Trinity Delta

# Avacta

Update

## Diagnostics business back into the spotlight

13 December 2022

**Avacta is seeking to capitalise on the positive perception shift in the diagnostic market since COVID-19 brought testing to the masses. An M&A-led growth strategy, complemented by internal capabilities, notably the proprietary Affimer platform, should create a self-sustaining Diagnostics business. The acquisition of Launch Diagnostics was the first step, with additional complementary targets being sought and the firepower to execute. Meanwhile in Therapeutics, lead asset AVA6000 continues to progress and should validate the pre|CISION platform's clinical utility. This remains the biggest near-term value driver. Our updated valuation is £587m, equivalent to 221p/share with potential upside from positive AVA6000 updates.**

| Year-end: December 31 | 2020 | 2021 | 2022E | 2023E |
|---|---|---|---|---|
| Revenues (£m) | 2.1 | 2.9 | 8.4 | 18.7 |
| Adj. PBT (£m) | (15.6) | (24.1) | (20.2) | (26.3) |
| Net Income (£m) | (18.9) | (26.3) | (21.6) | (28.7) |
| Adj.EPS (p) | (6.0) | (8.7) | (6.9) | (8.9) |
| Cash (£m) | 47.9 | 26.2 | 40.3 | 17.5 |
| EBITDA (£m) | (14.9) | (26.7) | (23.0) | (28.9) |

Source: Trinity Delta Note: Adjusted numbers exclude share-based payments and exceptionals

- **Therapeutics remains our key value driver** The pre|CISION platform is a central element in the Therapeutics division's prospects. Lead asset AVA6000, a prodrug of doxorubicin, is the largest single constituent of our valuation. It continues to make progress in its Phase I trial with completion of the fourth dose cohort anticipated in Q422; however, given the clean safety profile seen to date, reaching the maximum tolerated dose (MTD) may require additional, higher, dose cohorts. Successful proof-of-concept would lead to a portfolio of similar oncology prodrugs, with the second, AVA3996, on track for IND filing in 2023.

- **Diagnostics emerging as an integrated business** The recent acquisition of Launch Diagnostics for £24m in cash provides Avacta with a commercial organisation in the UK and some EU markets, to which complementary products could be added, either organically through in-house development or sought externally. These should provide the opportunity for Avacta to leverage both its internal expertise and Affimer platform to optimise product performance and economics, and the product development, regulatory, and compliance infrastructure established during COVID.

- **Funding in place to execute on M&A-led Diagnostics strategy** Following the £64m (gross) fundraise (via a £7m placing, an open offer of up to £2m, and a convertible bond of £55m) we estimate Avacta has c £33m of funds remaining post the £24m Launch Diagnostics acquisition cost. We believe this provides ample balance sheet flexibility to explore various potential complementary Diagnostics opportunities.

- **Valuation of £587m equivalent to 221p per share** Inclusion of Launch Diagnostics increases our valuation to £587m (from £557m), equivalent to 221p per share. We value Launch Diagnostics, based on a DCF, at £34m (13p/share) which suggests the deal was attractively priced. We continue to include AVA6000 and the pre|CISION and Affimer platforms in our valuation, with upside as AVA6000 progresses and the Affimer technology is incorporated into the emerging Diagnostics strategy.

| | |
|---|---|
| Price | 109.0p |
| Market Cap | £289.8m |
| Enterprise Value | £272.7m |
| Shares in issue | 265.8m |
| 12 month range | 41.4p-144.2p |
| Free float | 85.2% |
| Primary exchange | AIM London |
| Other exchanges | N/A |
| Sector | Healthcare |
| Company Code | AVCT.L |
| Corporate client | Yes |

### Company description

Avacta owns two novel technology platforms: Affimer and pre|CISION. Affimer proteins are antibody mimetics being developed as diagnostic reagents and oncology therapeutics. pre|CISION improves potency and reduces toxicity of cancer drugs by only activating them inside the tumour. Successful clinical trials would be transformative for Avacta.


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# Avacta: Building scale in Diagnostics

**Avacta is progressing its proprietary technology platforms across Therapeutic and Diagnostic applications. We view the Therapeutic opportunities as a key driver of longer-term value, with the focus on doxorubicin prodrug and lead pre|CISION programme AVA6000, as it completes its Phase Ia clinical trials. Successful proof-of-concept should provide the blueprint for an extensive pipeline of related products. However, less high-profile developments underway within the Diagnostics division should not be overlooked. The COVID pandemic has altered perceptions of the value the diagnostics industry offers, with significant shifts in clinician and payor attitudes. Notably, there is a growing recognition that point-of-care (POC) tests are a viable cost-effective alternative, or are complementary, to traditional laboratory testing. Avacta has emerged from this period with a well-defined operational structure and, as highlighted by the Launch Diagnostics acquisition, plans to create an integrated and self-sustaining Diagnostics business. Our valuation is £587m, or 221p per share.**

**Two technology platforms: pre|CISION and Affimers**

Avacta has two technology platforms with broad applicability: **pre|CISION** allows for the selective and precise activation of chemotherapy and other drugs within a tumour, offering the potential to enhance efficacy and, importantly, reduce systemic toxicities of many common cancer therapies; and **Affimer** proteins are next-generation antibody mimetic protein scaffolds that offer enhanced attributes to the equivalent antibodies across therapeutic and diagnostic applications, with characteristics such as better stability, greater versatility, and ease of production.

**Two distinct businesses: Therapeutics and Diagnostics**

The natural split of these applications is reflected in Avacta's organisation into Therapeutics and Diagnostics operating businesses. The commercial opportunities for Therapeutics are relatively clear, with well-defined timelines and value inflection points as clinical studies progress. We have covered these in depth in previous notes. The recent acquisition of Launch Diagnostics provides an opportunity for us to explore the prospects for the Diagnostics business, with an examination of the market evolution, the value drivers gaining prominence, and the position of Avacta's current operations within this setting.

**This note focuses on the Diagnostics business**

Avacta's goal has been to exploit the Affimer platform to create market relevant, commercially differentiated diagnostics. Its response to the COVID pandemic did not pan out as hoped, but it did demonstrate the Diagnostics division's abilities to develop and deliver a competitive Affimer-based LFT (lateral flow test). Importantly, it accelerated the creation of a fully integrated operational structure, with in-house product development expertise, an ISO134585 certified quality management system, and an experienced regulatory team. In our April 2022 Update we had questioned how management would capitalise on these skills and abilities in a timely manner to crystallise value.

**Valuation of £587m, equivalent to 221p per share**

It is now clear that management intends to build on this framework to form an integrated Diagnostics business that has sufficient product mass and geographic reach to become self-sustaining, both in terms of profitability and new application development. We expect a steady stream of news flow from both Therapeutics and Diagnostics into the coming year. We have revised our forecasts to reflect the Launch Diagnostics acquisition (and associated fund raise) and our valuation is now £587m, equivalent to 221p/share, from our previous £557m.

## Two technology platforms with broad application

**Two platforms that address therapeutic and diagnostic uses**

Avacta has two proprietary technology platforms with wide commercial applicability. The first, **Affimer**, is an engineered alternative to antibodies that can be employed broadly across multiple applications, most significantly as reagents for diagnostics or as drugs in therapeutic applications. The second, **pre|CISION**, addresses oncology indications with the prospect of targeting drugs specifically to a tumour, minimising toxicities, and increasing the tolerated doses. These platforms are described in depth in prior reports, including our June 2021 Initiation, so we only recap key attributes and features here.

