ALIGN
RESEARCH

Yourgene Health

13th August 2020

Rapidly growing in the molecular diagnostics market with significant upside potential from further market consolidation and COVID-19 product sales

Yourgene Health is an international molecular diagnostics group which develops & commercialises genetic products & services, mainly in the area of reproductive health. It works in partnership with global leaders in DNA technology to advance diagnostic science & positively impact human health.

Taking advantage of growth in the molecular diagnostics market

The molecular diagnostics market had a global value of $8.3 billion in 2019 and is forecast to grow at a CAGR of 9% up to 2026, according to analysts at GM Insight. Since the launch of its flagship product in 2015, the non-invasive pre-natal testing (NIPT) IONA® test, combined with expansion via acquisition, Yourgene has grown revenues at a CAGR of 61.3%.

Acquisition of Elucigene significantly expands product portfolio

The business was significantly expanded in April 2019 when Yourgene completed the £9.2 million acquisition of Manchester based neighbour Delta Diagnostics (trading as Elucigene), a molecular diagnostics manufacturer and developer. The deal brought with it a complementary suite of in vitro diagnostic CE (CE-IVD) marked products focused on reproductive health and oncology, including leading products for cystic fibrosis testing and invasive pre-natal aneuploidy screening.

Historic issues cleared and strong progress being made on strategic aims

The business has been significantly de-risked over the past two years. In September 2018, Yourgene settled a long-running patent infringement case with sequencing technology firm Illumina Inc., taking a licence under Illumina's patent pool for NIPT and planning to develop an IONA® test that runs using Illumina's sequencing technology. Then In February 2019 a major capital restructuring saw the writing off of £12.7 million of debt by shareholder Thermo Fisher, leaving Yourgene substantially debt free.

Expansion into COVID-19 products and services broadens portfolio

Attracting the attention of investors amidst the global pandemic, Yourgene has signed a contract manufacturing services agreement to support the production of COVID-19 diagnostic tests, launched a CE-IVD marked diagnostic test to detect the SARS-CoV-2 virus and expanded its laboratory capabilities to support the NHS & private users in COVID-19 laboratory service testing.

DCF valuation suggests 54% upside without considering further acquisition or COVID product potential

Our DCF valuation of the company suggests a target price of 26.63p per share. However, this ignores the company's focus on expansion by acquisition and the potential for upside from COVID products & services, thus suggesting significant further upside to our target price in the medium to long-term. We initiate coverage of Yourgene Health with a stance of **Conviction Buy.**

CONVICTION BUY
Price target – 26.63p

Key data

EPIC	YGEN
Share price	17.25p
52 week high/low	21.75p/7.75p
Listing	AIM
Shares issued	719,509,950
Market Cap	£124.12m
Sector	Pharma

12 month share price chart

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Corporate Background

Yourgene Health (YGEN) is an international molecular diagnostics group which develops and commercialises genetic products and services. It works in partnership with global leaders in DNA technology to advance diagnostic science and positively impact human health.

The business has its origins in Premaitha Health, a company which listed on AIM in July 2014 via the reverse takeover of ViaLogy PLC, raising £7.2 million at a price of 11p per share. The funds were raised primarily to spend on the commercialisation of Premaitha's first product, the IONA® test, a non-invasive pre-natal testing (NIPT) product used to determine the risk that a pregnant woman's fetus is affected with Down's Syndrome or other serious genetic diseases.

Since then the company's portfolio has been significantly expanded and now includes a range of products focussed on the reproductive health cycle from pre-conception, through pre-natal to post birth. These include Cystic Fibrosis screening tests, invasive rapid aneuploidy tests, male infertility tests and genetic disease tests. Meanwhile, a commercial presence has been established with clients, both directly and via distributers, in the UK, US, Europe, Australia, Middle East, Africa and Asia, with plans for further expansion into markets including Japan, China and Brazil.

Growth by acquisition

The company's first acquisition was completed in March 2017, that of Yourgene Bioscience, an NIPT provider in Asia with customers in Taiwan, India, Thailand, Indonesia and Malaysia which operated on the same sequencing platform as Premaitha's IONA® test. The consideration was c.£9.5 million, paid for mostly by issuing new shares in the company. In November 2018 the company changed its name to Yourgene Health to reflect its broadened product development and research service capabilities which extend across the lifecycle of DNA test development and commercialisation.

The business was significantly expanded in April 2019 when Yourgene completed the £9.2 million acquisition (£6.3 million cash and £2.9 million equity) of Manchester based neighbour Delta Diagnostics (trading as Elucigene), a leading molecular diagnostics manufacturer and developer. At the same time, £11.83 million was raised in a significantly oversubscribed fundraising to finance the deal's cash consideration and for working capital for the enlarged group. Elucigene is a Manchester-based molecular diagnostics manufacturer and developer with a suite of in vitro diagnostic CE (CE-IVD) marked products focused on reproductive health and oncology, including leading products for cystic fibrosis testing and invasive pre-natal aneuploidy screening.

The deal seemed to make perfect commercial and strategic sense, with Elucigene bringing with it a suite of 36 commercial products, in line with the company's strategy to offer a broad platform of products within the molecular diagnostics sector, along with a pipeline of new diagnostic solutions in development. Significant cross-selling opportunities were expected, with the acquisition adding 150 new laboratory customers worldwide, with direct or indirect sales increasing from 30 to 57 territories, as well as a strengthened sales force. Certain cost savings were also identified, with the deal expected to be immediately accretive to earnings. November 2019 saw the enlarged group move into newly integrated facilities and corporate HQ at Citylabs, in the centre of Manchester's genomics campus, with all departments combined into a single management structure and manufacturing concentrated onto the one site.

Capital restructuring leaves the business almost debt free

Another major event in 2019 occurred in February, with Yourgene announcing a major capital and commercial restructuring with major shareholder Life Technologies, owned by New York listed scientific instruments and services provider Thermo Fisher Scientific. Firstly, under the capital restructuring, Thermo Fisher exercised warrants in Yourgene worth £3.8 million (giving it a 9% stake) with the proceeds used to reduce outstanding borrowings due to Thermo Fisher.

In addition. Thermo Fisher agreed to write off £12.7 million of remaining loans and accrued interest, leaving Yourgene substantially debt free. The agreement was subject to Yourgene, once cashflow positive, paying up to a cap of £6.5 million via commissions on sales within South-east Asia under a new commercial agreement or via realised share price gains. The commercial agreement saw Thermo Fisher being granted a three-year period of exclusivity for the company's NIPT products in South-east Asia, with Yourgene exclusively promoting its NIPT products on Thermo Fisher's next-generation sequencing systems.

Further progress in 2020 attracts investors' attention

The current calendar year has been an eventful and successful one for Yourgene, with further expansion via acquisition and a move into products and services looking to help with the coronavirus pandemic.

