risk of overpaying for acquisitions, as well as failing to integrate
	Loss of key staff

Questions for Management

With working capital no longer a constraint to Novacyt, what is the mid- to long-term growth strategy for the company? How do you intend to deploy your cash?

How do you see the UK diagnostics landscape evolving post COVID-19 and what are your global plans?

Can you run through the logic of the adjacent markets you are now targeting? Would Novacyt get back into cancer diagnostics in the future?

What are your plans regarding manufacturing, distribution and direct sales going forward?

Source: Numis Securities Research

Risks

Market risks

COVID-19 testing outlook could reduce significantly in 2021

Demand for COVID-19 related diagnostic testing may peak over the winter 2020-21 flu season and then, should vaccines emerge in 2021 that offer a significant level of protection and see widespread adoption, these could, in an ideal scenario, put an end to the COVID-19 crisis, with demand for testing decreasing significantly, leading to possible non-renewal or loss of contracts. The FDA has set out guidance that COVID-19 vaccines should "prevent disease or decrease its severity in at least 50% of people who are vaccinated", which suggests that, even with full vaccination in place, in 2022 or beyond, there is likely to be virus still circulating and continued demand for testing. It is possible that vaccines will be approved even if they offer less protection (our core assumption in this note), as seen in the past with flu vaccines.

Customer concentration

UK Government a major customer

In H1 2020, Novacyt had two customers responsible for over 10% of its sales, both of which are in the UK, both essentially with the UK Government, which has quickly become a major customer of the company (UK >50%+ of sales in H1). These contracts are finite in length, though are extendable beyond the initial term. The initial DHSC contracts to supply the NHS extends to around the end of 2020, while the NTP contract currently extends to around the end of Q1 2021. If these were not extended, then our 2021 base and bull case forecasts could prove to be too optimistic. Similarly, there is significant upside risk here also, where the UK Government could significantly increase its orders with the company well beyond our initial forecasts. Also, with an expanded product range, Novacyt could win ex-UK contracts to diversify its revenue base.

Potential technology disruption

Significant innovation ongoing

There are a number of alternative molecular diagnostic technologies (such as lateral flow, NGS or CRISPR-based testing) that may emerge that could disrupt (e.g. through pricing) or even potentially replace the need for PCR testing of suspected SARS-CoV-2 infections. Our core assumption is that these would be largely additive to PCR, which is the gold standard, but this could be incorrect.

Acquisition / integration risks

COVID-19 has driven up the rating of many listed diagnostics firms

Novacyt has pursued several acquisitions that have been additive to the business, bringing in key new product lines to broaden its offering, new technologies or facilities. With its cash coffers significantly expanded, the risk now is that, as it moves up in scale, it begins to overpay for acquisitions, for example, by paying "COVID-enhanced" multiples for publicly listed companies rather than private firms on non-enhanced multiples, or by failing to adequately integrate acquisitions or retain customers and key staff.

Product development risks

Risk of technical or regulatory failure

Novacyt is investing in R&D to drive new product rollouts and top-line growth, with any of these at the risk of technological failure or failure to gain regulatory approval.

Sourcing and facilities risks

Key ingredients may run short

The manufacturing of Novacyt's diagnostics tests relies on a number of specialised ingredients that may be single-sourced and could run into short supply, particularly during the current period of extreme demand for tests. Novacyt has two main manufacturing sites, in Southampton and Camberley, UK, and were either of these to experience disruption through, for example, fire or cyberattack, Novacyt's ability to supply could be threatened.

Reliant on two manufacturing sites

Board of Directors

James Wakefield, Independent Non-Executive Chairman. James is an experienced private equity investor, having spent over 30 years in the finance industry. He has been involved with over 30 businesses of varying sizes and stages of development across a wide range of sectors, including board representation as chairman or Non-Executive Director in a number of these. He is also chairman of Promedics Orthopaedics Limited. James is chairman of WestBridge Capital LLP, of which he was a founder partner in 2008. He previously spent 18 years at Bridgepoint (previously NatWest Equity Partners) and, prior to that, spent four years at NatWest Markets/NatWest Investment Bank. He has been a Non-executive Director and Chairman of the Group since 2014 and is also Chairman of the Nomination Committee. James is a graduate of Harvard Business School (AMP).

