

Part of **BBI** Group

BBI Solutions Annual Review 2020







Serving the science of diagnostics



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More information about BBI Solutions can be found online at <u>bbisolutions.com</u> We create value by using our scientific innovation, world-class facilities and commercial responsiveness to serve the in vitro diagnostic industry. We provide



immunodiagnostic reagents and individual test components to our diagnostics customers, while also offering solutions that bring these components together in complete laboratory or point-of-care tests. For our employees, we have developed a working

environment and culture where they can progress their careers serving the science of diagnostics, and contribute towards providing healthcare on a global stage.



Financial highlights*

 Revenue
 Gross profit
 EBITDA

 £60.0m
 £32.9m
 £18.6m
 18.5%

* Figures stated are proforma unaudited results for BBI Solutions (see pages 40 - 43).

BBI Solutions at a glance



BBI Solutions businesses

BBI Solutions is the world's largest independent supplier of immunodiagnostic reagents, offering a portfolio of market-leading products and services for the diagnostic, pharma and life-science industries globally – tailored to the needs of individual projects and compliant with all relevant regulations.

BBI Solutions at a glance

Revenue

£60.0m 6.6%

Gross profit



EBITDA £18.6m 18.5%

 * Figures stated are proforma unaudited results for BBI Solutions (see pages 40 - 43).



Significant investment in facilities and systems has enhanced our excellence and extended our capacity over eight sites. _____Read more p16





- Eight sites on four continents enhances security of supply
- Over 400 employees
- Global ISO 13485:2016 certification







BBI Solutions

A leading expert in immunoassay reagent and test development and manufacturing services, providing an extensive portfolio of products and technologies to the global diagnostic market.



Novarum[™] DX

Pioneering technology that revolutionise point-of-care testing by utilising smartphones to allow untrained users to run lateral-flow tests, read results accurately and send them to healthcare professionals in real time.



Maine Biotechnology Services

MBS offers 30 years of knowledge and experience in antibody development, ensuring the best possible antibodies for any application.



DIARECT

Diarect's world-leading recombinant autoimmune antigen capability positions BBI as a complete immunoassay reagent supplier.



Chairman's letter

Welcome to the BBI Solutions Annual Review for 2020. It is not a mandatory requirement for a privately owned company to produce an annual review, but the company has developed and matured to the extent that we judge such a publication would be useful.

Delivering value through innovation, partnership and effective delivery

Alan Peterson OBE Chairman, BBI We believe it is good practice for a large, growing company to explain its purpose, model and governance. In addition, this review will help explain the bigger picture of BBI Solutions to the many partners that have a role to play along our value chain - whether a newly recruited scientist in one of our labs, a specialist supplier of crucial materials, or a healthcare customer who relies on our diagnostic components being the very best possible - or, indeed, a potential future funder of our business. With this review, we hope to offer all a greater insight into what we do, and some inspiration for the role they play in it.

Serving a growing market

So, what is BBI Solutions? We are experts in producing antibodies, antigens and assay 'labels' such as enzymes and gold nanoparticles – and in bringing these together to manufacturing assays used in laboratory investigative procedures. We are also experts in supplying all these materials to the large laboratories of the world's leading diagnostic and healthcare organisations. We particularly focus on the fastest growing or largest disease states, such as infectious diseases, heart disease and cancers.

The company's expertise has been built over 60 years, with a history in producing pure gold nanoparticles for use in diagnostic assays. We have now extended our expertise to many of the other critical components needed in a diagnostic test. These include an antigen - the molecule or protein that's causing whatever disease you're looking at - and for every antigen there is an equal, opposite and unique antibody. Then there are the controls that ensure each component in a test is working accurately. Today, 60%-70% of physicians' diagnoses of major diseases are based on test results. This is the large and growing market we serve.

Developing a highly valuable asset

My involvement with the company goes back to 2015 when Exponent acquired BBI Group. We saw it as an opportunity to bring together a selection of individual manufacturing assets and make a greater connection between them all – in what they were trying to do, and what our customers wanted from us. It took us some time to understand this fully, but we knew we could improve the quality and performance of the laboratories and production centres.

In an industry where accuracy and compliance are the key priorities, things have to be absolutely right, and so we have invested over £20 million in the infrastructure and equipment across our sites. We rationalised many smaller production sites, and have acquired

\bigcirc

"Components of our supply chain are now best-in-class and audited as such by regulators and customers."



new business assets to broaden and complement the scope of our products and services. We have also built a new centre of excellence in Wales, with the help of the Welsh Government. As a result, all our facilities and supply chain are now best-in-class, and audited as such by regulators and customers alike. We now provide those customers and our employees with world-class conditions for producing very sensitive and important materials.

The importance of our people

So BBI Solutions is now about worldclass laboratories and production facilities using world-class techniques. But we also have world-class scientists - as you can read in this review, we have accumulated some of the best talent in the scientific diagnostics world. They are led by a deeply experienced management team and supported by a highly skilled employee base. Here I must record my thanks for the outstanding commitment and dedication of our workforce, as all our sites were able to work continuously throughout 2020, despite the day-to-day challenges of the Covid-19 pandemic. During the year, we have also been working hard on career development and progression, so we can retain and grow this talent within our organisation.

Governance

The Board of BBI Solutions comprises a mix of senior executives and nonexecutive directors. The non-executive team has wide international experience in healthcare, finance and global business. The Board has sub-committees for Audit, Reporting and Controls, plus Remuneration, Appointments and Succession Planning. It also regularly reviews ESG matters. The prime Board responsibility is building the business strategy and then ensuring its execution, through rigorous controls and monitoring.

Our growth strategy

We are in effect a raw materials producer of the highest standards in antigens and antibodies, and then in the labels that form part of the diagnostic reagents mix. We combine these with appropriate manufacturing processes to make test kits, whether as part of a laboratory process or a point-of-care assay. We do this specifically to order for our customers, or for our own products.

As I mentioned at the beginning, our strategy is to focus on the fastest growing disease states. These diseases are global problems that are linked to a number of trends such as an ageing population, a generally deteriorating diet involving more sugars and fat, and environmental issues such as exposure to high pollution – cancer being a prime example. While there are many operators that produce reagents and critical components, and a few companies that specialise in point-of-care assays, nobody is working at the full depth, breadth and scale we are. All of which is what makes BBI Solutions not only a growing company in the fastest growing segment of a growing market, but also a company that can bring great value to society through its efforts.

All our facilities and supply chain are now first class, and audited as such by regulators and customers. Our growth and expertise have been greatly enhanced by the acquisitions of Novarum[™], MBS and Diarect, each featured in this review. These businesses have been integrated into our business 'value stream' model, while retaining the unique expertise that first attracted us. Our Group is truly international, operating in the US, South Africa, Germany, China and the UK, reflecting the global nature of the diagnostic sector. We look to grow both organically and by acquisition in our chosen markets, including in the new and growing arena of telemedicine.

To finish, I would like to thank all those employees, customers and business partners who have fuelled our journey so far and on whom we rely to propel our future growth.

Alan Peterson OBE Chairman, BBI

More information about BBI Solutions can be found online at <u>bbisolutions.com</u>

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Growth drivers for **BBI Solutions**

⇒ Attractive endmarkets with stable long-term growth \bigcirc Diversified product portfolio and working with the



13% of our employees have MSc

world's leading IVD companies ⊖ Well-invested, scalable global platform

⊖ Strong financial performance with high level of recurring revenue

⇒ Well positioned due to process know-how, regulation and products embedded in customer solutions



Over <mark>60%</mark> of our employees



⊖ Strong growth have degrees outlook including highly complementary strategic acquisitions \bigcirc Enhanced and highly experienced management team



Q&A with Chief Executive Officer

Here Dr. Mario Gualano, CEO of BBI Solutions since August 2017, describes the company's market and strategy and outlines its performance in 2020.

Dr. Mario Gualano CEO of BBI Solutions



Q To set the context, could you please explain the market BBI Solutions is in?

MG We develop and manufacture critical components for the in vitro diagnostic (IVD) industry. Patients presenting to a physician require a diagnosis, which in the majority of cases is supported with a diagnostic test - many of which are immunoassays. We are the world's largest independent producer of the immunodiagnostic reagents that form the basis of those assays, and focus our efforts on that market segment. As well as providing the individual test components to our customers, we also offer solutions that bring critical components together in complete laboratory assay or point-of-care test.

Q What's the basis of the science, for a non-scientific person?

MG An immunoassay detects the presence or concentration of a target molecule in a sample, by exploiting the basis of the immune response. Let's take coronavirus as an example. If the virus enters the body, the immune system recognises the threat and starts to react to it. As part of that reaction it may raise antibodies. In this instance we would call the virus the antigen, really a term for anything that triggers the production of an antibody. The antigen and antibody are exactly matched, a biological 'lock and key'. So, if we isolate the antibody, we have a way of very accurately 'capturing' the virus from other samples. It becomes part of our test and can be used to identify the virus if it is present in a sample.

Q How is it applied in practice?