In March 2020 Yourgene announced the acquisition of AGX-DPNI, a newly formed entity comprised of the NIPT distribution business of the company's IONA ® test distribution partner in France. The deal provided Yourgene with its first direct commercial presence in Europe, with France being a key growth market for the NIPT business.

Additionally, attracting the attention of investors amidst the current global pandemic, Yourgene has signed a contract manufacturing services agreement with cellular diagnostics business Novacyt to support the production of Novacyt's COVID-19 diagnostic tests, launched a CE-IVD marked diagnostic test to detect the SARS-CoV-2 virus and expanded its laboratory capabilities to support the NHS and other parties in COVID-19 laboratory service testing.

Further, in August this year Yourgene announced that it has conditionally agreed to acquire Coastal Genomics, Inc. a sample preparation technology company based in Vancouver, Canada. Consideration was up to US$13.5 million, comprised of US$3 million in cash and US$2.5 million in equity, with contingent consideration of up to US$8 million payable in cash and equity. Alongside the deal Yourgene raised gross proceeds of £16.15 million (£15 million net) via a placing of 95 million new shares at a price of 17p per share. This was to fund the initial cash consideration, for general corporate and working capital purposes and to acceleration existing programs. Due to strong demand, the amount raised was increased from an initial target of £13 million, with the additional funds being allocated to the acceleration of existing programs and other strategic growth initiatives, with excess funds used to support further M&A activity.

Strategy

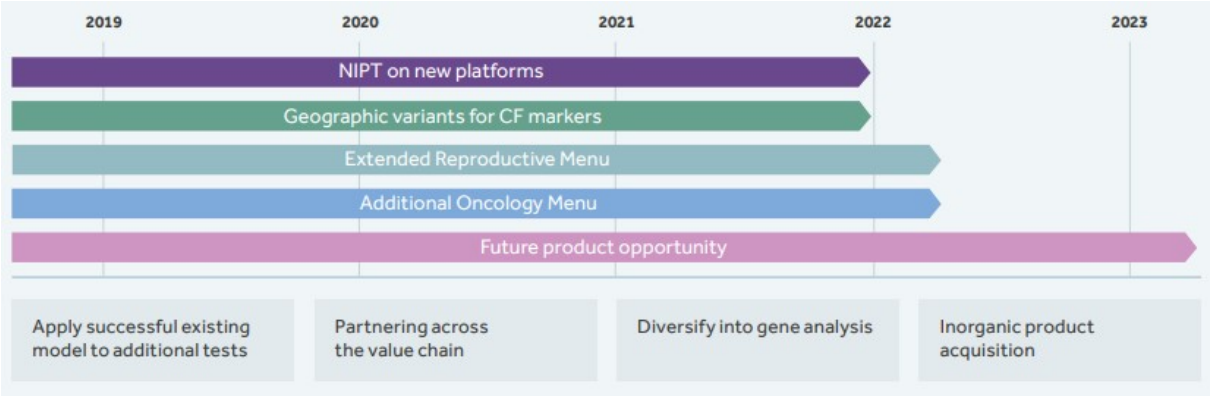
Following the appointment of CEO Lyn Rees in summer 2018, later that year Yourgene set out its strategy to create a significant molecular genetics business and deliver material increases in shareholder value over the subsequent 3-5 years. The strategy has been implemented amidst the backdrop of a molecular diagnostics market which, according to analysts at GM Insights, had a global value of $8.3 billion in 2019 and is forecast to grow at a CAGR of 9% up to 2026. To take advantage of this growth, Yourgene's plan focusses on four strategic priorities:

Product penetration – this element focuses on selling more of the company's products into existing channels by targeting further expansion through direct and key distribution channels.

Geographic penetration – similar to the above, Yourgene aims to expand directly and through distributors into new geographies, including those opened up by Illumina licence agreement.

Product expansion – Yourgene is looking to expand its current portfolio of products and services, using its technical and regulatory expertise and partnerships to extend its genetic testing offering and support diagnostic majors and bioinformatics specialists with IVD product contract development partnerships.

Acquisitive growth – Yourgene has already grown successfully through acquisition in the past few years and continues to consider additional synergistic M&A opportunities where it can identify earnings enhancement opportunities and complementary technologies, products and services. The company believes that with the market being fragmented with few medium-sized entities, there is a good opportunity for market consolidation.



Yourgene new product roadmap. Source: Company

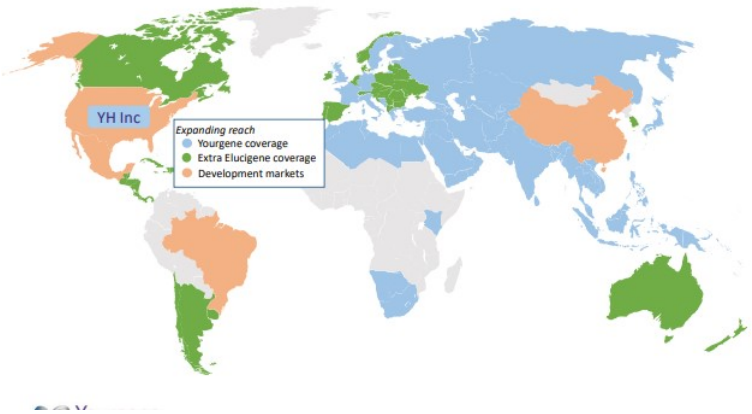
Operations

Yourgene is an international molecular diagnostics group which develops and commercialises simple and accurate genetic in-vitro diagnostic (IVD) products and related laboratory based services. The group works together with a range of global leaders in DNA technology, including Thermo Fisher, Illumina and Novacyt, to advance diagnostic science using proprietary DNA analysis technology to develop safer and improved non-invasive screening tests. Its product development, research service and commercial capabilities extend across the lifecycle of DNA test development, including regulatory submissions.

Following the Elucigene acquisition, Yourgene now has a suite of products based on Next Generation Sequencing (NGS) and Polymerase Chain Reaction (PCR) technology. These products are mainly focussed on reproductive health and include cystic fibrosis screening tests, invasive rapid aneuploidy tests, male infertility tests and genetic disease tests. The focus is on being 'platform agnostic', meaning that its diagnostic products can be used on a wide range of genetic analysis technologies used by the majority of laboratory customers.

Sales model

Through a direct sales and country partnership model Yourgene currently sells its products and services into over 60 countries around the world. The company currently has over 300 laboratory customers and a global network of distribution channels in place. Routes to market include company owned labs in the UK and Taiwan, local sales teams in countries including the UK, Singapore, Australia, France, India and Taiwan, with a range of distribution partners in other countries around the world. The company has recently made its first entry into the US market and is planning its strategy to enter into the potentially highly lucrative Chinese and Japanese markets.