Graham Mullis, Chief Executive Officer. Graham was appointed Chief Executive Officer of Novacyt in 2014, having previously been chief executive officer of Lab21 since 2008. He has over 30 years of experience in the healthcare, pharmaceuticals and medical device market. Over the years, he has led multiple successful exits, including that of Biocompatibles Eyecare, ClearLab, VisionTec and Optivue. Previous roles have included acting as a C-level executive with Biocompatibles International plc, a FTSE 250 company, and 1-800 CONTACTS, a NASDAQ-listed company. He holds degrees in BSc Biochemistry & Physiology from Southampton University, UK and an MBA Business Administration from Warwick Business School, UK.

Anthony Dyer, Chief Financial Officer. Anthony joined the Group in 2010 and has been Chief Financial Officer since January 2017. He has 20 years of experience in healthcare, pharmaceuticals and medical devices, working primarily with growth companies and executing M&A. Transactions executed include RiboTargets' combination with British Biotech, BioFocus' combination with Galapagos and Galapagos' €130 million divestment of its service division to Charles River Laboratories. He holds a BSc (Hons) degree in Maths and Management Science from University of East Anglia, UK. He is a Fellow of the Association of Chartered Certified Accountants (FCCA).

Andrew Heath, Independent Senior Non-Executive Director. Dr Heath is a healthcare and biopharmaceutical executive with in-depth knowledge of the US and UK capital markets with international experience in marketing, sales, R&D and business development. In addition to his role as Non-executive Director for Novacyt since 2015, he is currently NED of Oxford Biomedica. From 1999 to 2008 he was CEO of Protherics, taking the company from 30 to 350 staff and managing its eventual acquisition by BTG for £220 million. A former director of The BioIndustry Association, Dr Heath earlier served as Vice President of Marketing and Sales, for Astra Inc. in the US after a career in clinical and academic medicine at Vanderbilt University. He graduated in medicine from University of Gothenburg, Sweden, where he also completed his doctoral thesis in human toxicology. He is a fellow of the American Academy of Clinical Toxicology and a fellow of the UK Institute of Directors (IOD). Andrew is Chairman of the Remuneration Committee, and a member of the Audit and Nomination Committees.

Edwin Snape, Independent Non-Executive Director. Ed has over 40 years of experience in founding, investing in and guiding public and private healthcare and specialty materials companies. He was a founder and is current Adviser to NMT Capital and is a Senior Adviser to Maruho Co., Ltd. Prior to NMT he was Managing General Partner of leading east coast VC The Vista Group, Chairman of Orien Ventures, and a Director of the Cygnus Funds, two UK-based PE firms focused on Europe. Early in his career, he founded the Liposome Company, which listed and was later sold to Elan Corporation for over $500m. He has been a recipient of several awards in the material sciences industry, including the AB Campbell Award and the Hunt Silver Medal. He holds several patents in advanced materials where he has pioneered various technological innovations and authored numerous technical papers. He holds BSc and PhD degrees in Metallurgy from Leeds University, UK. Ed is a member of the Remuneration Committee.

Jean-Pierre Crinelli, Independent Non-Executive Director. Jean-Pierre is one of Novacyt's founders having established the business in July 2006. He has some 30 years of experience in the car and electrical components industry, with various roles in M&A and business restructuring. During this period, he was located for 10 years to Singapore, North America, Belgium and Italy. He holds a Diplôme from ESC Le Havre (business school, France) and a DECS (Diplôme d'Etudes Comptable Supérieures, national diploma). Jean-Pierre is a member of the Audit Committee.

Juliet Thompson, Independent Non-Executive Director. Juliet has 20 years of experience working as an investment banker and strategic adviser to healthcare companies in Europe. She has built a strong track record of advising companies on corporate strategy, equity and debt fundraisings and international M&A. Her experience includes senior roles (Managing Director, Head of Corporate Finance and Partner) at Stifel Financial Corp, Nomura Code Securities and WestLB Panmure. Juliet sits on the Board of Vectura, an industry-leading device and formulation business for inhaled products and GI Dynamics Inc., a US-based company. She is a member of the Institute of Chartered Accountants in England and Wales (ACA) and holds a BSc degree in Economics from the University of Bristol, UK. Juliet is Chairman of the Audit Committee and is a member of the Remuneration and Nomination Committee.