MG In practice we usually immobilise the antibody on a surface and pass a sample over it. If the target antigen is present it is captured and we can then use other reagents that we call labels to demonstrate its presence – a 'positive result'. The core assay principles are the same whether they're performed on large, high-volume automated analysers in hospital laboratories or on lateral-flow point-of-care (PoC) devices such as a home pregnancy test.

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Q&A with Chief Executive Officer continued

As a business, we produce the critical test components – such as antibodies, antigens, labels and controls – that are the basis of billions of tests performed around the world annually. We design and develop those components to bespoke specifications for our customers. We then make sure each component is working accurately in its own right, and bring them all together so they are all working accurately together in a final assay. That detailed focus on accuracy and quality is essential to diagnostic performance.

Q Who do you supply with these components and tests?

MG About 80% of our products are used in clinical laboratories or point-of-care tests, and the remainder support testing in markets other than healthcare such as food and industrial testing. In healthcare, our end users are hospitals, physicians, laboratories and near-patient testing environments.

Our reagent range generates more than 70% of our revenues. We typically provide those reagents to large 'bluechip' IVD manufacturers that supply diagnostic tests to hospitals on a global scale. As you can appreciate this is a highly regulated and exacting industry. Our reagents are validated into our customer platforms – so we typically sell our products and services to the same customers, year in, year out.

In our services business – the other 30% – we use our unique combination of individual reagent expertise and 'whole assay' system development to deliver for our customers. Finally, in our Novarum™ mobile app, we offer a telemedicine platform for providers requiring a solution that can help them deploy their tests and provide results to their customers on a 'real-time' basis via the Cloud.

Q Could you say a bit more about how these mobile apps work?

MG In our Novarum[™] platform we've developed proprietary, IP-protected, technology that allows previously untrained people to use a smartphone to accurately run their own test, accurately interpret it via the camera, and immediately send the results to their GP, central NHS data collection or any other recipient's IT system. The app exploits wider phone functionality to ensure procedural compliance via use of video instructions, timer alarms and prompts, and then using the camera to capture the result accurately, so there is no subjectivity in interpretation.

Q So it's a broad offer across reagents, services and mobile technology?

MG Yes, and it actually makes our offering unique, our team's depth of expertise in reagent development as well as their skill in bringing all of those components together into a fully functioning point-ofcare assay. There are many companies that operate in reagents and critical components, and a few that operate in point-of-care assays, but nobody has the full depth and breadth we have. There's an increasing trend toward outsourcing and our strategic focus makes us an attractive prospective partner.

Q Tell us more about this strategic focus?

MG Setting a clear, strategic direction was a priority when I started in the role. The immunodiagnostic segment of the IVD market is attractive, it's highly aligned with our core competencies and it's a large and growing market where we have ample room to grow our share. Our capabilities are also well aligned with the trend toward point of care, and our IP-protected mobile smartphone technology adds to our value proposition.

Q To take the first of those, how have you developed that world-class capability?

MG We've spent a number of years of investing to create a business that can be effective on the global stage. That process has encompassed recruiting a first-class leadership team, investing in a world-class centre of excellence, into which we've consolidated a number of facilities to reduce our footprint, and finally investing in industry-leading systems. The latter include a quality system that's accredited to ISO 13485 standards, a new global ERP reporting system, reporting and customer relationship management software, automation and a lean manufacturing programme. All of these have been key milestones in improving our productivity and our ability to serve our customers well.

Q You also mentioned building the commercial engine?

MG Yes, a key part of our strategy is ensuring we can have in-market,

"We are the world's largest independent producer of immunodiagnostics reagents, our focus being on the immunoassay segment."

Q Therefore your aim is to continue on this growth trajectory?

MG Absolutely. With a focus on our core critical reagents and lateral-flow service capabilities, we want to maximise our growth with our existing customers and exploit our growing in-market presence to serve new ones. I think there are three key elements to the growth story. The first is what we've done in the past three years to develop a world-class scientific and manufacturing capability while working on our productivity and margins. Then to add to that is the development of what I call our commercial engine. And the third element of growth is through targeted acquisitions, which extend our capability and customer offering.

peer-to-peer interactions with our customers. That has meant investing in local teams focused around key diagnostic 'hubs' within our major target markets. That customer proximity allows us to directly serve their needs, extend our in-market capability and create channels through which we can deliver portfolio extensions, whether organic or inorganic.

Q And growth by strategic acquisition was your third strand?

MG Yes, this year, we completed the acquisition of a company called Diarect, based in Freiburg, Germany – now BBI Freiburg – the largest acquisition the company has made. With Diarect, we not only acquired a





70% Amount of revenue our reagent range generates

30%

Amount of our revenue generated by customdeveloping reagents, and lateral-flow point-of-care tests for diagnostics companies leading supplier of autoimmune antigen products but also a core recombinant capability. Completing the acquisition was particularly pleasing given that the team had to do so whilst also managing the impact of the Covid-19 pandemic on our business, and ensure our customers, and their patients, remained supplied with key diagnostic reagents. Before that, in July 2017, we acquired Maine Biotechnology Services (MBS), based in Portland, Maine, US. With MBS, we added custom antibody development services, bringing over 80 new antibodies to our growing product portfolio, and the opportunity to significantly grow our portfolio of antibodies for a wide variety of targets. Both acquisitions enhance our position as the world's largest diagnostics components company, and as a natural partner for our customers.

Q Has the pandemic highlighted the importance of diagnosis?

MG It has and our contribution to global healthcare was recognised by governments in all of our operating territories as we were formally designated critical worker status during the Covid-19 pandemic. Requests from both government and private companies to assist in the diagnosis of Covid-19 has really underlined the importance of our products and services. I've been incredibly proud of our team's reaction to the challenges posed by the pandemic and their determination to deliver great performance and an underlying strengthening of the business despite them.

Q How have you been able to look after such a critical workforce?

MG Health and safety comes first in anything we do. Early action by our health and safety team together with leadership across the entire business allowed us to keep our colleagues safe. We paid particular attention to ensuring our site-based teams were safe as they continued to come into the workplace during the pandemic, and that their colleagues assisted them by respecting work-from-home directives. I'm delighted with the way our global team has responded to both the opportunities and challenges Covid-19 has presented during the year. They not only ensured our core customers could continue to deliver essential diagnostics, but have also responded to the urgent demands for coronavirus-related reagents, tests and services.

Q How do you see the future for BBI Solutions?

MG Over the last few years, we have transformed our business through a combination of strategic investment and focused leadership. We are very proud to have an international inmarket sales force supported by industry-leading scientists, facilities and systems – quite a platform. These have allowed us to grow our global revenue, establish a culture of continuous improvement, and achieve sustainable productivity improvements. The impact of these is clear in our results.

As we look forward, I am excited by the prospect of being able to build on that platform and significantly expand our unique mix of products and services, both organically and inorganically.

Dr. Mario Gualano CEO, BBI Solutions

Market overview

An overview of our market

The global IVD market is estimated at \$59bn in 2020, growing at 6% a year. Within that, the Immunodiagnostic IVD market is estimated at \$18bn.

It is a defensive sector, based on nondiscretionary spending made by governments and healthcare providers. Customers must validate products onto test systems, and then validate these systems with regulators. There are a number of drivers of growth in the IVD market that create a unique set of opportunities we are well positioned against.



BBI Solutions at a glance

The global IVD market is estimated at:



Market drivers

There are demographic shifts in developed markets, where ageing populations lead to the increased incidence of chronic diseases such as cancer, heart disease and diabetes.

Changing diets in both developed and emerging markets are causing a growth in the incidence of similar diseases.

Maturing emerging markets such as China are creating a large increase in the accessible market size.

To improve healthcare economics, there is a desire for early diagnosis. This is accelerating research and development of innovative technology and the growth of near-patient or point-of-care testing.

Global business and travel accelerate the spread of infectious disease, with coronavirus the best example to date.

The In Vitro Diagnostic Regulation (IVDR) comes into place in Europe in 2022, replacing the previous IVD Directive. This more stringent regulation of companies will accelerate consolidation as small players struggle to meet requirements. (We have certified all our sites globally to the standards required for our suppliers and customers.)

The increasing trend towards outsourcing means customers want partners with the scale and expertise to offer reagents and services that address their specific needs.

Source: Kalorama The Worldwide Market for In Vitro Diagnostic Tests, 13th Edition



It was \$59bn in 2020 and is forecast to be \$77bn in 2025

Within that, the Immuno IVD market is



The lateral flow point-of-care (POC) market is



IVD industry overview – Immunoassay



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> BBI SOLUTIONS

Business model and strategy

In its simplest sense, our strategy is to focus on the markets our product and service portfolio is better aligned. These are the core immunodiagnostic reagent market and the lateralflow point-of-care test market. Both are large – together \$18bn at present. Both are growing – a combined annual growth rate of 6%. Both are highly fragmented, leaving ample growth opportunity.

Our product and service portfolio

Antibodies and antigens are the critical components of an assay, along with enzymes (which detect and visualise results) and controls, to verify test performance. These are our reagent range, and generate 70% of our revenues. We also custom-develop some of the reagents, such as bespoke antibody development, and we develop and manufacture lateral-flow tests. This is our principal services range. To complement all of this, we have a telemedicine platform in our Novarum™ smartphone app and digital reader. The combined services business is 30% of our revenue.