## Affimer proteins: engineered to be better than antibodies

**Affimers can overcome many of the limitations of antibodies**

Affimers are small proteins that can mimic the properties of antibodies, such as specific binding to a target molecule or protein, but due to their small size and simple structures, they can bypass many of the issues and limitations of antibodies. Antibodies are now used widely in many applications; their specificity means they are ideally suited as diagnostics, with thousands of antibody-based tests and assays, and as therapeutics, with monoclonal antibodies (mAbs) representing some of the most potent, and best-selling, drugs. Their commercial success belies many limitations, including their large relative size limiting tissue penetration, complex architecture, intractability of some target classes, cost of manufacture, pH and temperature stability, and difficulty in ensuring batch to batch consistency.

### Exhibit 1: Affimer platform offers multiple advantages over antibodies

**High affinity, rapid development, and 10x smaller than antibodies**

- **Engineered specificity –** a large and adaptable binding area provides high affinity and exquisite sensitivity;
- **Rapid development –** selection and characterisation of a novel custom Affimer molecule can be undertaken in just 10 to 12 weeks;
- **Flexible functionalisation –** can be easily modified with standard chemical or genetic tools providing highly flexible formats;
- **Ease of manufacture –** produced through simple high-yield bacterial expression, with high consistency and reproducibility;
- **Small size –** around 12-14kDa, against 150kDa for a typical antibody, means greater tissue penetration and higher surface packing density. Plus the structure is more stable, robust, and soluble.

Source: Avacta, Trinity Delta

**Versatile, adaptable, easier to produce, and freedom to operate**

The key attributes of the Affimer platform are summarised in Exhibit 1. These properties mean Affimer molecules offer an attractive and viable alternative to antibodies across a range of therapeutic, diagnostic, or research indications. Affimer-based therapeutics can be combined easily with each other, antibodies, or other biomolecules by simple, rapid, and proven methods to design the desired molecule or complex. Importantly, their novelty means a full and unencumbered patent estate has been established, so there is freedom to operate even when addressing targets that are covered by specific and robust antibody patents.

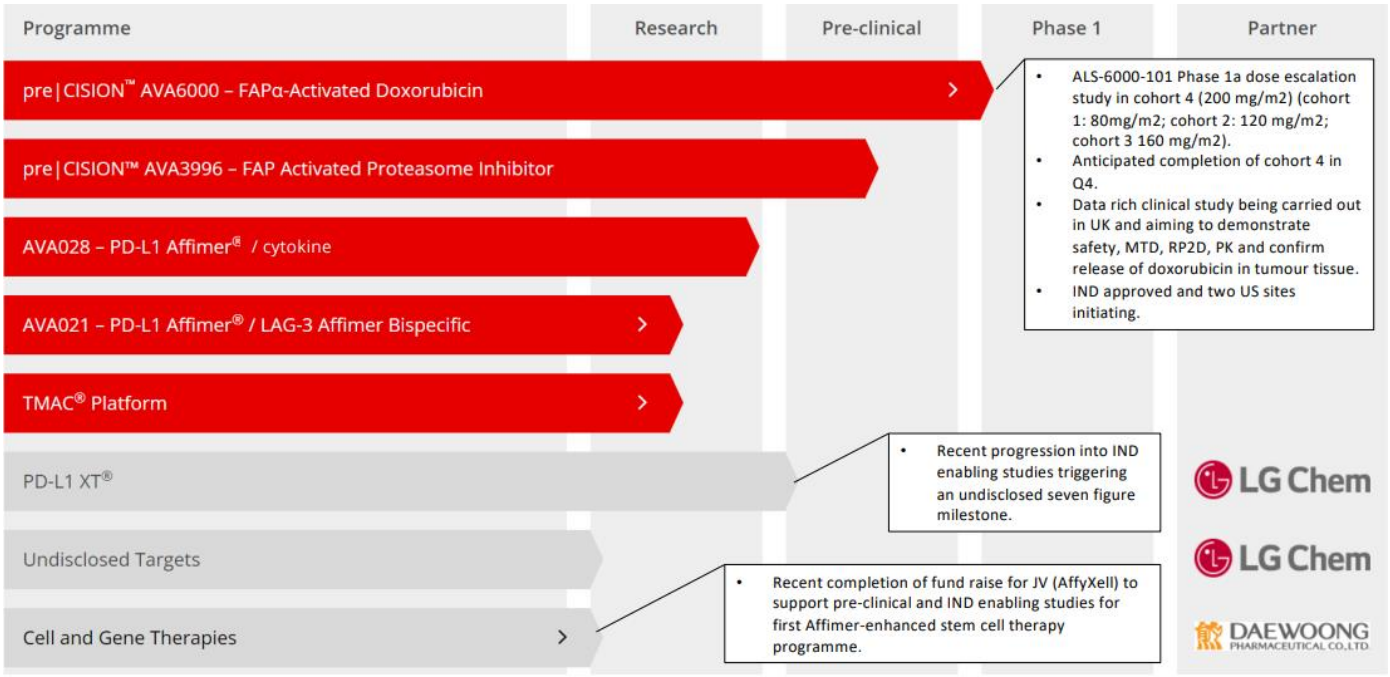
**COVID-19 response resulted in an integrated, coherent structure**

With such broad opportunities, the initial focus was to address life sciences research tools, which are minimally regulated and provide useful proof-of-concept, but now the focus is on the higher value diagnostic applications, which usually require CE certification in Europe and FDA device approvals in the US. Despite the frustrations, the COVID-19 opportunity not only demonstrated the viability of Affimer-based tests but accelerated the creation of a fully integrated operational structure, with in-house product development expertise and an ISO134585 certified quality management system, as well as securing a first CE mark approval.

**Affimer therapeutic applications require longer time frames**

Although therapeutic applications offer significantly larger market opportunities, the development process is more onerous, time consuming, costly, and generally carries higher risk. The strategy here is to initially progress only a select number of programmes in-house, with a broader portfolio in collaboration with larger, and better resourced, drug companies. These partnered programmes are fully funded, represent additional or incremental indications, provide expertise relevant to in-house programmes and, importantly, are useful external validation of the platforms' potential. Exhibit 2 summarises Avacta's Therapeutic pipeline, and also highlights the pre|CISION platform's progress.

**Exhibit 2: Status of the Therapeutics division's product pipeline**




Source: Avacta

## Pre|CISION: targeted tumour therapies

**FAPα cleavage tailors activity to site of tumours**

The pre|CISION platform creates drug conjugates that exploit the fact that the FAPα (fibroblast activation protein alpha) protease enzyme is highly upregulated in over 90% of solid tumours, yet its expression is very low in most healthy adult tissues (10x to 100x less). Using an appropriate substrate that is sensitive to cleavage by FAPα, a drug can be modified so that it is only activated selectively in the tumour microenvironment (TME). Hence the resulting inert prodrug has no (or little) systemic effect, minimising unwanted toxicities, instead only becoming active when FAPα selective enzymatic cleavage happens within tumour sites.