Glossary

Table 20: Glossary

Term	Meaning
Antibody	Proteins made by the vertebrate immune system to recognise and tag invaders for clearance by other parts of the immune system.
Antigen	The target that an antibody binds to.
Cell	The smallest structural and functional unit of an organism.
Coronavirus	RNA viruses that cause respiratory tract infections in mammals and birds that can range from mild to lethal.
COVID-19	Coronavirus disease 2019, an infectious disease first identified in December 2019 in Wuhan, China, caused by SARS-CoV-2.
Cycle threshold	Ct: the cycle number when PCR signal crosses a certain threshold. Inversely proportional to amount of genetic material present in test.
CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats. A system for editing the genetic information within a cell.
Diagnostics	The process of detection and identification of a disease.
cDNA	Complementary or copy DNA, refers to DNA copied from an RNA template by a polymerase enzyme reverse transcriptase. (RT).
DNA	Deoxyribonucleic acid. A polymer of four different types of nucleotide (or "bases") A,T,C and G that make up the genetic code of life.
DNA sequencing	The process of determining the precise order of nucleotides (A, C, G and T) in a DNA molecule.
Enzyme	Proteins that act as biological catalysts.
FDA	Food and Drug Administration.
Gene	The DNA that codes for an individual protein.
Genome	The entire DNA profile of an individual which determines their characteristics.
Genomics	The study of large numbers of genes or the whole genetic makeup of organisms.
Haematology	The study and treatment of blood and blood-forming organs.
HCV	Hepatitis C virus, which causes an infectious disease that primarily impacts the liver.
HIV	Human immunodeficiency virus, which can over time cause AIDS, a progressive failure of the immune system.
HPV	Human Papilloma virus, a group of viruses that affect human skin and mucosal membranes.
Immunotherapy	Therapy that uses substances to stimulate or suppress the immune system to help the body fight cancer, infection, and other diseases.
IVD	*In vitro* diagnostics, medical devices used for testing material external to a living organism.
LAMP	Loop-mediated isothermal amplification, an alternative to PCR that does not rely on temperature cycling making it instrument free.
LoD	Limit of detection: defined as the lowest concentration of virus that can be detected 95% of the time.
MERS	Middle East Respiratory Syndrome, a severe respiratory illness caused by coronavirus MERS-CoV first reported in Saudi Arabia (2012).
Microbiology	Branch of biology that deals with study of the structure and function of microscopic organisms (bacteria, viruses, fungi).
Molecular diagnostics	Applying molecular biology to determine a test result using markers such as DNA that are based on an individual's genetic code and how their cells express their genes as proteins
NGS	Next generation DNA sequencing
NPV	In diagnostics, negative predictive value: the proportion of negative tests that are actually negative.
Nucleus	The central part of a cell that contains the genetic material (DNA) used to make proteins.
Oncology	A branch of medicine focused on cancer.
Pathogenesis	The development of disease. Generally used in reference to the ability of microbes, viruses or other infectious agents to cause disease.
PCR	Polymerase chain reaction, a molecular biology technique that amplifies a DNA or RNA (RT-PCR) sequence to millions/billions of copies, which has many uses including identifying the presence of a specific DNA/RNA sequence, acting as a molecular diagnostic test.
PPV	Positive predictive value: the proportion of positive tests that are actually positive. With a disease of low prevalence, this can be low even with a highly sensitive and specific test, and the number of false positives can exceed actual positives.
Polymerase	An enzyme that synthesizes long polymer chains such as DNA (DNA polymerase) or RNA (RNA polymerase).
Protein	Proteins are building blocks of the cells and tissues with thousands of different types each playing either a structural or functional role.
qPCR	Quantitative real-time polymerase chain reaction.
Reverse transcriptase	A DNA polymerase enzyme that generates cDNA from an RNA template, reversing the classic central dogma that DNA codes for RNA.
RNA	Ribonucleic acid. A similar polymer to DNA that makes a temporary copy of DNA (transcription) that then codes for proteins (translation).
RUO	Research use only
SARS	Severe Acute Respiratory Syndrome, a viral respiratory disease that saw a serious outbreak over 2002-4, caused by a coronavirus
SARS-CoV-2	The strain of coronavirus that causes COVID-19
Sensitivity	Measure of the performance of a diagnostic test in successfully picking up positives (lack of false negatives who could infect others).
Serology testing	Testing to detect the presence of antibodies in the blood to an infectious agent (e.g. a virus)
Specificity	Measure of the performance of a diagnostic test in ruling out negatives (lack of false positives who may quarantine unnecessarily).
T cells	White blood cells of the immune system derived from the Thymus ("T") that search out and destroy invaders (tagged by antibodies).
Vector	A tool used to deliver genetic material (DNA or RNA) into cells.
Virus	Microscopic biological agents that are formed of either DNA or RNA and can only replicate within living cells.
Zika	A virus mainly spread by mosquitoes associated with higher incidence of microcephaly in babies born to mothers infected in pregnancy.