Focus on immunoassays

Our key addressable markets are immunodiagnostic platforms and lateral-flow point-of-care tests. We have worked to align our portfolio to customer requirements in these markets, investing in capability and scale, and establishing our products and services as recognised core competencies. Novarum™ complements this reagent and lateralflow capability. It also differentiates us in the market, and through licensing, we can add regular and repeat revenue.

Strategy in summary

- Concentrate on our key immunodiagnostic activity with its large addressable market.
- Target resources and capacity to areas where our recognised quality earns differentiated margins.
- Continue to align portfolio with immuno IVD market and seek to maximise share.
- Continue to align development and manufacturing capabilities with the market trend to lateral-flow point-ofcare testing.
- Promote added value through Novarum™ proposition.





Sales by product category Our reagent range generates 70% of our revenue. 30% of our revenue is generated by custom-developing some of the reagents, and design and manufacturing lateral-flow point-of-care tests for diagnostics companies.





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Feature: Our facilities

In recent years, we have focused investment on developing a world-leading capability, through which we can serve the science of diagnostics.

We've achieved this by rationalising four sites into a centre of excellence in Crumlin, and by enhancing our Cape Town and Sittingbourne facilities. Also strategic acquisitions – of Novarum™ in 2016, Maine Biotechnology Services in 2017 and Diarect in 2020 – have helped us create a comprehensive customer offering. Across all the facilities described below, we invest in our people and processes to ensure continuous improvement in efficiency and productivity. These sites are where the future of BBI Solutions lies.

Investing in world-class facilities





1. Crumlin, Wales

Our centre of excellence in Crumlin, a £14m investment, brings together our capabilities in lateral-flow assay development and manufacturing, enzyme manufacturing and gold nanoparticle production. Through our activities at this site, our customers can take advantage of our decades of experience in all stages of diagnostic development. We opened here in 2018, bringing together our facilities in Cardiff, Blaenavon (also in Wales), Madison in Wisconsin and Dundee in Scotland.

The site is purpose designed with two manufacturing areas, one for animalderived enzymes and one for non-animal. With everything under one roof, we can control key factors, such as the flow of production, the movement of people and the environment in each area. The facility is expandable, with the potential to increase capacity by 50% - a level of flexibility we will soon need, as we progress to the next level of production relating to Covid-19.

Employees: >256

- Key products: - Enzymes
- Conjugation
- Gold nanoparticles
- Lateral-flow development
- & manufacturing services





2. Cape Town, South Africa Our facility in Epping, Cape Town, converts raw materials from animal and plant sources to produce high-quality diagnostic and pharmaceutical enzymes. It supplies these to blue-chip companies. The site includes a new pharmaceutical-grade manufacturing facility.

Employees: 51 Key products: - Enzymes





3. Portland, Maine

Our Portland facility adds antibody development to our capabilities. Here, more than 27 years of knowledge experience, process development, and project management ensure we can bring our customers the best possible antibodies for any application. No lateralflow assay or immunoassay is complete without its antibody and antigens, and with MBS, the production of these critical reagents is now integrated into our operations. The team at this facility is expanding services from identifying and developing pure monoclonals to providing affinity chromatography, purified antibodies, and hollow-fibre manufacturing at scale. With this range of activities, we expect this site to grow by around 15% during 2021.

Employees: 32

Kev products: - Antibody development

- and production
- Antibodies





4. Sittingbourne, Kent

The company's native antigen centre of excellence. At this site our scientists extract and purify target proteins for use as antigens, calibrators and controls in immunodiagnostic tests. Four purpose built and sample specific labs specialise in extraction different antigen types.

The site's core competencies include:

- Establishing safe, secure and sustainable sources of human biomaterials
- Development of extraction and purification methodologies for native and recombinant proteins
- Leading on implementation of group ISO13485 compliant quality systems
- Delivery of analytical methods to match customer specification requirements
- High capacity manufacturing of Transferrin, a major cell culture media component.

Employees: 42 Key products:



72

Feature: Our facilities



5. Porton Down, Wiltshire

This facility is located strategically to support the Ministry of Defence contract we were awarded in 2018. Our close proximity allows us to work in partnership with this very important customer.







6. Freiburg, Germany

Our recombinant antigen centre of excellence. Here we develop and manufacture recombinant antigens for use in our assays. The site has core competencies in the areas of molecular biology and recombinant protein expression and World class expertise in the areas of autoimmune antigens, tick borne diseases.

Acquiring Diarect AG has given us an important leading position in autoimmune and infectious-disease testing, combined with new recombinant protein-production technology. With the Freiburg facility in our Group, we can offer customers an expanded antigen portfolio, as we now have the capacity to produce both native antigens from human-derived material and synthesized recombinant antigens. With such a strong role in our capability, this site is growing continually, in both revenue





7. Edinburgh, Scotland

We acquired this facility in 2016, when Novarum[™], originally a joint venture, became wholly owned by BBI Solutions. This is where we developed the technology that is revolutionising diagnostic testing, making it more accurate and user-friendly by transforming a smartphone camera into a test reader that also interprets, captures and communicates the resulting data.

Employees: 15

Key products: - Mobile applications to make performing, reading and sharing diagnostic test results from field easier





8. Shanghai, China

BBI (Shanghai) Co., Ltd is a wholly owned subsidiary of BBI Solutions registered in China. It was established in 2017 and is located at Zhangjiang High Tech Park, Shanghai, China.

The responsibility of BBI Shanghai is to serve our valuable customers and commercialise BBI products in Asia Pacific region. The team consists of five employees in sales, and one employee across the marketing department, technical support and customer services.





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Feature: Investing in people

Over the last four years, we've invested in our people, our processes and our ability to solve our customers' and their patients' problems.

With every improvement, we've enhanced our productivity and our capabilities in serving our customers and their patients.

This impressive performance is due largely to investing in our people, including training in Lean Six Sigma. In our technical operations teams, we now have two master black belts, two black belts and 13 green belts with further ongoing training courses each year. All employees are undertaking foundation training with further targeted learning from our in-house modular Lean training programme.

Our value streams also gain support from our technical operations teams, who help meet systemic challenges in the arenas of quality, supply chain and production equipment. They tackle problems with current products, and help develop future products and technologies. "As such", says lan, "they've been central to improving efficiency, productivity and profitability – over the last three and a half years, we've increased our gross margin from 49% to 59%."

Investing in people









bgggg Increased gross margin over the last three and a

half years

Also key to our improvements is our operating model - which is not only our organisational structure, but also the ways we work and our management systems. We've organised the business into four value streams: antibodies, antigens, enzymes and POCT. Based on customer input, each of these builds a set of processes designed to achieve greater than 98% performance. They are supported by our global supply chain, which ensures a consistent, timely availability of materials at the point of use - at the time of use - and underpins the worldwide dispatch of finished products to our global customer base.

A fundamental change has been the integration of all BBI operations into a single ERP system. This provides the real-time data we need to make critical decisions quickly, for our customers, operations and supply chain. As lan Elliott, Chief Operations Officer, explains, "Our ERP system has taken us to new levels of financial and stock accuracy, and it's become the foundation for our transactional movements of products and services. It's been a great investment over the last two and a half years."

In addition to the control measure that the ERP systems delivers, it has allowed us to now operate as a truly Global supply chain. In having a single source of truth and real time data we are able to visualise the supply chain end to end. This brings our suppliers the visibility to see our demand and track their shipments and their performance, understand our internal execution against service levels agreements and finally ensure our product meets courier, customs and Customer needs to expedite the flow of product and documentation in us serving the science of diagnostics.

Most importantly for us, it's an ongoing process; we've developed the ability to be better day after day. And to make sure all our gains are sustained, we've encapsulated them in our standard governance system. We constantly ask ourselves whether there's a more effective, safe or efficient way to meet our customers' needs. Ian concludes: "This continuous improvement makes me excited about what we've done, and even more excited about what we'll do in the future. Our journey over the last four years has been transformational, but we realise we still have a lot to do. Our next steps are all about keeping up the momentum."

"Our value systems tackle problems with current products, and help develop future products and technologies."



Ian Elliott Chief Operations Officer

Feature: What we do matters. Did you know?

Our reagent products and services matter in the world of diagnostics as there is always a person relying on a result at the end of the chain. To demonstrate and illustrate the impact that BBI is having on customers and their patients we have produced a range of facts across our value streams.

> Our scientists perform over 6000 custom conjugations every year

Last year we manufactured

>16m

Our gold nanoparticles are used in over 4000m lateral flow tests every year

In 2020 Novarum™ customers generated over

40GB

Our products are applicable across a wide range of end markets from human clinical and companion diagnostics through to veterinary, food safety, defence, and industrial applications.

Novarum™ has developed mobile readers for over





Since its foundation DIARECT has supplied into

>150m



We have

of enzyme expertise

ears

Over E1million of BBIs revenue is associated with reagents used in the Cardiac market

Each year we produce and deliver over **600,000** infectious disease assays for our customers



Damian Evans BBI Global Head of Quality and Director of Business Integration "The work that we do here at BBI really impacts and make a difference to people's lives, on a daily basis."