**Precise targeting is highly attractive for chemotherapies**

The pre|CISION prodrugs are particularly relevant for cytotoxic regimens where, despite proven efficacy, their clinical utility is hampered by debilitating side-effects. Many otherwise highly effective treatments are limited by systemic toxicities, for example anthracylines cause cardiotoxicity, proteasome inhibitors cause peripheral neuropathy, and taxanes cause neutropenia and peripheral neuropathy. The ability to selectively activate prodrugs of these molecules only at the tumour site could result in a re-evaluation of their role as part of combination regimens (as a component of tailored immune-based drug cocktails).

**AVA6000 is a prodrug of the well characterised doxorubicin**

The lead pre|CISION programme is AVA6000, a prodrug of the well-established cytotoxin doxorubicin, that is progressing through a two-part Phase I trial. Part A is a typical open-label, multi-centre dose escalation (3+3 design) study exploring safety, although some efficacy signals may be noted. The fourth cohort, dosed in patients with a variety of locally advanced or metastatic solid tumours, is expected to complete in Q422. Encouragingly, AVA6000 has shown a clean safety and tolerability profile; the dose finding portion of this trial has already escalated the dose of AVA6000 to three times the equivalent maximum dose of doxorubicin. This may mean that further, higher, dose cohort(s) are required to identify the maximum tolerated dose (MTD) of AVA6000. Assuming a successful outcome, the recommended dose, once defined, would be taken into Part B, in which 30 to 40 patients will be evaluated to confirm safety and tolerability and explore preliminary anti-tumour activity.

**Doxorubicin is still used widely in many treatment regimens**

Despite its cardiotoxicity limitations and largely generic status, doxorubicin consistently posts global sales >$1bn annually. Doxorubicin remains a mainstay in the treatment of multiple different cancers, both solid tumours and blood cancers, often in combination with other agents as part of a chemotherapy regimen

**AVA6000 efficacy could lead to multiple similar re-formulations for existing chemotherapies**

If AVA6000 demonstrates proof-of-concept this would validate the pre|CISION platform, and should lead to a portfolio of similarly acting oncology prodrugs. Avacta has identified other chemotherapies whose clinical utility would similarly benefit from improved efficacy and reduced toxicities. The most advanced is AVA3996, a prodrug of an analogue of Takeda's Velcade (bortezomib), which is commonly used for multiple myeloma. AVA3996 offers the prospect of reducing dose limiting toxicities, principally peripheral neuropathy and thrombocytopenia, that constrain Velcade use to multiple myeloma and mantle cell lymphoma.

**TMAC combines elements of the two platforms exquisitely**

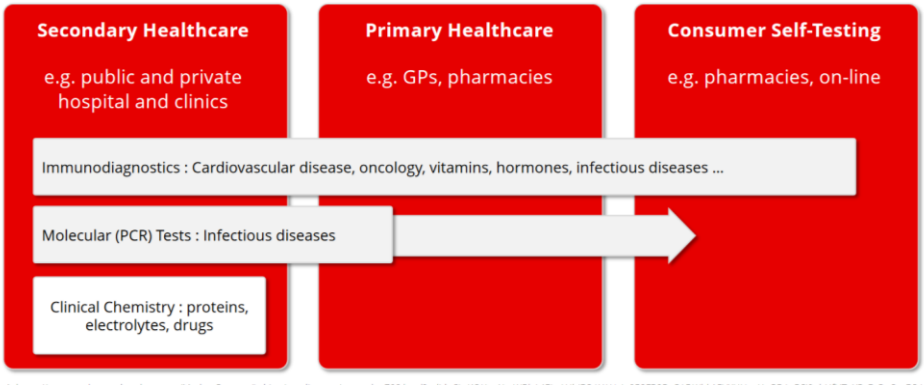
A clinically exciting, but still very early opportunity lies in the combination of the two technologies to create drug conjugates that could be tailored to exert specific effects within the tumour environment. Incorporating a FAPα sensitive pre|CISION chemical group within a linker to attach an appropriate Affimer molecule to a known chemotherapeutic creates a tumour-microenvironment activated drug conjugate or **TMAC**. These TMACs will only release their toxic payload in the tumour microenvironment when they encounter FAPα. These offer the possibility of highly specific delivery, low systemic toxicities, and potent anti-tumour activity through complementary modes of action.

## Diagnostics: stepping into the limelight

**Clinical, and economic, value of Diagnostics coming to the fore**

The Diagnostics sector has long been overshadowed by the higher profile Pharmaceutical market; yet the technological, and in turn clinical, advances in both fields are increasingly dependent on the use of highly specific tests to make timely diagnoses and, importantly, guide appropriate treatment(s). Such symbiosis is most apparent in oncology, where the early identification of a tumour and rapid characterisation of its genetic makeup results in highly targeted chemotherapy that can materially alter clinical outcomes. Equally important are the diagnostic tools that monitor how a tumour evolves over time, which inform decisions on altering treatment to maximise efficacy. Although often not as dramatic, equally life improving shifts in diagnosis and treatment are underway in many chronic, and often debilitating, diseases.

**Exhibit 3: The shift from centralised to point-of-care testing**




Source: MarketsandMarkets - In-vitro Diagnostics market report March 2022

**Technology advances mean a shift from central laboratories to personal care**

This reappraisal of the value of diagnostics reflects the emerging role, and relevance, of the broader technological advances underway. Arguably, this is mirrored across society as information that was once the preserve of institutions is now widely available to individuals. For healthcare this is demonstrated by the ever-growing availability of health management tools that literally place powerful decision-making information in our own hands. Consequently, over time, many chronic diseases will see the onus of treatment delivery shift from clinician to patient. Such patient-centricity will see a similar shift in the diagnostic and monitoring tools employed, with point-of-care (POC) diagnostics becoming an increasingly relevant segment of the *in vitro* diagnostics (IVD) market.

## COVID-19 pandemic highlights value of POC diagnostics

**Value of POC testing is now appreciated more widely**

This structural change, in our view, has been accelerated by the COVID-19 pandemic. The pandemic brought to light the importance of testing and, specifically, POC testing. Despite performance that falls below more time-consuming and expensive laboratory tests, lateral flow tests (LFT) brought a greater awareness, understanding and familiarity with such processes. POC diagnostics started as supplementary to standard lab-based testing but are increasingly becoming mainstream. All diagnostics are assessed primarily on the four key criteria of specificity, sensitivity, simplicity, and cost; the pandemic highlighted how POC testing, notably with LFTs, offers highly cost-effective and practical solution to regular repeat monitoring of certain disease markers, provides

privacy in some sensitive areas of health and, importantly, in some applications such as infectious diseases, rapid information to guide clinical decision making.