Yourgene global coverage. Source: Company

Facilities

Yourgene is headquartered in Manchester with offices also in Taipei and Singapore. Following the Elucigene acquisition the enlarged group moved into new integrated facilities and corporate HQ at Citylabs in the centre of Manchester's genomics campus. All departments were combined into a single management structure and manufacturing was concentrated onto the one site. The state of the art manufacturing facility supports contract manufacturing for clients as well as producing the company's own its products, currently making 30+ NGS and PCR products. It operates to Good Manufacturing Practice (GMP) standards and adheres to the ISO13485 quality management system.

Divisional Structure

In the last financial year Yourgene organised its business into the three product segments of NIPT, Reproductive Health and Molecular Genetics. We discuss the operations of the business, along with more details on the market background and technologies, using this framework.

NIPT - Non-Invasive Pre-natal Testing

Non-invasive pre-natal testing (or NIPT) is a method of determining the risk that a fetus will be born with certain genetic abnormalities. NIPT tests work by analysing fragments of DNA called cell-free DNA (cfDNA) that are circulating in a pregnant woman's blood, having been leaked into the maternal circulation from the fetus via the placenta. Crucially, cfDNA from the placenta can be detected in the blood of pregnant women.

The test simply involves taking a blood sample from the pregnant woman and then analysing it in a laboratory. Analysing the cfDNA provides an opportunity for the early detection of certain genetic abnormalities without harming the fetus. Such tests are considered non-invasive as they only take blood from the pregnant woman and not the fetus, although an invasive test will be required for a final diagnosis. Other advantages include no chances of miscarriage from the testing procedure, higher accuracy than other pre-natal tests and faster tests results.

This is a relatively young industry, with the first NIPT tests approved and launched in 2011. However, NIPT is one of the fastest growing segments of the molecular diagnostics markets, forecast by Meticulous Research to grow at a CAGR of 17.1% to reach $13.14 billion by 2027. Factors driving market growth include improvements in technology such as next generation sequencing (NGS), trends towards mothers giving birth at a later age and thus having an increased chance of certain abnormalities, an increase in chromosomal abnormalities and increased availability of reimbursement for NIPT from governments and insurers. Yourgene itself increased sales volumes of NIPT tests by 67% to 82,000 in the 2019 financial year.

IONA® test

The IONA® text is Yourgene's flagship NIPT in vitro diagnostic product which is able to estimate the risk that a fetus may be affected with trisomy 21, 18 and 13. A trisomy is a condition in which an organism has three instances of a particular chromosome instead of the normal two. It is a type of type of aneuploidy, which refers to an abnormal number of chromosomes being present, for example a human cell having 45 or 47 chromosomes instead of the usual 46 (23 pairs). An abnormal number of chromosomes is a common cause of genetic defects.

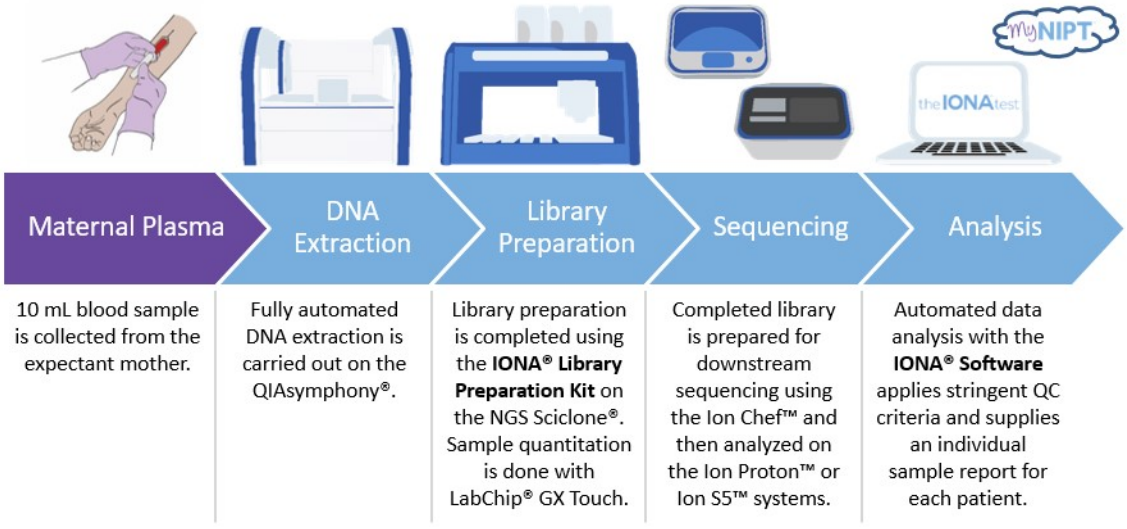
Trisomy 21 refers to Down's Syndrome, a condition associated with intellectual disability, physical growth delays and characteristic facial features.; trisomy 18 to Edward's syndrome, a disorder which can amongst other characteristics cause babies to be born with heart defects, kidney malformations and small heads; and trisomy 13 to Patau syndrome, a condition which can cause multiple and complex organ defects. Trisomies 18 and 21 are the most common that survive to birth in humans and in rare cases a fetus with Trisomy 13 can survive.

The IONA® test has been in development since before the company first listed on AIM in 2014. After receiving the CE mark in February 2015, becoming the first CE marked NIPT product for the European market, it was launched soon after. Receiving the CE mark for products is important as it indicates conformity with stringent quality standards set down by the In Vitro Diagnostic Medical Device Directive. Yourgene owns several patents and has made several further patent applications for the test, the most significant being (WO 2014/033455, Method of detecting chromosomal anomalies), with additional protections based on trade secrets around reagents used in the library preparation kit.

Sales of the IONA® test are mainly targeted at laboratory customers who offer their own NIPT services, with Yourgene also offering test processing services at its own labs in the UK and Taiwan. It has been designed to simplify and standardise the next generation sequencing workflow so that laboratory customers without a background in molecular technology can offer the tests. Included in the kit are DNA extraction reagents, plastic consumables, sequencing chips and reagents, IONA® Library Preparation Kit, IONA® Software, technical support and the Workflow Manager.

To support the test's clinical workflow, Yourgene has developed its own custom bioinformatics analysis software. Employing multi-core analysis algorithms, it analyses the relative amount of chromosomes 21, 18 and 13 to calculate a risk score for the presence of a trisomy. This result is then further detailed by automatically combining it with the age-related risk of the mother at the time of sampling to calculate an adjusted probability of the fetus being affected. A results report is generated individually for each patient.