Antibodies

Our scientists purify over 200 individual antibodies in a year totalling more than 100 grams of highly purified antibody.

Last year we collaborated with customers to deliver more than 50 distinct custom antibody development projects.

Our high-quality cardiac antibodies are utilized by more than 30 customers while our wide range of infectious disease antibodies are utilized by more than 45 customers in a variety of applications.



Antigens

BBI antigens are used as critical raw material components in the world's leading Laboratory Quality control materials used by hospital laboratories to verify the performance of IVD systems delivering results to guide patient care.

Leading IVD manufacturers across the world supported an estimated 3.4 billion immunoassays in 2020 delivering critical patient care information to physicians, they use BBI antigens in some of their assays to prepare their calibration materials.

Last year BBI manufactured over 30kg of Holo Transferrin used as a component of cell culture media for Research and Development of new therapies.



Enzymes

3 ½ tonnes of horseradish roots are processed per day to develop (Horseradish Peroxidase) for diagnostic assays.

415 million people suffer with diabetes globally. Every year 5 billion test strips contain our glucose oxidase for blood glucose monitoring. ANNUAL REVIEW 2020

Feature: Life at BBI Solutions

The people behind the science: BBI Solutions is focused on serving the science of diagnostics. Among our employees are world-class scientists who have the expertise and experience to make a real difference. Here are some of their stories.

Dr. Stephen Pelsue



Dr. Stephen Pelsue Position: Science Director Location: Portland, Maine Joined BBI Solutions: 2015 Education: BSc Chemistry, PhD Biochemistry, postdoctoral fellowship at The Jackson Laboratory, Associate Professor of Immunology and Molecular Biology at the University of Southern Maine

$\langle \rangle$

"We support the health sector in helping solve the key issues of identifying new ways of diagnosing and treating patients."

Your role at BBI...

My role is to be a technical leader within the division of BBI that is developing and producing antibodies, predominantly used to support diagnostics and clinical trials, and evaluate therapeutics. So a customer – internal or external – would have a target or medical condition they're interested in measuring, and we develop the antibodies that specifically detect or measure that target. All of them are based in what we call an immunoassay or an antibody-based assay. We also service other areas in human health, animal health and food safety.

The acquisition of MBS, now BBI Portland Maine, was part of BBI's move to develop an end-to-end ability to serve customers. This site provides the ability to either develop or manufacture the antibodies customers need to build their assays. We support the health sector in solving the key issues of identifying new ways of diagnosing and treating patients – whether for Covid-19, an autoimmune disease, a cardiovascular disease and so on.



...how it works day to day...

We develop monoclonal (single) antibodies and polyclonal (multiple) antibodies. We therefore purify them and produce them in a form that can be used for different types of technologies. In antibody development, there's a tremendous amount of innovation, and most of it is driven by the huge revolution in using antibodies as therapeutics, particularly to treat cancer and autoimmune disease.

However, one of the challenges for us is to identify the technologies that could improve our ability to serve our customers and meet their needs. This includes improvements that can get higher-quality products to our customers, faster, with better data to support their use and needs. For example, we've brought on a new production capability called hollow fibre filtration. That's allowed us to manufacture larger quantities for customers who need a higher volume of antibodies.

...and your journey here

Looking back, from a very young age, I always wanted to be a professor. Everything I learned on that academic path has been valuable, but it's interesting to think about things from the commercial side, where I am now. I'm using my experience and expertise in antibodies, but I have many other roles. I support the commercial side, working with customers to help them understand how our solutions can help them achieve their goals. Also on the development side, I'm looking at new technologies, new partnerships, and new ways of achieving goals to move the company forward. Then there are troubleshooting roles, and internal education and professional development activities. On any given day, I can be doing all these things.

Dr. Ken Murray



Dr. Ken Murray Position: Technical Manager (Enzymes) Location: Crumlin, Wales Joined BBI Solutions: 1988 (as Biozyme Laboratories) Education: BSc Biochemistry, PhD Biotechnology

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"We manufacture the high-purity glucose oxidase used in over five billion blood glucose tests each year."

Your role at BBI...

We manufacture the enzymes used in diagnostic tests. An enzyme is simply a biological catalyst. For example, when a person with diabetes measures their blood glucose, they put a drop of blood on the test strip, and the enzyme in the strip reacts with the glucose in the blood to enable a measurement of the glucose concentration. We manufacture the high-purity glucose oxidase used in over six billion blood glucose tests each year.

We use some weird and wonderful raw materials. The main ingredient of glucose oxidase comes from the fermentation of a fungus manufactured in ton quantities for use in the food industry. We take some of that and purify it to diagnostic grade. For other products, our team in Cape Town has the capacity to process large amounts of raw material, and then we do the higher purification in Crumlin. They process many tons of raw material to make several different enzymes; also tons of horseradish root, used to make an enzyme called peroxidase. There's another enzyme, alkaline phosphatase, made from offal. Peroxidase and alkaline phosphatase are used in a wide variety of tests.

For example, our customers might make the large instruments used in a hospital testing lab, which will have a menu of about 70 different tests. They could be checking for AIDS, or levels of hormones, or infections – a whole range of analytes. They will use different antibodies or antigens on the different tests, but all the tests will use the same enzyme – say alkaline phosphatase – to get the measurable signal at the end of it.

...how it works day to day...

We've been making these enzymes for many years and will continue to make them for many years, because they are seen to be the best available. Obviously there are improvements over time, so we focus on improving our processes to meet increased demand.

We've been supplying a lot of our customers for over 20 years, so we have a good idea of their need. But this year with the need for Covid-19 assays, we've had to react as quickly as we can to keep everybody supplied. All the manufacturers of the kits for healthcare providers, hospitals and health systems – all around the world – need the raw materials.

Traditionally, our biggest market has been the US, followed by Europe and Japan. More recently, we started doing more business in Taiwan, and in the last 10 years, we've had increased demand from China for some of the enzymes. With enzymes being biological products, there's always a little variety in the material, so the task is managing that while meeting the increased requirements. That's the focus of lots of my time.

...and your journey here

I think when you start an undergraduate degree, unless you're doing something like dentistry, you don't really know exactly what you're going to do. I chose biochemistry because I was interested in it, and I knew it would give me a broad range of opportunities. But then you want to feel as if you're contributing and doing something meaningful, and this job certainly gives you that.



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Hannah Siva



Hannah Siva Position: Antigens Lead Location: Sittingbourne, Kent Joined BBI Solutions: 2008 Education: BSc Biosciences



"The Covid-19 pandemic has highlighted the importance of both antigens and antibodies and their application for the diagnostic industry."

Your role at BBI...

We manufacture antigens for the diagnostic industry, both recombinant and native antigens. In simple terms, native is from a natural source, whereas recombinant is manufactured artificially. Our facility is predominately native antigens. The Covid-19 pandemic has highlighted the importance of both antigens and antibodies and their application for the diagnostic industry, and the general public now use these terms, which they may not previously have understood. Our role in the diagnostic industry is to provide antigens that go into a testing kit as controls and calibrators. Probably 80% of our site portfolio is for the diagnostic industry, with the remaining 20% for the cell culture industry.

In our antigen value stream we deal with ethically sourced materials from a unique and sensitive supply chain. An example of a living donor would be those who give urine. They have a particular illness they can live with, but it will secrete distinct proteins into the urine, which we can use to help diagnose others. We can't pay these donors, and we can't contact people directly, so we rely on doctors to make donors aware of us. Then they have to want to donate, so it can be a very long process to obtain a new donor. With deceased donors, the protein we can extract from, say, a heart is influenced by age, sex, height, weight and health, so we need rigorous processes to arrive at the same product in the end.

Our speciality is native antigens, but if customers are looking for unique proteins, recombinant might be the only option. At Sittingbourne, we do this only in a small-scale R&D setting, genetically modifying vectors to create a protein to mimic what would occur naturally in the human body.

...how it works day to day...

A new customer will come to us with a request. It might be for a new protein marker that's been discovered and is going into a new kit, or it might be a need caused by a shortage in the marketplace. That happened a couple of years ago with a shortage of markers for ovarian and breast cancer.

We then go through a qualification process and produce some batches for validation with their instrument. This can take time, sometimes as long as three years. Then we have to scale up production to fulfil their orders. There are also processes for creating a new product that might be bought by multiple customers. Here, ensuring product quality is essential. In my role now, I have strong links with supply chains and the supply chain manager on site, so we can plan for all this.

...and your journey here

I started out wanting to be a pathologist, and I'm not sure I knew businesses like this existed. My intent at BBI was to gain a bit of lab experience – but the more I got involved here, the more I realised I really enjoyed what I was doing. I loved that every day was different, because each protein is very different, and how you purify it. I also find the application of each product quite interesting – it could be a cancer marker, a cardiac marker, even a nutritional marker. When you go and get blood tests, for example, at the doctors, I think: "oh, yep, we manufacture that."