Source: Company and Numis Securities Research

Regulatory Notice & Disclaimer

The research analyst who prepared this research report was Stefan Hamill. The research analyst is not registered/qualified as a research analyst with FINRA. The research analysts who prepared this investment recommendation receives compensation based upon various factors (such as the general perception of the analyst's ability and commitment to their analytical work) and upon the overall revenues including the investment banking revenues and trading revenues of Numis and/or one or more of its affiliates. The research analyst is not registered/qualified as a research analyst with FINRA.

Numis and/or one or more of its affiliates may receive or may seek to receive compensation for investment banking services from Novacyt in the next 3 months.

Numis has received compensation for investment banking services from Novacyt in the past 12 months.

The company has seen a draft of the note and has made minor factual comments that have been incorporated.

Numis research is being produced in accordance with COBS 12.2 as Non-Independent Research.

The following disclosures are addressed to US-based recipients.

Analyst Certification

The analysts hereby certify that all of the views expressed herein accurately reflect the their personal views about any and all of the subject securities and/or issuers at the date of original publication of this document.

The research analysts who prepared this research report also certify that no part of their compensation was, is or will be, directly or indirectly, related to the specific recommendations or views expressed by them in the research report.

Important Disclosure

This research report has been prepared and approved by Numis Securities Limited ("Numis"), a securities dealer in the United Kingdom. Numis is not a registered brokerdealer in the United States and therefore is not subject to U.S. rules regarding the preparation of research reports and the independence of research analysts. This research report is provided in the United States for distribution solely to "major U.S. institutional investors" in reliance on the exemption from registration provided by Rule 15a-6 of the U.S. Securities Exchange Act of 1934, as amended. Any recipient of this research report wishing to effect any transaction to buy or sell securities or related financial instruments based on the information provided in this research report should do so only through Numis Securities Inc. ("Numis Inc."). Numis Inc. may be contacted in writing or by phone: Numis Securities Inc., 575 Fifth Avenue, 25th Floor, New York, NY 10017, U.S. phone (212) 277 7300. Numis Inc. is an affiliate of Numis. Under no circumstances should any recipient effect any transaction to buy or sell securities or related financial instruments through Numis. Numis Inc. accepts responsibility for the contents of this research report, subject to the terms set out below, to the extent that it is delivered to a U.S. person other than a major U.S. institutional investor.

Numis, Numis Inc. and/or their affiliates, directors, officers, and employees may have or have had interests, or long or short positions, and may at any time make purchases or sales as a principal or agent of the subject companies mentioned or referred to in this report.

Additional Disclosure

This Numis Securities Limited ("Numis") research report is for distribution only under such circumstances as may be permitted by applicable law. This research report has no regard to the specific investment objectives, financial situation, or particular needs of any specific recipient, even if sent only to a single recipient. This research report is offered solely for informational purposes and is not to be construed as a solicitation or an offer to buy or sell securities or related financial instruments, nor is it to be construed as a recommendation for Numis to effect any transaction to buy or sell securities or related financial instruments on behalf of any recipient. There is no express or implied understanding between Numis or Numis Securities Inc. ("Numis Inc.") and any recipient of this research report that Numis will receive any commission income in connection with this research report. The securities that may be described in this research report may not be eligible for sale in all jurisdictions or to certain categories of investors. This research report is based on information believed to be reliable, but it has not been independently verified and is not guaranteed as being accurate. This research report is not guaranteed to be a complete statement or summary of any securities, markets, reports or developments referred to in this research report.

Any statements or opinions expressed in this research report are subject to change without notice and Numis is not under any obligation to update or keep current the information contained herein. All statements and opinions expressed in this research report are made as of the date of this research report and are not held out as applicable thereafter. Neither Numis nor any of its directors, officers, employees, or agents shall have any liability, however arising, for any error, inaccuracy or incompleteness of fact or opinion in this research report or lack of care in this research report's preparation or publication; provided that this shall not exclude liability to the extent that this is impermissible under the law relating to UK financial services.