The test works by taking a blood sample from the pregnant woman and performing analysis on the cfDNA. In clinical laboratories, the IONA® test is currently analysed on the Ion Torrent suite of Next Generation Sequencing (NGS) instruments from Thermo Fisher – NGS refers to the technology used to sequence DNA and RNA and to identify the presence of the trisomies. Put simply, the workflow sees the blood sample spun down to plasma with the DNA then isolated and prepared for sequencing on the instrument. Sequencing data is transferred to IONA software which calculates the probability of the fetus being affected. Test results are available within just 3 days with a >99% detection rate and <1% false positive rate. Women with a high risk result are recommended to take a confirmatory diagnostic test. If specifically requested, the IONA® test is also able to identify whether the fetus is genetically male or female but this is only available in regions where this is permitted.



IONA® test automated workflow. Source: Company

Alongside the IONA® test, Yourgene also offers the Sage™32 plex test, which similar to IONA® is an NIPT analysis solution for clinical laboratories. However, Sage™ differs from the IONA® test in that it offers screening on a wider range of clinical conditions, including trisomy 21, trisomy 18 and trisomy 13, sex chromosome aneuploidies and some clinically relevant microdeletions (a small deletion of a chromosomal segment). The analysis element is undertaken via a cloud-based bioinformatics and software solution called Sage™ Link, which has been enhanced with additional features and an improved user-friendly interface. Sage™ is primarily available as a service from Yourgene Laboratory Services in Taipei and targeted more at Asian markets.

IONA® Nx

The IONA® test currently runs on the Ion Torrent suite of NGS instruments from Thermo Fisher. However, for the past 18 months or so Yourgene has been developing an updated test (IONA® Nx) to run on the rival Illumina NGS platform.

In September 2018, the company agreed to take a licence under Illumina's patent pool for NIPT and is now free to operate in countries where Illumina holds rights to the relevant granted patents. To take advantage of this, Yourgene began to develop an IONA® test that runs on Illumina sequencing technology, the Illumina NextSeq 550Dx NGS platform. Yourgene will pay Illumina a royalty per sample tested using the new IONA® test based on Illumina sequencing technology.

On 15th June 2020, Yourgene announced that it had received CE-IVD marking for the IONA® Nx test, which is now being prepared for commercial launch across the European Union, including the UK, as well as other countries that accept the CE-IVD mark. The company expects to roll-out the test to its laboratory customers across the UK and Europe in the coming months and establish its own laboratory based test service in Manchester.

It is worth noting that the current IONA® test is only available on the Thermo Fisher NGS machines, which make up approximately 30% of the global NGS market. However, Illumina's machines are the market leader, having an over 60% share. Therefore, strong revenue growth is expected once the new test is launched, with newly addressable markets in Asia Pacific and North America also expected to be targeted in 2020 and beyond.

In preparation for the product launch and as a contingency for Brexit, in September 2019 Yourgene transferred its quality accreditation process to a new Notified Body, BSI NL (Netherlands), allowing it to continue to sell its systems in the European Economic Area (EEA). As part of the transfer, Yourgene was issued with a renewed CE-IVD Certificate covering the design and manufacture of the IONA® test, having been successfully audited against the requirements of the European Union In Vitro Diagnostic Directive.

Launch of software platform

In October 2019 the company announced the launch of its Yourgene Flex™ Analysis Software, developed to support its product diversification ambitions. The software allows Yourgene to work in collaboration with product development partners to customise its analysis platform for their NGS applications beyond NIPT, opening up opportunities to develop products such as in vitro diagnostic tests, or in reproductive health, oncology or other clinical diagnostic fields. The software will also be deployed in-house to support the internal product development pipeline across the reproductive health and oncology portfolio.

Expansion by acquisition

French distribution partner

In March 2020 Yourgene announced the acquisition of AGX-DPNI for an initial cash sum of €2.4 million (£2 million) and up to a maximum of €1.7 million (c. £1.4 million) in cash earn-out payments based on sales growth performance criteria. AGX-DPNI is a newly formed entity comprised of the NIPT distribution business of the company's French IONA ® test distribution partner. Alongside the deal Yourgene raised £2.5 million via a direct subscription of shares with BGF Investment Management at a price of 14.3p. The net proceeds were used for the initial cash consideration and for working capital.

This deal provided Yourgene with its first direct commercial presence in Europe, with France being a key growth market for the NIPT business. The country delivered 75% growth in NIPT volume sales in 2019, boosted by the government introducing reimbursement for NIPT, with the acquisition timed ahead of further expected growth and the launch of the Illumina-based IONA® Nx test. An immediate EBITDA uplift of £0.5 million was expected in the first year following the deal from internalising distributor margins, with the presence in France also opening up access to new high growth markets in the French-speaking Africa and Middle East regions. Range-selling opportunities are expected, including further uptake of the reproductive health product portfolio.

Canadian sample preparation technology firm - Coastal Genomics

On 4th August 2020, Yourgene announced that it had conditionally agreed to acquire Coastal Genomics, Inc. a sample preparation technology company based in Canada. Consideration for the deal is up to US$13.5 million, with an initial cash consideration of US$3 million and US$2.5 million in equity, with contingent consideration of up to US$8 million payable in cash and equity. We note that the initial equity element was taken at a price of 18.3p per share, a modest premium to the 17p placing price (see below) and the previous day's closing price of 17.5p.

Coastal Genomics is an ISO 9001 accredited, Vancouver-based sample preparation technology company which has developed the proprietary Ranger® Technology, facilitating cfDNA with primary applications in NIPT and oncology. The two companies have worked together in the past, with Yourgene being an early adopter of the technology, spending over two years evaluating it and embedded it into its own products, IONA® Nx NIPT Workflow and Sage™ 32plex.

Sample preparation is an important step in molecular diagnostics which sees a representative piece of material (e.g. DNA) extracted from a larger amount and readied for analysis. As discussed above, in NIPT the cfDNA in the mother's blood is the material of interest. In oncology, cancerous cells and tumours can express fragmented DNA in the bloodstream. Put simply, Coastal's technology automates the sample preparation stage, enabling faster throughput and cheaper sequencing by enabling multiple samples to be sequenced at the same time. Its two Ranger® Technology platforms are; Lightbench, a cost effective bench-based instrument for 12 gel size selection; and NIMBUS Select, which enables accurate, high yield recovery of up to 96 DNA samples.