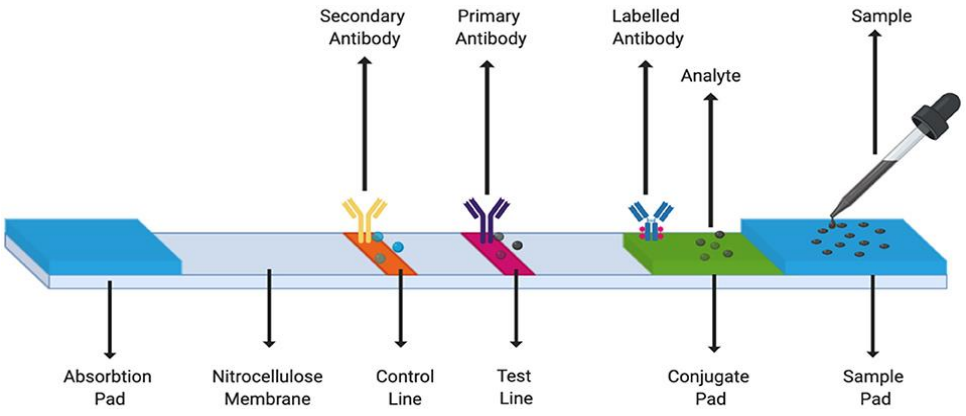
**Rapid, easy to use, inexpensive and clinically relevant**

Numerous "real world" clinical studies, across many indications, have shown that appropriate use of POC diagnostics can reduce overall per patient cost, length of hospital stays, and aid faster decision making compared to traditional laboratory testing. Equally, the data show clinicians particularly value tests that are simple to operate, do not require specialist equipment or training, and have a rapid turnaround time. From a payors' perspective (typically one of the key decision makers) such tests must produce reliable and meaningful results consistently across all users, be able to be introduced easily into existing workflows, and in what will remain a highly price conscious environment, are inexpensive.

**LFT applications are benefitting from innovation in many fields**

Lateral Flow Tests (LFTs) have become the most widely used POC diagnostics. In the clinical setting they can be easily employed with different biological fluids such as plasma, blood, urine, saliva, and serum. LFTs are relevant to multiple applications aside from diagnosis of disease: these include wider well-being purposes (eg monitoring hormone levels, vitamins, stress, reproductive health) as well as testing for drugs of abuse. The simplest LFTs use antibodies (or their synthetic equivalents) to recognise antigens, proteins, or hormones; but more sophisticated biomarkers, such as specific DNA/RNA sequences, can also be targeted. Increasingly a variety of cancer specific biomarkers can be identified using appropriately designed multi-channel LFTs. Advances in LFT development include novel signal enhancement techniques, the use of new labels, improved quantification systems, and simultaneous detection.

**Exhibit 4: a simple Lateral Flow Test (LFT) test strip construction**




Source: Microfluidic Point-of-Care Testing: Commercial Landscape and Future Directions, Sachdeva et al, Front Bioeng Biotechnol Jan 2021; 8: 602659

**Simple construction lends itself to ease of mass production**

An LFT works by the capillary flow of a sample through a series of sequential pads, each having different functionalities that generate a signal to indicate either the absence or presence (and, in some cases, the concentration) of the target analyte(s). It typically consists of four elements (Exhibit 4):

- **Sample pad:** The section of the strip where the pipetted biological sample is placed and gets absorbed. This pad may be treated, eg with certain salts or surfactants, to maintain the pH or control the sample flow rate.
- **Conjugate pad:** This consists of immobilised pre-labelled sample recognition elements. Different types of reporter labels - eg gold nanoparticles, fluorescence quenching labels, quantum dots - can be used.

- **Detection zone:** A porous layer, usually made of nitrocellulose membrane, allows the interaction of antigen and antibody or DNA/RNA hybridisation. This area contains the test line and the control line. The antibody or nucleic acid hybrid specific to the sample is immobilised on the test line and the control line consists of a secondary sample recognition element. More lines or separate channels can be added to check for different analytes from the same sample simultaneously.
- **Absorption pad:** Usually the last section of the lateral flow strip. This collects excess waste and ensures that there is no back flow of the fluid.

**Increasingly versatile, accurate, reproducible, and reliable**

LFTs have evolved significantly from simple qualitative results, for instance home pregnancy tests (originally introduced in 1976), to the point that they completely satisfy the ASSURED criteria established by WHO (World Health Organization), covering the whole range of target product profile (TPP) from level one to level five. However, the test accuracy relies heavily on the quality and preparation of the antibodies. Additionally, antibodies have a number of limitations such as high batch-to-batch variation, poor stability, long development time, difficulty in functionalisation, need for ethical approval, and effective cold chains. Antibody mimetics, such as Affimer proteins, are well placed to address these challenges.

## Affimer proteins can address many diagnostic needs

**Affimers proteins are arguably able to perform better than antibodies**

Antibodies have become a mainstay of diagnostic applications, where they underpin many of the established gold standards of investigative assessments (eg ELISA, RIA, and Flow Cytometry). Their high specificity, selectivity, and flexibility makes them particularly suitable for assays that require minimal amounts of reagent and small concentrations of analyte. However, as testing needs become more sophisticated, so the limitations embodied by antibodies are increasingly apparent. As a result, numerous alternatives have been proposed, including antibody fragments, nucleic acid aptamers, and engineered non-antibody protein scaffolds. Affimer scaffolds are, arguably, the best-in-class of these alternatives and can be used in all typical antibody applications.

**High specificity, low variability, and stable across environments**

Affimer proteins can be designed to be highly specific to a desired target, with little (if any) cross-reactivity with even closely related targets. They are produced easily, with high consistency across batches, and are stable across a very broad range of pHs and temperatures. They can be combined easily with each other, antibodies, or other biomolecules by simple, rapid, and proven methods to design the desired molecule or complex.

**Applications are as broad, if not more so, than antibodies**

Affimer properties mean they can be employed widely in key life sciences areas such as biomedical immunoassays, bioprocessing, and imaging. Avacta has chosen to focus on clinical and consumer diagnostics, which offer sizeable commercial opportunities and can more readily realise the benefits of Affimer reagents. Avacta has employed the technical benefits of Affimer reagents to develop a broad array of IVD tests that address existing limitations. These can range from incremental improvements, such as better sensitivity, specificity, robustness, speed of development, security of supply, and addressing targets not possible for antibodies, right though to broader opportunities, such as offering the freedom to operate by not encroaching on existing intellectual property (IP).

## How to capture a share of the strategic opportunity

**Previous approach was to demonstrate Affimers' value**

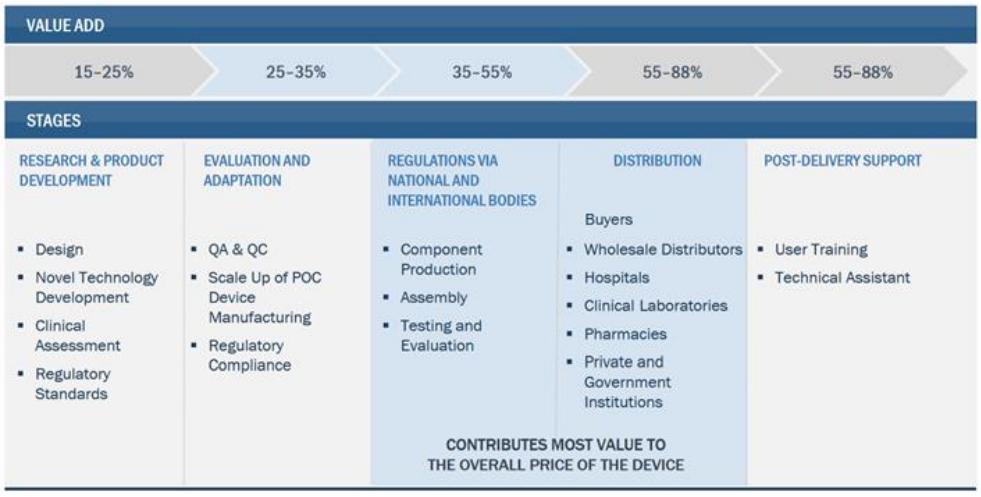
Historically, Avacta aimed to provide Affimers to third parties for use in their diagnostic applications and, over time, the technical benefits of Affimer reagents would result in a comprehensive array of IVD tests that address existing limitations. The initial campaigns to build awareness of the utility of Affimer reagents consisted of two complementary approaches:

- **Paid-for evaluations:** prospective partners or customers explored the use of Affimer reagents in a variety of potential applications. The aim was to embed the relevant Affimer molecule into their commercial diagnostic portfolio and strike a royalty bearing licensing agreement.
- **In-house development:** a more proactive approach involved the generation of selected diagnostic applications, complete with the supporting regulatory data packages, and then out-licensing (at a higher royalty rate) on completion of this work.

**Rapid response resulted in an integrated organization**

The COVID-19 pandemic marked a turning point. The pressing need for accurate diagnostics, particularly POC tests, was clear and entered public consciousness. Avacta, among many others, responded promptly and, once the SARS-CoV-2 structure was made public, identified, and generated Affimer-based reagents within five weeks. Several different approaches were tried, but soon the bulk of internal resources were directed to develop what became AffiDX SARS-CoV-2. Partnerships with appropriately skilled partners saw the creation of an LFT that had a competitive profile with potentially class-leading clinical performance. Whilst the outcome of AffiDX SARS-CoV-2 LFT (January 2022 Lighthouse) was not as hoped, the Diagnostic business itself has been transformed.

**Exhibit 5: Diagnostics value chain – typical value gained across the process**




Source: MarketsandMarkets – Point of Care & Rapid Diagnostics Market January 2021

**Diagnostics value chain becomes more attractive as it approaches the end-user**

Exhibit 5 shows the typical value chain for POC diagnostics and illustrates where the greatest commercial opportunities lie. Some players, and AIM-listed Aptamer Group is an apt example, are focused exclusively as service providers of novel reagents and components. The larger players tend to operate across the board with fully integrated operations.

**Rationale of Launch Diagnostics acquisition is clear and suggests more in-fill deals to come**

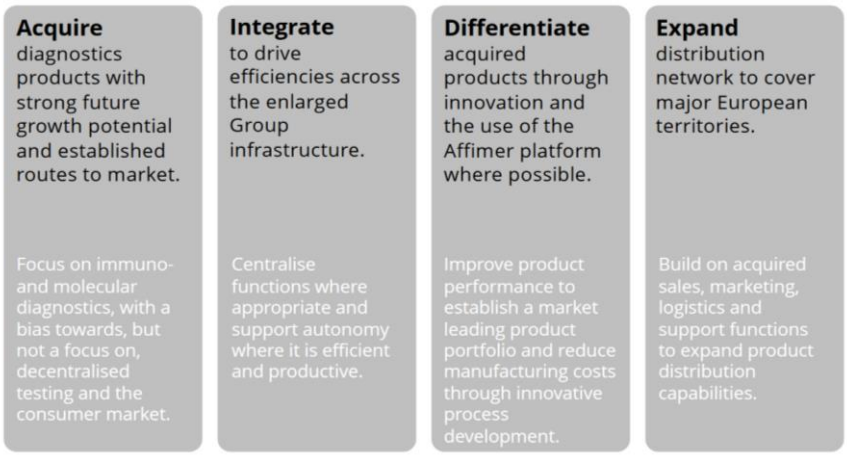
Given these market dynamics and the breadth of potential opportunities, both across the value chain and by end use, the rationale underpinning the acquisition of Launch Diagnostics becomes clear. Evidently the acquisition is the first step in Avacta's M&A-led growth strategy for its Diagnostics division. Launch provides the commercial infrastructure in the UK and some EU markets to which complementary products (and capabilities) could be added either organically through in-house development or sought externally. The latter potentially provides the opportunity to leverage Avacta's internal expertise and platform technologies to optimise the performance and economics over the medium- and longer-term. The size and nature of the October 2022 financing (£64m gross, £56.8m net) provides balance sheet flexibility to explore such opportunities.

## Diagnostics M&A-led growth strategy

**A strategy to develop an integrated European-based diagnostics business…**

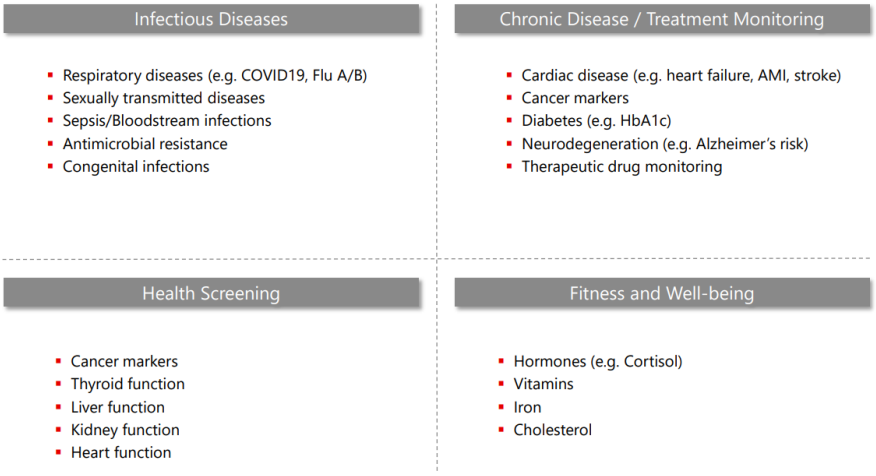
Management has spent a year working on this M&A-led growth strategy for its Diagnostics division, establishing a pipeline of potential acquisition targets in the European diagnostics sector, and executing the first deal: Launch Diagnostics. We expect additional acquisitions will help flesh scale up and accelerate the build out of a broad IVD product portfolio for both consumer and professional use.

**Exhibit 6: The model for creating an integrated IVD business**




Source: Avacta

**Exhibit 7: Focus areas for future Diagnostics opportunities**




Source: Avacta

**...that targets decentralised testing and growing applications**

Avacta has previously stated its ambitions to expand into decentralised testing in other key areas: respiratory infections, cardiovascular disease, cancer, and general health and well-being Exhibit 7). Given the in-house new product development expertise and regulatory processes already in place (validated by ISO13485 accreditation), coupled with the Launch Diagnostics distribution capabilities, we expect management strategic efforts will focus on the creation of a business that provides access to the entire value chain. The opportunities to consolidate within a highly fragmented European sector suggests the next steps will be to augment the product offering further and strengthen the UK and European infrastructures.