Paul Christopher



Paul Christopher Position: Operations Excellence Leader Location: Crumlin, Wales Joined BBI Solutions: 1999 Education: Applied Biology

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"We work closely with our customers to ensure we develop the product that meets their needs."

Your role at BBI...

I look after BBI's continuous improvement activity and also our product transfer team, at our Crumlin site. Transfer is our term for the process of moving a product from development into routine production, whether it's something we've developed internally or something a customer wants us to manufacture.



Our Crumlin transfer activities centre mostly on BBI's point-ofcare testing products, which are predominantly lateral-flow tests. In format, these are like the pregnancy test strip, where a relatively untrained operator can add a sample and obtain an easily read result within minutes. Our products are used across a wide range of industries, including medical diagnostics, environmental monitoring, food safety and even military applications. We now also have a Covid-19 antibody test that went through validation in late 2020, a consortium project with two other UK-based companies, led by the Government.

...how it works day to day...

Based on a customer's detailed specification, or sometimes just a product concept, we work to assess manufacturing compatibility as early as possible, so we can judge the feasibility and likelihood of success. We would then be able to estimate timelines for development and transfer activities, and a final product cost.

A standard product, where we can make large batch sizes with existing equipment and processes, would be relatively straightforward to manufacture. If it's a highly complex or bespoke process needing specific manufacturing equipment, we consult closely with the customer.

At the start of the transfer process, we look to align the new product with our standard materials, equipment and processes where possible. We then oversee collaboration across BBI sites and departments covering raw material supply, reagent and component preparation, manufacturing and quality control. During this time, we work closely with our customers to ensure we develop the product that meets their needs. With required controls and processes in place, we produce three validation batches for the customer to verify product performance, before we establish routine production.

...and your journey here

After university, I held a research post for three years before leaving academia to pursue a career in diagnostics. I focused on assay development and lateral point-of-care testing even before joining BBI. I've been at BBI for 21 years now – there were about 12 of us in a small facility in Cardiff when I joined. We grew over the years, sporadically adding rooms or using multiple buildings. So the opportunity to establish the Crumlin facility meant we could design it specifically to meet our needs. I'm now looking forward to converting some major new transfer opportunities and expanding into the growth in capacity we've allowed for.

Dr. Thomas Simon



Dr. Thomas Simon Position: Head of R&D Location: Freiburg, Germany Joined BBI Solutions: 1998 Education: Studies of Biology and Chemistry, Diploma (Master equivalent) Biology, PhD Molecular Immunology, Postdoctoral studies in Cambridge, UK and Martinsried, Germany

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"What I love about my job is simple, I will never be tired of taking fundamental research with us and turning them into products with real life importance."

Your role at BBI...

Every adult has one kilogram of immune system distributed in the blood and a number of different organ structures in the body. Its function is to destroy bacteria, viruses and other foreign structures. It has to learn which structures and molecules belong to the body – anything else is, by definition, foreign. This learning is a fantastically complicated process and if it goes wrong, it results in an immunological attack by the body on itself. The resulting autoimmune diseases are serious, chronic and incurable.

However, some of these diseases are quite rare, difficult to recognise, or start with very unspecific symptoms. The typical GP may never see them in a career. When I started in the field, the average time to a correct diagnosis of systemic lupus was something like five years after the first symptoms. But any hope for a patient's quality of life lies in timely diagnosis and immunosuppressive treatment. Good therapy is preceded by good diagnostics. So our work aims to improve diagnostics by making fast, accurate, meaningful and accessible test results available to an increasing number of people in an increasing number of clinical settings.

...how it works day to day...

For an autoimmune attack, one of the ways to diagnose is to check the presence of autoantibodies that will bind to the autoantigens. So you have the autoantigens as a central component in a test. In the 22 years since we started our business, we have established a market-leading position for commercial production of recombinant autoantigens – that is, producing proteins by genetic engineering and biotechnological techniques. This is bringing a new area of diagnostic tools to BBI. In very practical terms, we are restructuring internally right now, moving know-how from specific scientific departments into a R&D group structure, and I am overseeing that transition.



A far-off wish beyond our scope of diagnostic work, and possibly not in my lifetime, is that autoimmune disease could one day be fundamentally cured. If clinical research finds a way to manipulate a specific autoimmune attack and leave the rest of the immune system well and healthy, that would be fantastic news. A more practical ambition is to get more of what we call multiplex assays into the diagnostic world – this is where you use a combination of analytes to arrive at a wider diagnostic picture of what can be done for a certain patient. The power of this has not yet been realised by far, but we have considerable assay know-how we can apply to this approach.

...and your journey here

When I started university, I saw myself in the general area of biochemical research, but could never have predicted how my interests in immunology, molecular genetics and biotechnology would develop. But then, during university, one looks to areas that are new in science, and that set me on the road to my PhD antibody work. Then making the jump to antigens is not a big step at all. I'm still using and applying all these things today.

I did discover a certain joy in just producing things, making things happen, and that explains how I left academic research and went into industry. From then, I think getting recombinant human autoantigens into diagnostic practices is something Diarect and its predecessors played a key role in. With therapeutic success and ultimately patients' quality of life at stake, well, perhaps our role is not so small after all, and it is well reflected in BBI's core values.

Bethan Chandler



Bethan Chandler Position: Value Stream Leader POCT (Point of Care Testing) Location: Crumlin, Wales Joined BBI Solutions: 2017 Education: BSc First class Honours in Forensic Science and Chemistry, Kepnor Trego Project Management Qualification

Your role at BBI...

I'm the Value Stream Leader for Point of Care Testing services at BBI. I am responsible for our contract development, our gold business both colloid and bespoke conjugation and our routine contract manufacture for lateral flow applications. I also work closely with Novarum™ our mobile diagnostic platform.

...how it works day to day...

Firstly, a client will come to us needing an application in a lateral flow format. A highly skilled and knowledgeable team of scientists are allocated on all phases of the project and we work with the client using our robust development framework. Our partnership approach will take the form of working with the customers to understand what are their assay needs are and if applicable develop a bespoke lateral flow solution. I am

involved in overseeing the feasibility of the project, characterisation and selection of final materials and the transfer to manufacture process. During the development phase we advise on appropriate reader applications and work with if applicable our Novarum™ team to calibrate it specifically for the test. This enables tests to be read at the point of care. On a day to day basis, I am involved in discussions with customers from varying industries like human clinical, veterinary and food safety, which I enjoy greatly.



...and your journey here

The great thing about my job and why I love being a Value Stream Leader here at BBI is really the diversity and the human clinical element which sources back to my interest in Forensic Science and Chemistry. No day is the same at BBI and I work with some great people on very different specialisms in terms of their knowledge and expertise. They are ultimately why I come to work every day and the reason point of care value stream is so successful. Lateral flow continues to be a strong market and is an exciting place to be and I look forward to seeing the growth in our capability in this area.

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"There is real scalability and robustness in our process at Crumlin Headquarters. We can do the design, development and contract manufacture all under one house enabling us to deliver in a very streamlined and efficient way for our customers."

Feature: Novarum™

As the need for speed and accuracy in diagnostic testing increases, our Novarum[™] technology is making the process not only more precise, but also much easier for everyone involved. Most importantly, it gets test results where they are needed, quickly and securely.

The vital link in the testing chain



About Novarum[™]

Novarum™ DX was founded in 2012 and led by Dr. Neil Polwart. It was acquired by BBI Solutions in October 2016. Neil is now BBI Group Head of Mobile and has more than a decade's experience in developing next-generation diagnostic technologies covering not just mobile health, but environmental, veterinary and industrial applications. He explains the basics: "Novarum™ uses the camera on a smartphone to read the results of point-of-care tests and lateral-flow tests. The results can then go anywhere you want them to, via the internet." This seemingly simple process lies behind an enormous potential to enhance testing methods in numerous fields - potential that is already becoming a reality.

As well as turning a smartphone camera into a test reader, Novarum[™] guides the user on how to perform the test. It provides results in minutes, and communicates them directly to those who need to know them – whether that's the user's doctor, or other healthcare providers or systems. And its uses go far beyond medicine, into sectors such as agriculture, food safety and environmental testing. With patents in Europe, the US, China, Japan, Russia and beyond, Novarum[™] is set to revolutionise diagnostics across the world.



Rapid results from any location

What makes Novarum[™] such a breakthrough is the way it can be used by anyone, virtually anywhere, with minimal training. It connects patients and doctors, field workers, lab researchers, primary care clinicians and specialist practices, all through mobile technology.

As well as speeding up the process for each test, this connectivity also minimises the need to run tests several times – for example, someone who runs a home test using Novarum[™] will not then need to book an appointment and wait at the doctor's surgery to take much the same test again. Also, enabling people to test themselves at home for infectious ailments such as flu keeps them out of doctors' surgeries, helping prevent the spread of infection and making more time for seeing other patients.

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More information about Novarum™ can be found online at <u>bbisolutions.com</u>



"Any test you can read by eye, we can train a phone to read."



Novarum[™] step by step

For any organisation wanting to use Novarum[™] for rapid testing, we begin by developing a smartphone app specific to their needs.

1

Their end users then download the app, ready to run the test – and it can be almost any test where the result is normally read by the human eye.