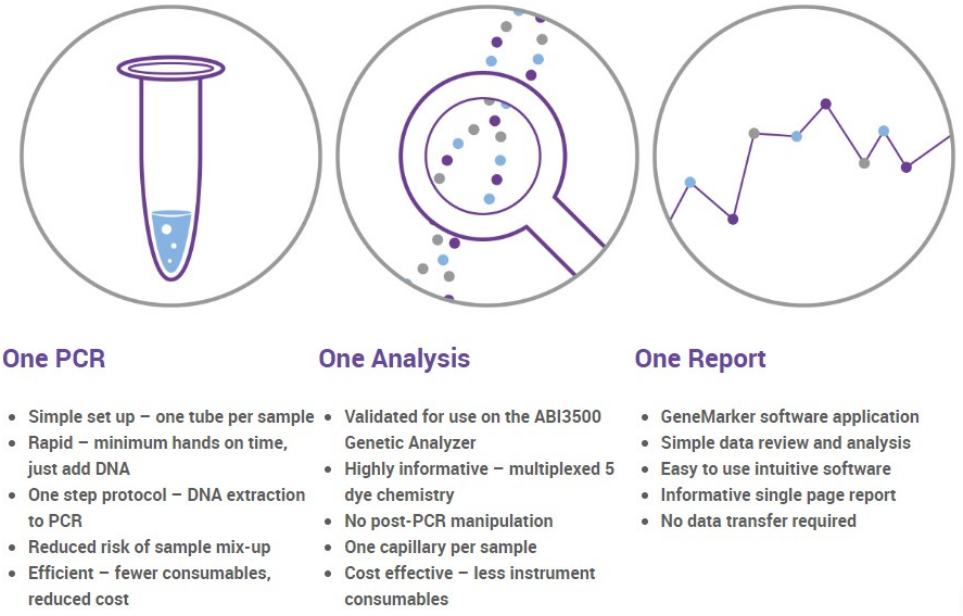
The acquisition brings with it a complementary DNA sample preparation technology which enables customers to choose and use Yourgene for a wider range of diagnostic and genomics solutions and adds core IP-based technology which is key for the future genomic diagnostic industry, especially NIPT and oncology, expanding Yourgene's technology portfolio with a further 5 patents in 13 jurisdictions. The deal will help to accelerate Yourgene's diversification into the oncology market and provide access to the DNA sample preparation market. Also, a number of commercial synergies have been identified including cross selling and margin improvements through vertical integration.

For the financial year ended 31st December 2019, Coastal Genomics posted revenues of US$0.6 million, up 25%, but as an early stage company it generated an EBITDA loss of US$0.6 million. However, Yourgene believes that Coastal is at an inflexion point following technology validation phases with its strategic blue-chip commercial partners which are set to lead to commercial wins. **Reflecting the growth potential seen here, the contingent cash consideration for the year to March 2022 is dependent on US$4 million of revenues being generated, rising to $8.5 million in 2023, both being well ahead of current levels.** Further, two US$1 million equity based payments are due for early strategic customer wins. We understand that Yourgene beat off stiff competition to acquire Coastal, which has attracted interest from other major players in the molecular diagnostics market.

Alongside the deal Yourgene raised gross proceeds of £16.15 million (£15 million net) via a placing of 95 million new shares at a price of 17p per share. This was to fund the initial cash consideration for the acquisition and for general corporate and working capital purposes. Due to strong demand, the amount raised was increased from an initial target of £13 million, with additional funds being allocated to the acceleration of Yourgene's existing programs and other strategic growth initiatives. Any excess funds will be used to support further M&A activity.

Reproductive Health

The acquisition of Elucigene brought with it a complementary range of 36 CE-IVD marked products based on polymerase chain reaction (PCR) technology in the area of reproductive health. PCR is a method developed in the 1980s by the American biochemist Kary Mullis who was awarded the Nobel Prize in Chemistry in 1993 for his work. It is based on using the ability of DNA polymerase to synthesize new strands of DNA complementary to an initial template. Using PCR it is possible to generate thousands to millions of copies of a particular section of DNA from a very small amount of DNA (DNA amplifying) making it a useful tool in medical and biological research. As such, it is now available in the majority of testing laboratories, and compared to NGS can deliver faster results at a lower cost. The company's major product lines in this segment are discussed below.



Elucigene's PCR base test solution. Source: Company

Cystic Fibrosis

Cystic fibrosis is a common and life-threatening disease that is passed on through an autosomal (any chromosome that is not a sex chromosome) recessive mutation in the CFTR gene, which was discovered in 1989. It leads to a chronic obstructive lung disease as a result of a thickened mucus blocking the airway and can also affect the pancreas, liver, kidneys, and intestine.

More than 2,000 mutations and variants of the CFTR gene have been described, including rare versions only found in one patient or family. Therefore, routine testing for all possible mutations is neither feasible nor cost effective so confined to testing for the most common mutations. Cystic fibrosis screening is routinely performed on newborn babies as part of the newborn blood spot test, with early prognosis shown to have beneficial effects by enabling the patient to start treatment early to halt or delay the progression of the condition.

Yourgene's market leading PCR test for cystic fibrosis, Elucigene CF-EU2v1, is the only commercially available pan-European cystic fibrosis testing kit designed specifically to address the most common mutations found across populations of European origin. Adding to this are several other tests in the product range targeted for specific regions, including France, Italy, the UK and Germany, as the frequency of cystic fibrosis mutations varies between different ethnic populations. A test specifically for the US market is also in development.

Male infertility

Studies have shown that sex chromosome aneuploidy and microdeletions of specific regions of the Y-chromosome can play a role in male infertility. The Elucigene Male Factor Infertility (MFI) kit detects deletions of the Y chromosome and sex chromosome aneuploidies associated with male infertility, thus helping with the more effective clinical management of patients. Supporting product, the MFI-Yplus Kit, is a single tube extension assay used in conjunction with the MFI Kit which contains 11 additional markers for characterisation of Y-chromosome microdeletions.

Pregnancy loss

Pregnancy loss test are useful for patients who have suffered a miscarriage, in order to investigate the potential cause (especially if recurrent) and offer guidance on future pregnancy attempts. 50% of first trimester recurrent miscarriage cases have been shown to be caused by a chromosome abnormality (primarily aneuploidy), with the most commonly noted being trisomies, which account for 60% of all chromosome abnormalities in miscarriage. The company's QST*R-PL Pregnancy Loss test is for the routine in vitro quantitative diagnosis of the six most common autosomal trisomies associated with pregnancy loss and also includes X and Y chromosome markers and the TAF9L marker for the determination of sex status.

Rapid Aneuploidy Analysis

Elucigene's QST*R kits detect common chromosome abnormalities at the end of pre-natal screening programmes using the DNA based QF-PCR (Quantitative Fluorescence-Polymerase Chain Reaction) technique. The "rapid" part of this product set is reflected in individual results being able to be obtained within a few hours of receipt of samples. The QST*Rplusv2 test for example is a highly multiplexed single tube assay which comprises a total of 22 markers for chromosomes 13,18,21, X and Y and will detect the most common viable autosomal trisomies and sex chromosome aneuploidies.