## Launch Diagnostics: the first deal in the Dx M&A strategy

**Launch seems ideally placed to act as the core backbone for developing structure**

Launch Diagnostics is a profitable, independent distributor established in 1990. It provides immunodiagnostic and molecular test products, technical support, and maintenance supplies from global manufacturers to public and private healthcare systems, mainly for microbiology applications. The UK accounts for over 70% of sales, which are primarily to NHS hospital laboratories, with a smaller presence in Belgium, Luxembourg, the Republic of Ireland, and France. Launch has over 500 active customers, of which c 90% are public body laboratories with the remainder being clinical trial centres, cancer centres, and commercial laboratories. Customer contracts typically run for three to five years, and around 95% of sales are repeat business. There are currently 31 manufacturers partnered, although the top five account for the majority of recurring sales (ie non-COVID).

**Revenues distorted by a large COVID spike**

2021 revenues were £32.8m, although these were boosted by COVID testing revenue of £18.6m (treated as non-recurring in our forecasts) to leave core sales of £14.2m. In FY20 sales were £29.6m, with COVID-related sales of £14.6m and core revenues of £15.0m. Both years' core revenues were down on FY19 (pre-COVID) sales of £18.5m as many normal diagnostic functions were disrupted. However, a return to typical ordering patterns is underway and we expect FY23E core revenues (the first year which will be fully consolidated in Avacta's accounts) of £17.0m, which represents a two-year core revenue CAGR of c 10%.

**Attractive margins and a large degree of visibility**

Gross margin has been consistent at c 44-50% since FY19. FY19 EBITDA was £0.8m, with the impact of COVID-related revenues evident in the leap in EBITDA to £7.2m in FY20 and to £7.6m in FY21 (£8.5m when adjusting to a market rate Managing Director salary and the removal of non-recurring professional fees). The residual COVID effect should continue to boost EBITDA in FY22, but we expect a return to a more normalised EBITDA of £1.3m in FY23E growing to a sustainable £2-3m from FY25E.

**Seeking to maximise cross-selling opportunities, whilst retaining core values**

Post-acquisition, Launch Diagnostics will remain an independent operation, with plans in place to grow sales and margin through geographical expansion, cross-selling to new customers gained during the pandemic, and expansion of the product range. The near-term will see efforts to sell an extended array of microbial tests to existing and new clients. Further out, the product portfolio will be expanded through both in-house development and acquisition/in-licensing. The existing Launch infrastructure in France will be strengthened with investment in commercial, logistics, and support teams to allow geographic expansion into Germany, other European countries, and French-speaking North African countries.

## Diagnostics market is large, fragmented, and growing

**Already a sizeable market, and set to grow further**

The diagnostics market is large, growing, and very diverse. Laboratory testing still accounts for the highest volume, but POC or near-patient tests are becoming increasingly prevalent. The COVID-19 pandemic disrupted the market make-up, but the underlying trends remain in place. Greater automation is driving changes within central laboratories, with larger players such as Abbott and Roche providing advanced flexible platforms that are capable of multiple operations. The major players are also active in POC, but this segment is more diverse with certain segments better suited to the smaller, and arguably nimbler, companies.

**POC set to gain material clinical traction post-pandemic**

Estimates do vary, reflecting differing inclusions, on the size of the global POC market, with these ranging from $29.6bn to $43.2bn, and growth forecasts varying from 5.2% to 11.4% CAGR to give a range of $50.6bn to $72.0bn in 2027. Until the COVID-19 pandemic upended market dynamics (which these figures attempt to allow for), this was driven by home glucose testing (principally Type I diabetics) and pregnancy tests (one of the earliest examples of a consumer LFT). The US dominates, representing 39.3% of global share and growing at 12.1% CAGR, but POC uptake has only really gained traction in recent years. The picture across Europe is not uniform, with strong adoption in countries such as Germany, the Netherlands, and Scandinavia, offset by relatively low penetration in countries such as France and the UK.

**Central laboratory testing seen as fundamental, but POC expected to grow faster**

In all industry commentaries and expert reviews, the central laboratory model remains seen as the dominant testing format, as greater automation and workflow optimisation allows the analysis of large sample numbers at low relative costs. This is well established for routine haematology and biochemistry markers and is being extended to, among others, anatomical pathology and microbiology testing. However, the need for improved point-of-care decision making, coupled with a more patient-centric approach (effectively treating more patients in primary care rather than in the more expensive hospital settings) means POC testing is expected to show volume and value growth despite continuing pricing pressures.

**LFTs expected to become a central tenet of future growth**

LFTs are expected to remain a core element of this growth as they are cost-effective, rapid, and can be used with minimal training, which means they can be a critical part of testing strategies globally. Again, estimates vary (it is here that COVID-19 impacts cause most distortion), but the LFT segment size ranges from $7.5bn to $9.2bn currently to $11.6bn to $14.2bn in 2027. Growth is expected to be driven by rising use in the rapid diagnosis of infectious diseases, ranging from pneumonia to STDs (sexually transmitted diseases). Swift identification of the causative agent is seen as a major factor in limiting microbial antibiotic resistance.

**Technology advances should broaden clinical utility further**

Importantly, in most cases an LFT's analytical performance is more than sufficient for the required clinical purposes. However, advances in miniaturisation, increased computing power, and the ubiquity of smart phones means LFT-based POC testing will expand materially beyond what is currently available. Many of these tests will still require the appropriate antibodies to identify the desired characteristic but their limitations, particularly physical, should facilitate the adoption of synthetic mimetics such as Affimers.

# Valuation

**We value Avacta using an rNPV model for Therapeutics and a simpler DCF for Diagnostics**

Following the fundraise and the Launch Diagnostics acquisition, we have updated our valuation to reflect these developments, in addition to H122 results and Avacta's latest cash position. Our valuation continues to be based on an rNPV of the lead clinical asset AVA6000, and an aggregate rNPV for the remainder of the proprietary platforms, Affimer and pre|CISION. For these, we employ conservative assumptions throughout and the success probabilities are based on standard industry criteria for the respective stage of clinical development but, importantly, flexed to reflect the inherent risks of platforms that are as yet unproven in human studies. In addition, we now include a DCF valuation for Launch Diagnostics, based on the key assumptions outlined in this report.

**Valuation for Avacta is £587m, equivalent to 221p per share**

We then net these against operating costs (excluding specific assumptions for Launch Diagnostics), which together with forecast end-December 2022 net cash generates a new Avacta valuation of £587m (from £557m), equivalent to 221p per share. The increase in rNPV is largely driven by the incorporation of Launch Diagnostics. Our updated valuation is shown in Exhibit 8. We envisage revisiting our models as news flow on AVA6000's clinical progress is released and, importantly, as further plans for the Diagnostics business emerge.