3

This test-reading method brings several important benefits: using the camera eliminates any ambiguity in interpreting the results, and leaves no room for subjectivity, bias or opinion. It can also increase consistency in the reading, especially for tests that are very time-sensitive.

2

Following guided instructions, with video cues, timers and alarms, the user performs the test, and the smartphone camera reads the results.

4

Once the camera has read the results, the app can capture and store them securely, or send them directly to the organisation's IT system – for example in the UK, to the NHS when collecting data from people testing themselves at home. Communication can be via any of the connectivity on the phone – whether on wifi or roaming, each result requires less data than sending a typical email. The results are where they need to be, almost instantly.

BBI SOLUTIONS

A major boost for our business

Being designed around a smartphone app, Novarum[™] can put testing into the hands of unskilled users outside a controlled environment, while ensuring accuracy, security and speed of communication. In a nutshell, this is why it offers such a wealth of opportunities for organisations in many fields – and why it's such a significant development for BBI Solutions.

Most importantly for our business, the majority of Novarum™ revenue comes from customers dedicated version of the Novarum™ app for each customer, and get licence revenue each time a test is used. This creates valuable 'annuity' revenue and scalability.

New customers come from various sources. We are fortunate to have referrals from existing customers – often to organisations in the early stages of developing an assay, looking ahead to how they can use our test in the field. And, as the technology can adapt to all kinds of scenarios, we can respond to enquiries from many industries.



Transforming testing in many settings

The accuracy, connectivity and ease of use of Novarum[™] make it ideal for a variety of applications. In human medicine, infectious diseases are an obvious area of great potential. Covid-19, in particular, is completely changing our business, compelling us to work on a scale as never before. Also, workplace drugs screening, toxicology and gastroenterology are starting to take advantage of this technology, with emerging possibilities in pregnancy and fertility testing. And there are growing opportunities across a wide range of chronic diseases, where patients who once had to take a sample to the doctor's surgery can now do their own test at home.

Veterinary medicine can also benefit from the precision and adaptability of Novarum[™], and we see this as a particular growth area. As Neil explains, "Our first veterinary customer is just about to launch, and we expect more to follow, as the regulatory pathway is easier than in human clinical. Novarum™ offers some real advantages in farmyard applications, where there isn't the normal laboratory infrastructure, but where there are implications for the food chain." Related to this, in food protection, Novarum™ can improve both agricultural practices and food safety standards, testing for spoilage and contamination.

Over a quarter of testing is for non-human use, there is also great potential for Novarum[™] across a range of industrial and environmental applications. Smartphone diagnostics enable maintenance technicians in many fields to inspect, report on and repair critical systems, ensuring safety and efficiency with minimal operational downtime. The Novarum[™] app has also been used for contamination testing in aviation and diesel fuel – where a fungus can block fuel lines – and for waterquality testing. Over a quarter of testing is in Non Clinical (Veterinary, Environmental, Food safety and Industrial)



Novarum[™] technology has facilitated a 400% increase in usage of Conidia's FUELSTAT aviation fuel test over the last 12 months



The future of diagnostics

As Neil Polwart points out: "People have been talking about point-of-care testing for many years, but in most of the world, testing is still performed in clinical laboratories. There are two main reasons for this: the need for quality control, with trained people running the tests; and the need to get test data into a central system. With Novarum™, we believe we are meeting both of these needs. We are genuinely getting testing right, whoever does it, in whatever location. Moreover, by taking some testing out of the labs, we are freeing up those facilities for more sophisticated procedures."

In this way, Novarum[™] is already influencing the development of diagnostic testing in key scientific fields. And that influence is set to grow significantly, as more and more organisations see how it streamlines the testing process, boosting usability, effectiveness and reliability.

As Neil concludes, "For many healthcare organisations, mobile technology provides an opportunity to revolutionise patient care. The benefits of adopting a mobile strategy vary depending on the client, and it's my job to provide guidance on how our software can transform their capabilities. Any test you can read by eye, we can train a phone to read."

"Novarum[™] uses the camera on a smartphone to read the results of point-of-care tests and lateral-flow tests."

BBI SOLUTIONS

Feature: Diarect

In June 2020, BBI Group completed the strategic acquisition of Diarect AG, a leading supplier of autoimmune antigen products, based in Freiburg to create BBI's recombinant Antigen Centre of Excellence.

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Freiburg, Germany

The move enhances our position as a 'complete' immunoassay reagent supplier, and the world's largest independent antigen manufacturer.

With BBI Freiburg on board, we are now leaders in autoimmune antigen production with recombinant proteinproduction technology supporting our growth. Our capability also enables us to service high-growth disease segments, such as cancer, cardiac conditions and diabetes.

Global Head of Quality and Director of Business Integration, Damian Evans, explains further: "BBI Freiburg's expertise in recombinant antigen manufacturing is a key addition to BBI. Until now, our antigens primarily originated from natural sources, whereas BBI Freiburg synthesizes proteins from scratch. Autoimmune diagnosis is another great strength. Our strategic fit is a portfolio fit."

BBI Freiburg also brings significant research and development capability to the business. As Damian says, "The scientists within BBI Freiburg are incredibly impressive, as are their core competencies."

At the same time, the acquisition benefits BBI Freiburg, as BBI contributes its products, services and decades of experience in diagnostic development – and offers opportunities for BBI Freiburg to input into projects and programmes across the Group. Perhaps most importantly, the deal gives BBI Freiburg a commercial presence in the US and in China, where they had sold through distributors.



Creating BBI Freiburg



Good news for our customers

As well as giving BBI's customers access to an expanded antigen portfolio, the acquisition enables us to improve our services. With a greater range of products, we can develop broader and longer-term relationships, as Damian observes: "It's really developing more of a partnership approach – obviously with procurement departments, but also with our customers' technical teams as well."







Successful integration We are working through the full integration of Diarect AG into BBI.

BBI Freiburg has an incredibly talented and successful team and through this integration we are striving to enhance connections across the business. This allows us to leverage the skills and expertise to improve product offerings and ultimately the customer experience.

Another vital aspect of our integration is that of culture. The integration teams have been terrific and have really come together despite the challenges a global pandemic presents. As a combined team we are working systematically to:

- Provide support throughout the integration process
- Understand how the work gets done and learn from both sides
- Set priorities for integration that are clearly understood

Our integration plan takes us to August 2021. Damian comments on current progress: "The integration has progressed well; we have some challenging projects ahead, as is the case with any integration, but the energy, commitment and attitude of the team are fantastic and continue to drive the integration forward."



Conducting the transaction through a pandemic

Working through an acquisition usually means a lot of meetings where people need to be physically present. The process with Diarect started that way in December 2019, with regular flights to Freiburg and some meetings in Wales. But with the dangers of Covid-19 becoming apparent in early 2020, that had to change. Damian remembers: "We were approaching this very much as a partnership, and working very, very well in building the whole strategy together. Obviously that stopped as we went into March. The lawyers and accountants working on the deal couldn't even travel from Frankfurt to Freiburg. We managed to do everything by Teams, Skype or Zoom, but it did make things difficult."

Read more online at bbisolutions.com

10.8% year on year business growth in Germany



"It's really developing more of a partnership approach."



Damian Evans BBI Global Head of Quality and Director of Business Integration **Growing together**

The BBI Freiburg business in Germany is growing at 10.8% a year, with its products now selling to BBI customers. Similarly, BBI products are reaching more and more Diarect customers.

Opportunities are particularly strong in China, where the autoimmune market is growing very well, and sales in the US are growing at 8-9%. Our future together is about building the capacity and capability to continue this growth.

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BBI SOLUTIONS

Feature: Putting people first

As a major employer with sites around the world, we have created a cohesive HR strategy to ensure we attract, develop and retain the right people – people who will help us realise our mission of serving the science of diagnostics.

The need for a consistent approach to HR became apparent after we integrated our Blaenavon, Dundee and Cardiff sites into our Crumlin HQ, in 2018. With many individuals now under one roof, we looked for ways to break down the silos that had developed between local communities. We also needed to bring our other sites, including those in the US and South Africa, into the strategy.

With such a disparate audience, only a very simple, single sense of purpose would bring everyone together. Thinking about our mission of serving the science of diagnostics, we realised all our people's work is focused on one target: wherever someone works within BBI, they contribute towards saving someone's life. In this way, everyone here is important. We built our strategy around this very powerful statement. As Group HR Director, Andrea Morgan, puts it, "The key message to all our employees is that you are not a number. What you do contributes to everything we believe in. Without you, our business does not exist."

Putting people first






Simple message, simple structure

Our HR strategy is founded on the pillars of Resourcing and Talent Management, Employee Engagement and Wellbeing, and Reward and Recognition - as well as the HR operating model and systems that hold it all together. In Resourcing and Talent Management, a key aim is to develop a consistent learning and development function across the Group. Initiatives include a learning academy, with environments suited to diverse learning styles - from informal spaces to more traditional classroom settings. Self-learning is an important aspect of the academy, and we give employees access to a range of resources, including laptops.