Thrombosis risk panel

Venous thromboembolism (VTE) is a condition in which a blood clot forms, most often in the deep veins of the leg, groin or arm (known as deep vein thrombosis, DVT), with an estimated 100,000 - 300,000 VTE related deaths in the US each year, along with 544,000 in Europe. Certain genetic factors are known to contribute to an individual's risk of VTE and Elucigene offers a number of tests to detect the most common associated genetic mutations.

Molecular Genetics

The Molecular Genetics division comprises the company's activities in oncology, research services and infectious disease (COVID-19 testing).

Oncology & Research services

In September 2019, Yourgene announced the launch of its first oncology product, the Elucigene DPYD assay. This is a simple-to-use genotyping test that can identify cancer patients with Dihydropyrimidine Dehydrogenase (DPD) deficiency, a condition which can cause severe and sometimes lethal side effects in patients being treated with chemotherapeutic drug 5-Fluorouracil (5-FU), commonly used in the treatment of a variety of cancers including colon, oesophageal, stomach, pancreatic, breast and cervical cancers. It is estimated that over 2 million people are treated with 5-FU every year around the world and up to 20% of these will be hospitalised due to DPD deficiency and up to 1% may die.

Since launch, initial feedback from potential customers is said to have been positive and the firm secured its first UK contract with an NHS Trust. UK sales are growing with several public sector key customers routinely using the test to pre-screen cancer patients ahead of being prescribed a treatment therapy. In February 2020, Australian regulator the Therapeutic Goods Administration (TGA) approved Elucigene DPYD as an IVD. This will be sold via Yourgene's Australian distribution partner, Southern Cross, which will arrange for the registration of the product and will be the company's sole distributor in the country.

Yourgene's research services meanwhile, provided from its laboratories in Manchester and Taiwan, include whole genome sequencing, exome sequencing and metagenomic sequencing. Additional genetic analysis services include cfDNA screening for breast, colon & lung cancer, cancer hotspot screening, NIPT and pre-implantation genetic screening (PGS). Yourgene Laboratory Services in Manchester is Care Quality Commission (CQC) registered and Yourgene Laboratory Services in Taipei is ISO17025 accredited and TAF (Taiwan Accreditation Foundation No: 2738) certified.

The research services were added to in July 2020 when Yourgene completed a small acquisition, that of Ex5 Genomics Ltd for an initial £275,000. Ex5 offers services including DNA/RNA extraction, genomics testing, assay development and bioinformatics.

Expansion into COVID-19 Products and Services

Deal with Novacyt to produce COVID-19 diagnostic tests

Yourgene's first announcement regarding the expansion into COVID-19 related products and services came on 25th March 2020. The company revealed the signing of a contract manufacturing services agreement with clinical diagnostics specialist Novacyt to support the production of PCR based COVID-19 diagnostic tests developed by Primerdesign, Novacyt's molecular diagnostics division. Making use of its manufacturing facility at Citylabs in Manchester, Yourgene is working with Novacyt to ramp-up production, initially manufacturing critical components for the test. The first batches were expected to be shipped in the weeks following the announcement.

At the time of the announcement Yourgene also announced its intention to expand its laboratory capabilities to support the NHS in COVID-19 laboratory service testing. A further update on 26th May confirmed that a testing service had been launched supporting private testing demand where there are defined testing populations such as UK GP surgeries, private clinics and other corporate clients across the UK.

Collaboration agreement

On 16th June 2020 Yourgene revealed the signing of a collaboration agreement with international payments company Caxton and immunity passport app Prova. Created by London-based Hooha Innovations, Prova enables employees to download and request a COVID-19 test. Once a test sample has been taken and the sample processed, the results will be automatically delivered securely to the Prova app within 24-36 hours after the sample is received in the lab, allowing the user to share and prove their COVID-19 status without revealing any personal information.

Under the deal, Yourgene will be providing the clinical and technical expertise, by providing sample collection kits, training healthcare professionals to take the sample safely and then running the COVID-19 test in its Manchester facility. The collaboration will use the Clarigene™ SARS CoV-2 CE-IVD assay (see below) and the patient results will be uploaded securely to the Prova app. Caxton meanwhile will offer COVID-19 tests to its network of corporate clients and their employees.

Launch of COVID-19 assay

On 30th June 2020, Yourgene revealed the launch of its Clarigene™ SARS-CoV-2 test for research use only (RUO). The test was initially made available to Yourgene's customers as evaluation kits, with a CE marked in vitro diagnostic kit for diagnostic use released at the start of August following the receipt of the CE-IVD mark.

The molecular PCR based assay is able to detect the SARS-CoV-2 virus's ribonucleic acid (RNA) from a swab of the patient's throat, then nose, to confirm the presence of the virus and whether individuals are currently infected. It does not detect the presence of antibodies and only detects SARS CoV-2 RNA. The assay uses two viral RNA targets, nucleocapsid gene ('N') and envelope gene ('E'), which are SARS-CoV-2 specific and this prevents any cross reactivity with other coronaviruses. The assay has a turnaround time of 1hr 20min following RNA extraction & set up and has been developed to reduce the chance of false negative results being generated, a problem which has been seen amongst other tests. Clinical validation of the test has shown >99.9% accuracy with no false positive or false negative results. Additional studies have shown 100% repeatability data and an average >99.7% reproducibility. Kits contain up to 960 tests per kit for high throughput testing.

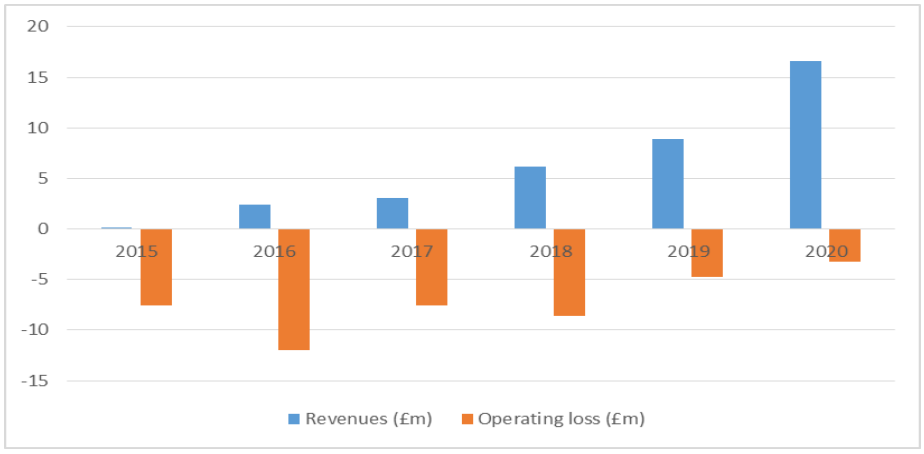
Sales of the kits will be driven via the company's c.300 laboratory customers and its global network of distribution channels. In addition, the test will be run in Yourgene's service laboratory in Manchester and will allow Yourgene to provide corporate partners and healthcare settings, such as care homes and private GP practices, with a fast and reliable COVID-19 lab testing service. We understand that the government is not being considered as a potential client at the current time due to potentially onerous requirements of the approval process and the fact that sales are not guaranteed even if it is approved. **While the company has kept quiet about potential sales volumes of its test, given the current market dynamics and shareholder interest in the product it recently committed to updating shareholders on the commercial take-up on a quarterly basis.**

Yourgene continues to explore additional opportunities to expand its contribution to global COVID-19 testing efforts with increased usage of its manufacturing facility in Manchester, as well as exploring additional routes to market.