Investing in any non-U.S. securities or related financial instruments (including ADRs) discussed in this research report may present certain risks. The securities of non-U.S. issuers may not be registered with, nor be subject to the regulation of the U.S. Securities and Exchange Commission. Information on such non-U.S. securities or related financial instruments may be limited. Foreign corporations are typically not subject to audit and reporting standards and regulatory requirements comparable to those in effect within the United States.

Past performance is not an indication or guarantee of future performance and no representation or warranty, express or implied, is made by Numis with respect to future performance. The value of any investment or income from any securities or related financial instruments discussed in this research report is subject to volatility and can fall as well as rise. Investors may not get back the full amount they originally invested. The value of any investment or income from any securities or related financial instruments discussed in this research report denominated in a currency other than U.S. dollars is subject to exchange rate fluctuations that may have a positive or adverse effect on the value of or income from any securities or related financial instruments discussed in this research report.

The following disclosures are addressed to non-US-based recipients.

Numis regards this document as an investment recommendation. It has been approved under part IV article 19 of The Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the “FPO”) by Numis Securities Limited (“Numis”) for communication in the United Kingdom only to investment professionals as that term is defined in article 19(5) of the FPO. Its contents are not directed at, may not be suitable for and should not be relied on by anyone who is not an investment professional including retail clients. Numis does not provide investment advisory services to retail clients. This investment recommendation is not directed at you if Numis is prohibited or restricted by any legislation or regulation in any jurisdiction from making it available to you. You should satisfy yourself before reading it that Numis is permitted to provide investment recommendations to you under relevant legislation and regulations. This investment recommendation is not an offer or a solicitation to buy or sell any security. It does not constitute a personal recommendation and recipients must satisfy themselves that any dealing is appropriate in the light of their own understanding, appraisal of risk and reward, objectives, experience, and financial and operational resources. It has not been prepared in accordance with legal requirements designed to promote the independence of research. Non independent research is not subject under the Markets in Financial Instruments Directive (“MiFID”) to any prohibition on dealing ahead of the dissemination of research. However, Numis is required by the FCA to have policies in place to identify and manage the conflicts of interest which may arise in its production, which include preventing dealing ahead. The prices of the investments referred to in this investment recommendation and the income from them may go down as well as up and investors may realise losses on them. Neither past performance nor forecasts are a reliable indicator of future results. Numis accepts no fiduciary duties to the reader of this investment recommendation and in communicating it Numis is not acting in a fiduciary capacity. Neither Numis nor any of its directors, officers, employees, or agents shall have any liability, however arising, for any error, inaccuracy or incompleteness of fact or opinion in this research report or lack of care in this research report's preparation or publication; provided that this shall not exclude liability to the extent that this is impermissible under the law relating to UK financial services.

All statements and opinions are made as of the time and date on the face of this document and are not held out as applicable thereafter. Numis makes no commitment to any planned frequency of updates to investment recommendations. Investment recommendations carry the date and time of dissemination. In the absence of contrary words, Numis considers that an investment recommendation is only completed at the point at which it is disseminated. Where a price is quoted in an investment recommendation it will generally, in the absence of contrary words, be the latest practicable price prior to distribution. Unless otherwise stated, prices in this investment recommendation are derived from quotations on the London Stock Exchange. A list of significant items which could create a conflict of interest and other material interests in relation to investment recommendations, together with Numis’s policy for managing such conflicts of interest, is set out on the Numis website (www.numis.com/x/regulatory.html).

Numis or one or more of its associates or a director or an employee of Numis or of an associate may from time to time have a position, or may have undertaken or may undertake an own-account transaction, in a security referred to in this document or in a related security. Such a position or such a transaction may relate to the market making activities of Numis or to other activities of Numis.

Numis or one or more of its associates may from time to time have a broking, advisory or other relationship with a company which is the subject of or referred to in this investment recommendation, including acting as that company’s official or sponsoring broker and providing corporate finance or other financial services. It is the policy of Numis to seek to act as corporate adviser or broker to many of the companies which are covered by the Research Department. Accordingly companies covered in any investment recommendation may be the subject of marketing initiatives by the Investment Banking Department.

Numis acts as a market maker (as defined in point (7) of Article 4(1) of Directive 2015/65/EU) in the subject company of this report. Additionally, at any time Numis

may have a long or short position in the companies mentioned in this investment recommendation, and may have received customer orders to buy or sell instruments in the companies mentioned in this investment recommendation. If Numis holds a long position of >0.5% or a short position of <-0.5% in the subject company of an investment recommendation, this is separately disclosed.