To complement the academy, we have introduced a learning platform that provides bite-sized learning for any employee at any time. It's available in all our countries, and is very popular, as it fits around individual schedules. More formally, we run graduate programmes, and have drawn down apprenticeship levy funding in Scotland, Wales, England and South Africa, and the equivalent in the US. Those taking part gain recognised qualifications that are transferable. Most recently, we have launched our talent and resourcing hub, a one-stop shop where our people can access a calendar of training events and book places on them.

As learning opportunities can lead to career opportunities, our various learning initiatives complement our career pathway programme – and so dovetail into the Reward and Recognition pillar of our HR strategy. Most importantly, this blend of learning and career progression ensures we have the capability within our teams to achieve the sustainable growth we need to support our organisation's strategic vision.

Although our career pathway programme is tailored to specific roles, a governance framework ensures a consistent approach and measurements. We apply it to all levels, including the senior leadership team, so every employee has the opportunity to reach their full potential. When a vacancy arises, we can see across the organisation and identify who is ready to move to that level. This goal of our Reward and Recognition pillar - to build skills and knowledge from within – has also led to the creation of initiatives such as our global length-of-service award and employee of the month recognition, the latter being judged by both managers and employees across the Group.



Listening and supporting at every level

For the Employee Engagement and Wellbeing pillar of our strategy, a key ingredient is local employee forums, designed to give a voice to our employees. Through them, our people have the chance to fully understand business requirements, keep up to date with local developments and find out how they can influence things at their site.

We launched the first forums in the UK – at Crumlin, Porton Down, Sittingbourne and Edinburgh – and then quickly expanded them into South Africa and the US. And following the acquisition of Diarect in Germany, in June, the first forum was held in August. We have launched the global forum, giving local representatives the opportunity to talk directly with Group CEO, Mario Gualano, each quarter.

Our employee forums have been a major success, giving rise to a range of activities, such as photography clubs, Halloween and Christmas parties, and rugby celebrations. The forums are also heavily involved with our chosen charity of the year, the NSPCC. There's a lot of healthy competition between them in fundraising ideas, which included a BBI Christmas card last year. Even in the pandemic, the employee forums have helped maintain high levels of employee engagement across the organisation. Part of the same pillar, employee wellbeing is vital to our success. Even before Covid-19, we were providing a range of resources through our wellbeing and benefits hub – more than 200 podcasts, exercises, articles and other materials, all designed to support mental, physical and financial health across the organisation. We have offered opportunities for our people to have subsidised gym membership and podcasts that offer exercise videos, and have run very successful financial roadshows, where experts talk to our people in confidence about any money-related concerns.

With a particular focus on mental health, we've introduced mental-health first aiders across the UK and South Africa, and are currently introducing the program in the US and Germany. We have created a mental-health forum, and have a wellbeing room at each site where employees can talk to a mental-health first aider in confidence. We offer mental-health first-aid training globally to all managers and employees, and this has been extremely well received. This training will be formally accredited by workplace-wellbeing specialists, Unum, recognising the importance we place on mental health among our people.



200+ Podcasts, exercises, articles and other materials provided to our staff as part of our

Employee Engagement and Wellbeing pillar







"The commitments we make to our people boost their commitment to BBI. It really does work both ways."



Andrea Morgan Group HR Director



An unusual year

When the pandemic arrived, our wellbeing initiatives took on even greater significance. We have made sure everyone has key-worker status, so we can continue our vital work, and we provide financial support for any employee who has to self-isolate, paying their basic salary from day one of the isolation period. Our HR team calls each isolating employee every two days, to make sure they have the support they need, whether that's mental, physical or financial. We've also implemented a loan scheme for those who need extra financial help. As a further health precaution, we offer flu vaccinations

for all our employees. We are doing all we can to keep our people well in every sense.

As Andrea Morgan summarises: "Everything we do as part of the HR strategy is intended to support our employees' health, happiness and motivation – and thereby maximise retention and performance across the organisation. We are certainly achieving this. The commitments we make to our people boost their commitment to BBI. It really does work both ways."

Environmental, social and corporate governance at BBI

As a business devoted to providing products and technologies people rely on, we understand the need to engender trust in all those we deal with.

Aligning our approach to the United Nations Sustainable Development Goals

Through all our activities, we work to – and often set – industry standards, and we have aligned our approach to the United Nations Sustainable Development Goals.



Good Health

At BBI we provide our employees with access to a number of Health and Wellbeing platforms. As part of this strategy, we offer support around the three pillars of Wellbeing: Mental, Physical and Financial. As a result we offer the following services:

- Help at Hand which offers health support not only to our employees but also to family members.
- Life Works assistance to our employees on a range of everyday issues including work, family, relationships, money and health.
- Aviva Wellbeing, lifestyle and fitness support.



At BBI our we recognise the value of a more diverse workforce by embedding an inclusive approach to recruitment, talent management and development. We have introduced a number of initiatives to foster the right environment for women to feel empowered and supported to achieve their career ambitions. We have engaged the services of nongovernment organisations that promote or have a focus on women's career development. This includes Chwarae Teg, Code Clan and Girl Geek Scotland.

O Clean Water and Sanitation

Our facility in Cape Town, South Africa faces significant challenges when it comes to water supply. In 2015 the city of Cape Town began experiencing a drought that was followed by three consecutive years of dry winters. Water levels in the City's reservoirs declined from 72% in 2014 to less than 35% by 2018.

We have successfully approved and commissioned a water treatment plant at our facility in South Africa that purifies ground water for use in our production, therefore minimizing the impact we have on the municipal supply and ensuring business continuity in the event of water shortages.

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For more information on these matters and details of relevant policies, please see our Corporate Responsibility Report by visiting the BBI website <u>bbisolutions.com</u>





At BBI we strive to be more environmentally responsible by reducing the environmental impact from our operations and supply chain.

We focus on Environmental and Energy saving Projects and observe the Energy Saving Opportunity Scheme (ESOS) requirements and we are taking a number of steps to reduce our consumption:

- Set temperature points throughout our buildings along with timers
- Evening and weekend shut-downs
- Renewable energy sources
- Awareness campaigns across the business
- Motion sensitive lighting
- More energy efficient LED (light-emitting diode)

Responsible Consumption and Production

Through 2020 we launched a global Waste reduction initiative successfully achieving the Zero waste to landfill at our UK facilities. Following this success, we are focused on increasing our recycling across all our sites.

Some of our products at BBI include gold, which is considered a conflict mineral. We have strict supply chain processes in place that ensure all gold is ethically sourced. This helps to ensure that any products entering our supply chain are not Counterfeit, Fraudulent or Suspect Items that are being marketed as legal goods.

Our supply chain process is also compliant with the Dodd Frank Act which was passed by US Congress which requires companies to disclose their source of mineral supply and allow their supply chains to be traced and audited to ensure compliance.

CFO statement



2020 has been another successful year for the Solutions business, with strong organic revenue and profit growth in addition to pleasing results from the Diarect business acquired in June.

The financial information described below is taken from pages 41 to 43 of this report. This unaudited information is derived from the audited results of relevant entities within the BBI Group, on the basis set out in the notes on p43 of this report.

Total revenue on a proforma basis grew by 6.5% to £60.0m, with organic growth of 5.6% reflecting the increasing return from our strategy to invest in in-market commercial resource to ensure the needs of our customers are met. This strategy is driving a healthy pipeline of future growth opportunities and enables market penetration to enhance growth from acquisitions such as Diarect.

Proforma gross margins grew from 53.8% to 54.8%, underpinned by continuous improvement across our international centres of excellence, as well as scale economies and mix benefits. The c£20m investment we have made in our facilities infrastructure, together with the roll out of Sage X3 as our global ERP system and embedded lean practices, means we are well positioned to identify and deliver ongoing initiatives to drive margin accretion.

The addition of Diarect moves our proportion of revenues in reagents, which are highly recurring and relatively high margin, to 75%. As our strategy is geared towards growth of reagents revenues, we also expect to see ongoing margin improvement from sales mix.

Proforma EBITDA growth from £16.5m (27.9% of sales) to £18.6m (31.0% of sales) reflects the gross margin improvement along with the full year benefit of cost right-sizing measures undertaken in 2019. We will continue to invest selectively in SG&A in order to deliver sustainable profitable growth.

Net cash inflow from operating activities was £12.6m (76% conversion of EBITDA).

We invested £3.2m in Capex during 2020, of which £1.9m related to new investment to support future growth including expansion of our automated lateral-flow capacity and the global implementation of our Sage X3 ERP system.

A key element of our investment strategy in relation to our business processes and control environment has been the global roll out of the Sage X3 ERP system. The roll out to our operations in the US and South Africa in 2020, followed by Germany in Q1 2021, means that Sage X3 now supports the entire Solutions business, facilitating consistent controls and performance measurement in support of future growth and profitability

In conjunction with the acquisition of Diarect in June we restructured and refinanced the Group's debt facilities, resulting in a multi-currency senior debt facility of £114m with ancillary facilities to provide funding for capex and acquisitions if required. Alongside this we secured a £10m Revolving Credit Facility, providing ample liquidity to meet the working capital and investment needs of the Group out to 2027.