Clarigene™ SARS-CoV-2 test. Source: Company

Financials

Since the IONA® test completed its first full year of commercialisation in 2016, and following the expansion of the product portfolio, Yourgene has grown revenues strongly. Between FY2016 and FY2020 revenues grew at a compound annual rate (CAGR) of 61.3%. Operating losses have also been reducing steadily.



Yourgene Health revenues and operating losses FY 2015 to 2020. Source: Company accounts

Full year results to March 2019

FY2019 was a landmark year for Yourgene, with the major corporate events being the previously discussed debt restructuring, name change, licensing agreement with Illumina and the appointment of Lyn Rees as Chief Executive Officer. The operational performance was also good, with revenues rising by 45% to a record £8.9 million following a particularly strong performance from international markets. The adjusted EBIDTA loss reduced by 29% to £3.1 million, with operating losses falling by 44% to £4.8 million. However, after accounting for £9.4 million of financing income related to the debt restructuring, the net profit for the year was £3.39 million, up from a loss of £9.54 million. This was a non-cash accounting entry, with the cash used by operations amounting to £4.04 million.

Full year results to March 2020

In July 2020 Yourgene announced yet another record set of results, for the year to 31st March 2020, with the numbers benefitting from a first contribution from Elucigene. Revenues for the period grew by 87% to £16.6 million, driven by organic growth of c.36%, an 11 month contribution from Elucigene and three weeks' contribution from the French NIPT distribution business. Sales would have been £0.4 million higher if it were not for March orders being delayed into the new financial year due to COVID-19 related transport restrictions, thus being in line with consensus analyst forecasts for revenues of c.£17 million.

By geography, sales growth was strongest in the firm's European markets, up 133% to £4.1 million. While there were disruptions seen from COVID-19 issues, including slight timing delays, customers in Europe continued to operate as normal. International markets saw sales up by 78% at £10.5 million following a good performance from South-east Asia, offset by travel disruption having an impact on the launch in the US, which saw its first revenues. UK sales meanwhile, grew by 62% to £2 million.

By product line, the core NIPT segment grew revenues by 29% to £10.1 million, with Reproductive Health growing from a base of zero to £3.7 million, and Molecular Genetics up by 174% to £2.8 million.

Notably, gross profits for the year more than doubled, from £4.6 million to £10.2 million as a result of gross margins rising from 52% to 62%, benefitting from the higher margin Elucigene product mix as well as an increasing proportion of revenues in the international markets. At the adjusted EBITDA level Yourgene posted its first profits, turning the previous year's loss into a £1.3 million gain, with the operating loss reduced from £4.8 million to £3.2 million.

On the balance sheet, Yourgene ended the period with cash of £2.8 million (net cash of £2.4 million), with this having been boosted post period end by the receipt of £0.8 million for warrant and option exercises, R&D tax credits worth £0.5 million, and by the net proceeds of the August placing. Cash used by operations in the year halved to £2.1 million.

On the outlook, Yourgene commented that it remains confident that the growth trajectory will continue and it remains on track to hit ambitious growth targets for 2021 in line with consensus expectations.

Management

Adam Reynolds - Non-executive Chairman

Adam began his career in the City in 1980 with stockbrokers Rowe Rudd then joined Public Relations business Basham & Coyle heading their Investor Relations Division. In 2000 he established his own PR/ IR and Corporate Finance firm, which listed on AIM in November 2000. In 2004 the company was sold making shareholders 15X their investment. Adam was approached in 2005 by the largest shareholder in International Brand Licensing Plc, the owner of the Admiral sports brand, to become Executive Chairman. Adam alongside the major shareholder re-financed the business. In 2009 Adam brought into the company David Evans and Julian Baines - the two leading diabetes specialists in the UK and the business changed direction. Today it is known as EKF Diagnostics Plc. Adam is a non-executive director and a substantial shareholder.

Dr Stephen Little - Vice Chairman

Stephen is a successful serial biotechnology entrepreneur. He is the former CEO of DxS, an innovator in the field of personalised medicine, developing and manufacturing companion diagnostics. DxS was funded with £3.5M in 2001 and was sold to QIAGEN BV in 2009 for £85M. DxS pioneered the use of molecular diagnostic tests such as KRAS and EGFR mutation analysis to predict the use of novel cancer therapies. In 2009, DxS was acquired by QIAGEN and Stephen became Vice President of Personalised Healthcare, responsible for developing companion diagnostic partnerships with the pharma industry. Prior to his leading role at DxS, Stephen worked for 20 years in various senior positions in the diagnostic divisions of Astra Zeneca and ICI. He holds a PhD from Heriot-Watt University in Edinburgh.

Lyn Rees - CEO

Lyn is a seasoned executive in global healthcare and IVD markets. Prior to joining Yourgene Health, Lyn was Group CEO at British Biocell International (now BBI Group) for over 9 years. He began that role at BBI Group following the acquisition of BBI Holdings by Alere in 2008 and in his time, he oversaw the doubling of revenue growth and has developed an accountable and highly effective senior management team with clear focus on innovation, commercial delivery, compliance and operational efficiency. Lyn has completed 7 acquisitions during his tenure at BBI Group, all of which have been successfully integrated. He founded BBI Detection and BBI Animal Health and has demonstrated a strong track record of organic and acquisitive growth. Before this role, he spent several years as the Managing Director and founder of BBI Healthcare in 2006 following the successful purchase of the GlucoGel product.

Dr Bill Chang - Chief Scientific Officer

Bill is the Chief Scientific Officer at Yourgene Health and he was the Chief Executive Officer of Yourgene Bioscience, which he founded. After completing his PhD at University of Melbourne, Australia, Dr Chang joined Academia Sinica in 2007 as a research specialist and established the bioinformatics core facility at the Institute of Plant and Microbial Biology. In 2010, Bill established Yourgene Bioscience to provide Next Generation Sequencing and bioinformatics services. He co-founded Sofiva Genomics in 2012 to provide pre-natal genetic testing services. He is now also an Honorary Fellow at the Faculty of Veterinary Science, University of Melbourne.