**Exhibit 8: Avacta sum of the parts valuation**

| Programme | Total NPV (£m) | Total NPV ($m) | Success probability | rNPV (£m) | rNPV ($m) | rNPV/ share (p) | Notes |
|---|---|---|---|---|---|---|---|
| **AVA6000** (doxorubicin prodrug) | 653.8 | 784.5 | 10% | 61.6 | 74.0 | 23.2 | Royalty: 15%; Launch year: 2026; Peak sales $1.5bn |
| **pre\|CISION platform** (various preclinical) | 1,758.6 | 2,110.4 | 10% | 270.9 | 325.1 | 101.9 | Royalty: 15%; Launch year: 2027+ |
| **Affimer platform** (various preclinical assets & diagnostics) | 2,228.6 | 2,674.3 | 6% | 267.7 | 321.3 | 100.7 | Royalty: 20%; Launch year: 2028+ |
| **Diagnostics** | 34.2 | 41.0 | 100% | 34.2 | 41.0 | 12.9 | Launch Diagnostics |
| Operating costs | (39.5) | (47.3) | | (39.5) | (47.3) | (14.8) | |
| Net cash | (8.0) | (9.6) | | (8.0) | (9.6) | (3.0) | At FY22E |
| **Total** | **4,795.1** | **5,754.1** | | **587.0** | **704.4** | **220.8** | |

Source: Trinity Delta Note: assumptions include a 12.5% discount factor, £/$ FX rate of 1.20

**Total pre|CISION rNPV, including AVA6000, is £333m or 125p/share**

We have calculated the rNPV of the lead development project, AVA6000, and attributed an indicative value to the pre|CISION platform. Positive outcomes for AVA6000 would not only drive an increase in its rNPV, but also materially act as validation for, and de-risk, the pre|CISION platform, resulting in sizeable upside potential. The valuation for AVA6000 is £62m, equivalent to 23p per share, with £271m, 102p per share, for the as yet non-clinical pre|CISION portfolio.

**Affimer valuation is £268m or 101p/share, with upside as this is incorporated into the emerging Diagnostics strategy**

The Affimer platform has utility across Therapeutic and Diagnostics applications. The valuation we assign to the Affimer platform is £268m, or 101p per share. As the Diagnostics strategy emerges and Affimer technology is incorporated, the inherent value in this platform should unlock and be realised, which could see a material uplift in our valuation.

**Launch Diagnostics DCF of £34m or 13p/share suggests deal was attractively priced**

For Launch Diagnostics, we now include a DCF valuation of £34m or 13p per share, based on the key assumptions outlined earlier in this report. Our approach is conservative, notably around inclusion of only core Revenues (excluding any major further COVID-19 related sales contribution), plus on gross margins and profitability. Despite this stance, our DCF valuation of £34m suggests the deal, with an acquisition cost of £24m (excluding any future potential earn-outs), was attractively priced. This is also confirmed by deal multiples, with an undemanding 1.35x FY21 sales multiple (discounting the £18.6m COVID-19 revenues by 80%) and a similar c 1.37x FY23E sales multiple based on our forecasts.

## Financials

**An over-subscribed equity raise, coupled with a convertible bond, to fund Diagnostics strategy**

In October 2022, Avacta raised a total of £64m through a combination of £55m in convertible bonds (issued at 95% of the principal for gross cash proceeds of £52.25m), £7m through an oversubscribed institutional placing, and £2m from an open share offer, resulting in total gross cash proceeds of £61.25m (we estimate total net proceeds of £56.8m). These were used to fund the acquisition of Launch Diagnostics, which completed in October 2022, for £24m (on a debt free/cash free basis), with a potential future performance based earn-out, capped at £13m. The earn-out only becomes payable if there is a significant recovery in future COVID test revenues, with the consideration representing 50% of the gross margin on sales over £2m (annualised) over the next three years. Our Launch Diagnostics forecasts assume no COVID-19 revenues over this period, hence the potential earn-out does not feature in our model. The balance of funds raised are destined for the planned M&A growth strategy, to invest in those acquired businesses, and to provide working capital for the wider group.

**CB will amortise over its five-year life, with option to pay it and coupon in shares or cash**

The £55m Convertible Bond (CB) is senior, unsecured, due in October 2027, and issued at 95% of the principal for gross cash proceeds of £52.25m. The coupon is 6.5% per annum, payable quarterly in arrears in either cash or new shares, at the option of the company. The principal amortises quarterly at 5% of the original amount, equivalent to £2.75m per quarter, and is payable in either cash or new shares, also at the option of the company. This results in the total repayment of the CB by October 2027. The new shares will be priced at the lower of the prevailing conversion price (a 25% premium to the 95p offer price ie 118.75p) or 90% of the weighted average market price. The CB can be converted by the holder at any time. After 18 months, if the share price falls, there is an option to reset the conversion price to the higher of the offer price or the then volume weighted market price. If this reset is activated and the market price recovers, the company has the option to claw back to the original conversion price. For the purposes of our model, we assume the CB and coupon are repaid over the five years, in shares priced at 118.75p. Until the CB is settled there are likely to be non-cash fair value adjustments recorded in the accounts, on which we have limited visibility and hence do not include in our model until reported.

**Placing raised c £7m (gross) with open offer raising a further c £2m (gross)**

The Placing element of the share issue raised c £7m (gross) through issuance of 7.38m new shares at 95p to institutional investors, to both new and existing shareholders. Management subscription shares of 15,000 were also taken up. The Open offer was heavily over-subscribed and raised the planned c £2m (gross) through the issue of 2.1m new shares, also at 95p, to qualifying shareholders (three new open offer shares were available for every 365 ordinary shares held).

**Revenues to be driven by Launch Diagnostics from FY23E**

Avacta's H122 revenues were £5.5m (H121: £1.5m; FY21: £2.9m). The Therapeutics Division was the major contributor with £5.4m (H121: £1.4m; FY21: £2.2m), mainly from milestones achieved under collaborations with LG Chem (£1.5m in cash) and AffyXell (£3.7m in new equity in the JV), with the residual from FTE reimbursement. Diagnostics revenues were £0.1m (H121: £0.1m; FY21: £0.8m) reflecting the focus on in-house R&D and fewer custom projects. For FY22E we forecast core Avacta revenues of £5.9m, which do not include any assumed milestones during H222, and reflects underlying H122 trends; we also include £2.5m of consolidated Launch Diagnostics revenue, for total revenues of £8.4m. For FY23E we forecast core Avacta revenues (excluding any contribution

from Launch Diagnostics) of c £1.2m, largely from the Therapeutics division; in-line with our conservative approach we do not include any potential milestone income, which could provide revenue upside.

**Forecast stable R&D but SG&A to increase as Launch Diagnostics is consolidated**

During H122, R&D spend was £6.4m, a decrease from £6.7m in H121 (FY21: £14.3m), whereas SG&A costs increased to £5.6m (H121: £4.2m; FY21: £9.6m). This led to an Operating loss of £9.6m (H121: £11.3m; FY21: £29.1m), with a net loss from continuing operations of £9.0m (H121: £10.2m; FY21: £26.4m). The sale of the Animal Health Division in March 2022 for £0.9m upfront and a deferred contingent consideration of up to £1.4m resulted in a £1.1m discontinued operations profit. For FY22E we forecast R&D spend of £14.0m, slightly below FY21, and SG&A expenses of £12.0m (including c £1m of consolidated Launch Diagnostics costs), above FY21. We assume both continue to grow on an underlying basis in FY23E, albeit the consolidation of Launch Diagnostics, outlined below, leads to a more material uptick in SG&A costs. This drives an Operating Loss of £25.4m in FY22E and £31.1m in FY23E, and a Net Loss of £21.6m and £28.7m, respectively. End-June 2022 cash and equivalents were £17.0m (end-December 2021: £26.2m). Adjusting for H222 cash burn, the £64m (gross) fundraise, and the £24m Launch Diagnostics acquisition, we forecast end-December 2022 cash of £40.3m.