We continue to ensure that we have stringent governance and controls in place across the business. This is implemented and monitored by the Board of Directors (the "Board"), appointed by the company's which is responsible for the effective oversight of the company and has implemented a governance structure to support the long-term success of the company to deliver sustainable shareholder value.

BBI also has an Audit Committee, a Remuneration Committee and a Nominations Committee comprising of directors and non-executive directors. Each of these committees meet regularly, has specific Terms of Reference and are required to advise the Board on their respective areas.

In summary, we are pleased with the financial performance of the business in 2020 and have confidence that the business is well positioned to continue to deliver sustainable profitable growth.

Richard Couzens

Chief Financial Officer, BBI

Combined unaudited profit & loss account for the year ended 31st December

	2020 £'m	2019 £'m
Turnover	55.5	47.9
Cost of sales	(25.4)	(22.7)
Gross Profit	30.1	25.2
Administrative expenses	(26.2)	(22.5)
Operating profit before exceptional items and loss on disposal	3.9	2.8
Exceptional items	(2.6)	(2.0)
Loss on disposal of operations	0.0	0.0
Operating profit	1.3	0.8
Depreciation	2.5	2.7
Loss on sale of tangible assets	(0.0)	0.0
Amortisation	10.2	7.0
Exceptional items	2.6	2.0
Loss on disposal of operations	0.0	0.0
EBITDA	16.5	12.5
Finance income	2.2	2.5
Finance cost	(13.2)	(14.0)
Loss before taxation	(9.7)	(10.7)
Tax on loss	(0.2)	0.5
Loss for the financial year	(9.9)	(10.2)

BBI Solutions – proforma information for the years ended 31st December

The Total Proforma BBI Solutions information shown below includes the pre-acquisition trading results of Diarect GmbH, which BBI acquired on 3rd June 2020, for illustrative purposes. The combined unaudited financial statements for BBI Solutions, shown on pages 41 to 43, should be read in conjunction with the notes shown on page 43.

			2020			2019
£'m	BBI Solutions	Diarect Pre-acquisition	Total Proforma BBI Solutions	BBI Solutions	Diarect Pre-acquisition	Total Proforma BBI Solutions
Turnover	55.5	4.4	60.0	47.9	8.4	56.3
Gross Profit	30.1	2.8	32.9	25.2	5.0	30.3
EBITDA	16.5	2.0	18.6	12.5	3.2	15.7

Combined unaudited balance sheet as at 31st December

2020	2019
£'m	£'m
78.9	36.2
16.9	16.4
0.1	0.1
96.0	52.7
9.6	7.8
14.5	11.4
6.4	5.2
30.4	24.4
(15.1)	0.6
15.3	24.9
111.3	77.7
(168.7)	(125.1
(3.4)	(3.9
(60.7)	(51.3
	78.9 16.9 0.1 96.0 9.6 14.5 6.4 30.4 (15.1) 15.3 111.3 (168.7) (3.4)

Combined unaudited cash flow statement for the year ended 31st December

	2020 £'m	2019 £'m
Net cash generated from operating activities (excl. tax)	12.6	7.3
Corporation tax (paid)/received	(0.6)	0.5
Net cash used in investing activities	(45.3)	(1.8)
Net cash used in financing activities	34.5	(6.3)
Net increase/(decrease) in cash and cash equivalents	1.2	(0.3)

Notes:

- 1. The historical financial information shown on pages 41 to 43 for the years ended 31 December 2019 and 2020 shows the unaudited profit & loss statement, balance sheet and cash flow statement BBI Solutions.
- The historical consolidated financial information has been extracted or derived from the audited financial statements of BBI Group Holding Limited and the audited consolidated financial statements of BBI Healthcare Limited for the years ended 31 December 2019 and 2020 respectively.
- 3. The BBI Solutions' historical financial information has been derived by subtracting the BBI Healthcare Limited consolidated results from the BBI Group Holding Limited results for each accounting year.
- 4. This historical financial information has been prepared on this basis as there is no natural sub-group within the BBI Holdco Limited group structure, which presents group of companies.
- 5. The financial information set out on the previous pages does not constitute any BBI company's audited statutory accounts for 2019 or 2020.
- 6. Statutory accounts for BBI Group Holding Limited and BBI Healthcare Limited for the financial year ended 31 December 2019 and 2020 have been audited and reported on by PricewaterhouseCoopers LLP, our independent auditors. The audit opinions of the financial statements of BBI Group Holding Limited and BBI Healthcare Limited were unqualified for the accounting years ended 31 December 2019 and 2020 and did not draw attention to any matters by way of emphasis.
- 7. Statutory accounts for BBI Group Holding Limited and BBI Healthcare Limited for the year ending 31 December 2019 have been filed with Registrar of Companies and are available from Companies House. The 2020 statutory accounts for both companies will be filed with the Registrar of Companies ahead of the statutory deadline (i.e. 30th September 2021).
- BBI Solutions Proforma information includes the pre-acquisition trading results of Diarect GmbH, which BBI acquired on 3rd June 2020, for illustrative purposes. The Total Proforma BBI Solutions information shows the Turnover, Gross Profit and EBITDA of BBI Solutions as if they had owned Diarect GmbH for the whole 12 months of the years ended 31 December 2019 and 2020.

Board of directors

Overview of the Board's CVs, skills and experience.



Alan Peterson OBE Chairman

Alan offers over 30 years' leadership experience across the UK, Europe and North America. During that time he has held the role of CEO or Chairman at several large manufacturing, industrial and retail companies, including Meyer International, Rockware Group, Enterprise Group, Attends Healthcare Group, Refresco, Azelis and Pattonair. He currently also serves as Chairman of HSS Hire Group.

Alan served four years as Industrialist in Residence for 3i Group. He is a Vice-President for the NSPCC UK Council and Honorary Colonel for the Army Cadets in Wales.

Joined BBI Solutions: 2015



Richard Couzens Chief Financial Officer

Since qualifying as a Chartered Accountant with PricewaterhouseCoopers, Richard

has over 15 years' experience working in finance and general management roles within multi-national FTSE companies including Serco and, most recently, Mitie.



Dr. Mario Gualano Group Chief Executive Officer

With more than 20 years' experience in the diagnostics industry, Mario has a wealth of commercial, technical and operational experience.

He spent more than 20 years with Thermo Fisher Scientific in various operational and commercial roles, most recently as a Division President.

Mario completed his first degree at Cardiff University and has a long association with South Wales. He has a PhD in Microbiology and Immunodiagnostics and an MBA from Henley Management College.

Joined BBI Solutions: 2017



Dr. Peter Corish Group Technology Officer

Peter joined BBI in 2007.

He is responsible for M&A, licensing and external partnerships for the BBI Group, including academic collaborations, product introductions, open innovation and intellectual property development.

Peter has a BSc in Genetics, a PhD in Molecular Genetics from the University of Cambridge and postdoctorates from the University of Leicester and the University of Oxford.

Joined BBI Solutions: 2007



lan Elliott Chief Operations Officer

lan joined BBI in June 2018.

Previously working in a global role for Johnson & Johnson, Ian has 30 years' experience in management roles around the world, covering manufacturing, planning, quality and supply chain management.

Ian has worked in key roles in Australia and Switzerland. He has a Biochemistry degree from Cardiff University and a master's degree in Lean Operations from the University of Wales Business School.



Damian Evans Global Head of Quality and Director of Business Integration

Damian is an experienced Quality Director with a career spanning 10 years in pharmaceuticals and Medical Devices.

Prior to joining BBI Damian spent 10 years at GE Healthcare, in various Global Leadership roles; latterly heading QARA for the Cell Therapy, Healthcare IT platforms and Consumables divisions.

He is a Chemistry Graduate and Six Sigma black belt with experience in major acquisitions and integrations.



Andrea Morgan Group HR Director

Andrea joined BBI in 2018. She is an experienced Human Resource Director with 15+ years within FTSE 250 companies; these include Tesco, DS Smith and Sodexo. Andrea holds a strong track record of delivering people value in fast-paced growth orientated organisations and is committed to continuous improvement.

Andrea is responsible for all HR activities across the group, including driving change to support growth and improvement, processes and procedures and enhancing employee engagement.

Joined BBI Solutions:

2018

Joined BBI Solutions: 2018



Michael Hawley Chief Commercial Officer

With more than 20 years' experience in medical devices and diagnostics, Michael brings a track record of success in sales, marketing and commercial operations.

Breadth of industry experience has been gained through numerous international leadership roles, most recently at Abbott in its Rapid Diagnostics Business. Joined BBI Solutions: 2016



Mathew Hobbs PMO and Performance Director

Having joined BBI in 2019, Mathew brings over 20 years' experience in UK and international finance, commercial and change management roles across both large-scale organisations and SMEs, including KPMG and Mitie.

Mathew's previous roles have seen him lead and deliver significant business change, including in M&A, business restructuring, process improvement and cost management, outsourcing and systems implementations, as well as leading large cross-functional teams.

Joined BBI Solutions: 2020

Joined BBI Solutions: 2020



Part of **BBI** Group







More information about BBI Solutions can be found online at <u>bbisolutions.com</u>