A company covered in this investment recommendation may have paid for an analyst's reasonable expenses to visit their premises or offered modest hospitality or entertainment; further details are available on request.

Unless otherwise clearly specified in this document, the author(s) of this document does not own a long or short position in the issuer, whether received or purchased before or subsequent to a public offering of such shares.

Investment recommendations will specifically identify sources of information for material facts, where these are not regulatory company announcements and published company financial documents. In those cases (but not otherwise) where the subject company has seen a draft of the investment recommendation and has suggested factual amendments which are incorporated by the analyst, this will be noted on the investment recommendation.

The archive of investment recommendations, available to all clients who normally receive Numis investment recommendations, is available on the Numis website (http://www.numis.com/x/research-sectors.html).

Numis accepts no responsibility whatever for any failure by a person resident outside the United Kingdom to observe the foregoing. No part of the content of any research material may be copied, forwarded or duplicated in any form or by any means without the prior consent of Numis and Numis accepts no liability whatsoever for the actions of third parties in this respect.

Numis believes that its research service as a whole amounts to 'substantive research' as defined by the FCA.

Valuation, Key Assumptions and Risks

In longer investment recommendations, typically over four pages, details relating to valuation (including material information about proprietary models), key assumptions and risks will typically be included in the document. For other investment recommendations please refer to http://www.numis.com/x/research-sectors.html for this information, the relevant company section of the Numis website.

Ratings Key

A target price is set with a 12 month horizon from the time of publication. In making a rating the analyst should compare their target price with the actual share price and then make a rating derived from the percentage thus calculated:

As from 14 February 2005, the formula is:

Buy	>= +20%
Add	>= +10% to +19.99%
Hold	0% to +/-9.99%
Reduce	<= -10% to -19.99%
Sell	<= -20%

Upon the initial establishment of a rating and target price for a company, an additional 10 % deviation in the price from the default bands set out above is permitted before the rating has to be changed in subsequently published investment recommendations.

At the discretion of the Head of Research, the return targets shown in the table above may be applied as a total return target, rather than a share price target. In this case, this will be made explicit in the text of the research, and the total return calculation will be described.

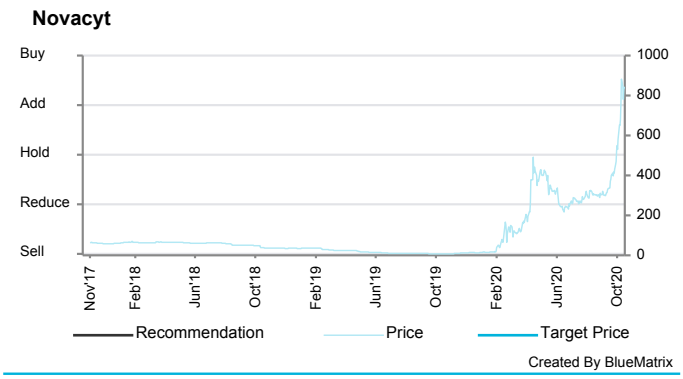
Distribution of Ratings

	US Requirement 01/10/2019 - 30/09/2020		UK Requirement 01/07/2020 - 30/09/2020	
	All Securities	Corporate Clients	All Securities	Firms provided with material banking services
Buy	52.7%	75.9%	58.4%	74.6%
Add	16.3%	15.0%	16.6%	17.1%
Hold	23.8%	9.0%	18.3%	8.3%
Reduce	5.8%	0.0%	4.7%	0.0%
Sell	1.4%	0.0%	2.0%	0.0%
Total	100%	100%	100%	100%
	The above table shows the split of recommendations based on the last recommendation for each research stock during the last four calendar quarters.		The above table shows the split of recommendations based on all recommendations during the last calendar quarter for all securities and within each category the proportion of issuers to which Numis supplied material banking services.	

For a list of all ratings on any financial instrument or issuer disseminated by the Research Department of Numis Securities Ltd. during the preceding 12-month period, please refer to www.numis.com/x/mars.html. On request, the Numis Securities Ltd Compliance Department will provide a list of all ratings disseminated by other employees of Numis Securities Ltd.

The following graphs display the three year rating, target price and share price history for the subject corporation(s) of this investment recommendation. In those instances, where the subject corporation(s) have been publicly traded for less than three years, the graph will show the history since the date the subject corporation(s) were admitted to trading. Prices in the graph(s) below are in pence unless otherwise stated.

Three Year - Recommendation, Target Price, Share History



Source: Numis Securities Research