**Forecast Launch Diagnostics FY23E core revenue of £17.0m and longer-term sustainable EBITDA of c £2-3m per annum**

As outlined earlier in this report, for Launch Diagnostics we forecast fully consolidated core revenues of £17.0m in FY23E, with a minor £0.5m contribution from COVID-19 related sales; we do not include any further contribution from COVID-19 beyond FY23E. Our forecasts assume a return to pre-COVID-19 revenues and sustainable c 10% core revenue growth from FY24E. We assume long-term gross margins of 42%, likely conservative given these have been around 44-50% since FY19. We include underlying Launch Diagnostics SG&A of c £6-7m per annum, which we increase sequentially, for adjusted EBITDA of around £2-3m per annum from FY25E.

## Exhibit 9: Summary of financials

| Year-end: Dec 31 | £'000s | 2019 | 2020 | 2021 | 2022E | 2023E |
|---|---|---|---|---|---|---|
| **INCOME STATEMENT** | | | | | | |
| **Revenues** | | **5,511** | **2,144** | **2,941** | **8,369** | **18,705** |
| Cost of goods sold | | (1,440) | (962) | (924) | (2,513) | (10,429) |
| **Gross Profit** | | **4,071** | **1,182** | **2,017** | **5,856** | **8,276** |
| Manufacturing expenses | | 0 | 0 | (2,143) | 0 | 0 |
| R&D expenses | | (10,062) | (9,715) | (14,301) | (14,015) | (16,117) |
| SG&A expenses | | (11,700) | (6,996) | (9,598) | (12,048) | (18,501) |
| **Underlying operating profit** | | **(17,691)** | **(15,529)** | **(24,025)** | **(20,207)** | **(26,342)** |
| Share-based payments | | (338) | (3,070) | (5,058) | (4,575) | (4,803) |
| Exceptionals | | 0 | (217) | 0 | (646) | 0 |
| Other revenue/expenses | | 0 | 0 | 0 | 0 | 0 |
| **EBITDA** | | **(14,080)** | **(14,921)** | **(26,707)** | **(22,989)** | **(28,918)** |
| **Operating Profit** | | **(18,029)** | **(18,816)** | **(29,083)** | **(25,428)** | **(31,145)** |
| Financing costs/income | | (25) | (46) | (111) | 15 | 64 |
| **Profit Before Taxes** | | **(18,054)** | **(18,862)** | **(29,194)** | **(25,413)** | **(31,082)** |
| **Adj. PBT** | | **(17,716)** | **(15,575)** | **(24,136)** | **(20,192)** | **(26,278)** |
| Current tax income | | 2,439 | 2,464 | 2,820 | 2,803 | 2,418 |
| Discontinued operations | | 0 | (2,494) | 58 | 1,055 | 0 |
| **Net Income** | | **(15,615)** | **(18,892)** | **(26,316)** | **(21,555)** | **(28,664)** |
| | | | | | | |
| **EPS (p)** | | **(13.0)** | **(8.4)** | **(10.5)** | **(8.3)** | **(10.6)** |
| **Adj. EPS** | | **(12.7)** | **(6.0)** | **(8.7)** | **(6.9)** | **(8.9)** |
| **DPS (p)** | | **0.0** | **0.0** | **0.0** | **0.0** | **0.0** |
| Average no. of shares (m) | | 120.3 | 225.6 | 249.5 | 259.9 | 271.7 |
| | | | | | | |
| **BALANCE SHEET** | | | | | | |
| **Current assets** | | **13,526** | **53,254** | **34,736** | **51,160** | **27,238** |
| Cash and cash equivalents | | 8,788 | 47,911 | 26,191 | 40,309 | 17,476 |
| Accounts receivable | | 2,082 | 2,895 | 4,327 | 6,878 | 5,125 |
| Other current assets | | 2,500 | 2,200 | 4,029 | 2,733 | 2,637 |
| **Non-current assets** | | **14,884** | **14,208** | **12,266** | **34,795** | **33,625** |
| Property, plant & equipment | | 2,304 | 2,696 | 2,612 | 2,381 | 2,315 |
| Intangible assets | | 11,800 | 9,417 | 7,925 | 31,258 | 30,669 |
| Other non-current assets | | 780 | 2,095 | 1,729 | 1,156 | 640 |
| **Current liabilities** | | **(1,955)** | **(3,781)** | **(4,368)** | **(4,778)** | **(4,062)** |
| Short-term debt | | 0 | 0 | 0 | 0 | 0 |
| Accounts payable | | (1,778) | (3,491) | (3,731) | (4,204) | (3,546) |
| Other current liabilities | | (177) | (290) | (637) | (573) | (516) |
| **Non-current liabilities** | | **(646)** | **(1,752)** | **(1,412)** | **(48,989)** | **(37,473)** |
| Long-term debt | | 0 | 0 | 0 | (48,303) | (37,303) |
| Other non-current liabilities | | (646) | (1,752) | (1,412) | (687) | (171) |
| **Equity** | | **25,809** | **61,929** | **41,222** | **32,188** | **19,327** |
| | | | | | | |
| **CASH FLOW STATEMENTS** | | | | | | |
| **Operating cash flow** | | **(13,015)** | **(10,642)** | **(20,505)** | **(17,492)** | **(21,261)** |
| Profit before tax | | (18,054) | (18,862) | (29,194) | (25,413) | (31,082) |
| Non-cash adjustments | | 4,245 | 4,702 | 7,529 | 6,999 | 6,967 |
| Change in working capital | | (717) | 722 | (1,129) | (1,913) | 277 |
| Interest paid | | 72 | 42 | 17 | 15 | 64 |
| Taxes paid | | 1,439 | 2,754 | 2,272 | 2,820 | 2,514 |
| **Investing cash flow** | | **(2,527)** | **(21,899)** | **18,703** | **(25,542)** | **(1,572)** |
| CAPEX on tangible assets | | (2,527) | (1,665) | (1,314) | (1,542) | (1,572) |
| Acquisitions/disposals | | 0 | (217) | 0 | (24,000) | 0 |
| Other investing cash flows | | 0 | (20,017) | 20,017 | 0 | 0 |
| **Financing cash flow** | | **19,110** | **51,647** | **232** | **57,152** | **0** |
| Proceeds from equity | | 19,331 | 51,902 | 522 | 9,001 | 0 |
| Increase in loans | | 0 | 0 | 0 | 48,227 | 0 |
| Other financing cash flow | | (221) | (255) | (290) | (76) | 0 |
| **Net increase in cash** | | **3,568** | **19,106** | **(1,570)** | **14,118** | **(22,833)** |
| Cash at start of year | | 5,220 | 8,788 | 27,894 | 26,191 | 40,309 |
| **Cash at end of year** | | **8,788** | **27,894** | **26,328** | **40,309** | **17,476** |
| **Net cash at end of year** | | **8,788** | **47,911** | **26,191** | **(7,994)** | **(19,826)** |

Source: Company, Trinity Delta Note: Due to restatement of accounts FY19 relates to 17 month period ended 31 December 2019; and FY20 to 12 month period ended 31 December 2020. Revenue forecasts do not include products that have not yet been approved or launched, nor milestones yet to be received.

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