Barry Hextall - Chief Financial Officer

Barry is a Chartered Management Accountant with over 20 years' experience in senior financial roles, including with international AIM-listed organisations. He has managed many businesses through major changes and rapid growth, and has significant experience working in the global medical devices and in vitro diagnostic sectors. His previous employers include Immunodiagnostic Systems plc, JRI Orthopaedics Ltd, C J Garland & Co Ltd, Ernst & Young LLP and Zeneca plc (originally ICI). He holds a Diploma in Company Direction from the Institute of Directors, an MBA from Cranfield School of Management and is a Chartered Global Management Accountant through CIMA.

Hayden Jeffreys - Chief Operating Officer

Hayden has over 20 years' experience in the clinical diagnostics industry, much of which has been spent within molecular diagnostics. He has a proven track record of formulating and implementing commercial strategy and driving the next stage of global growth for businesses. Prior to joining Yourgene Health, Hayden was Chief Operating Officer at Cambridge Epigenetix. Hayden has also held several senior positions within the ERBA group, including Head of Corporate Business Development and Strategy. He has been responsible for licensing and partnership opportunities in addition to leading acquisition strategies.

Non-Executive Directors

Dr. John Brown - has over 20 years' capital markets experience in the healthcare and life sciences sector. He is currently a Senior Independent Director of BioCity and Acacia Pharma and is Chairman of Cell Therapy Catapult and Synpromics. Additionally, he has previous significant board experience with roles including Chairman of Axis-Shield, Chairman of BTG, Non-executive Director of Vectura and Chief Executive Officer of Acambis.

Nicholas Mustoe - started his career in 1981 working in London advertising agency Foote Cone and Belding followed by nine years at Lowe Howard Spink. In that time Nick worked across many clients including Tesco, Heineken, Whitbread, Vauxhall, Wicks, Weetabix, Bauer Publishing and Hanson Group Companies. Nick started his own agency, Mustoes Merriman Levy ("Mustoes"), in 1993, which he ran as an independent agency for 15 years, with a brief period under the ownership of Japanese multi-national Hakuhodo. In 2008 Mustoes merged with a leading PR agency Geronimo to form Kindred, the first fully integrated PR & Advertising agency. Nick subsequently led an MBO of Kindred in 2010. He was Chairman of Kempton Park Racecourse, is currently Chairman of charity Starlight Children's Foundation and Chairman of Big Sofa Technology Plc., as well as a non-executive director of Hub Capital (corporate finance).

Jonathan Seaton - has extensive experience working for leading global life sciences and diagnostic companies having worked on more than 40 merger and acquisition transactions. Including seven years at Roche Diagnostics (2008-2015) where he held the position of Vice Director, Global Business Development, advising leading merger and acquisition activity and strategic partnerships. He then moved to Becton, Dickinson and Company in 2015 where he focused on key strategic programmes, followed by Illumina in 2017 where he was Head of Corporate and Business Development and Government Affairs. Jonathan is currently a Director at GenomOncology a real-time clinical oncology informatics company. Prior to Roche Diagnostics, he worked as a life sciences investment banker for Deutsche Bank Securities.

Key Risks

Patent protection and intellectual property litigation

Yourgene is focused on protecting its Intellectual property and to that end has secured and is seeking to secure patents. However, there is the risk that the company may face opposition from third parties to patents that it seeks to have granted and that third parties may infringe its IP. As seen in the case with Illumina, the life sciences industry is characterised by significant litigation from patent-holders and their licensees, with non-invasive pre-natal testing having seen a high level of activity in the US, Europe and elsewhere, primarily from Illumina.

Legal and regulatory risks

The life sciences industry is highly regulated across the world, with the company's diagnostics products required to obtain regulatory approval. It is not certain that new products will successfully obtain the necessary regulatory approvals in the territories in which Yourgene seeks to sell them. Also, changes in laws, legislation and international relations affecting the diagnostics market could have a negative impact on the company's activities and consequently may have a detrimental effect upon trading performance.

Competition risk

Yourgene faces competition from a range of other providers of NIPT and other services and products, many of which have significantly larger financial resources to spend on product marketing and development. There is a risk that competitors could achieve greater than expected market penetration and/or continue with aggressive price discounting and bundling of NIPT with other genetic or clinical service offerings. In addition, with technologies in the diagnostics marketplace constantly evolving and improving, competitors could develop products that make Yourgene's offerings outdated or obsolete.

Early stage nature of operations/financing risk

While Yourgene is making significant progress towards being a cash positive business it currently remains loss making. However, cash outflow from operations has been steadily reducing year on year and with cash of £2.8 million as at 31st March 2020, plus the recent £0.8 million from option and warrant exercises, £0.5 million R&D tax credit and net proceeds of the August placing, it is in a very strong position to fund its activities through to cash flow positivity. The company may still need to raise additional funding to finance its activities and there is no certainty that future fundraisings will be possible or on acceptable terms, with any equity financings being dilutive to current shareholders.

Forecasts

To put a valuation on the business we have compiled a 5 year discount cash flow analysis, covering the years 2021 to 2025 inclusive, adding in a terminal value to reflect growth beyond that period. Our assumptions are based on a range of sources including Yourgene's historic financial statements, market updates, investor presentations and wider industry data. Discussed in more detail below, our core model assumes no contribution from the company's COVID-19 products and services.

Key assumptions

P&L

We begin by forecasting revenue growth at the product segment level, adding in the recent acquisition of Coastal Genomics separately. We expect particularly strong growth from the NIPT division over the forecast period, especially following the launch of the new IONA® Nx test and as NIPT testing continues to be allowed for reimbursement by an increasing number of countries and insurers. For 2020 we forecast 35% revenue growth in the division, ahead of the 17.1% expected by Meticulous Research for the NIPT industry as a whole and ahead of 29% growth seen in 2020. Growth is then assumed to fall by 5 percentage points per annum, settling at 15% in 2025.

Meanwhile in Reproductive Health we are looking for 15% growth in 2021 falling by 1 percentage point a year, with Molecular Genetics growing at a flat 9% in line with the wider molecular diagnostics industry. Accounting for Coastal Genomics, we make some conservative assumptions on revenues which are lower than the earn-out targets through to 2023. We expect the business to be profitable by 2023.

Elsewhere in the P&L account, gross margins are forecast at a flat rate of 61% over the forecast period (in line with 2020), with admin expenses in the core three divisions in line with historic spending and growing at 10% per annum. We also add in assumptions for admin expenses at Coastal. Modest interest costs of £25,000 are expected on the firm's remaining debt, with a 19% corporation tax rate – which is conservative as we note that the company had a potential deferred tax asset of approximately £5,695,765 as at 31st March 2020.

Balance sheet items

Capital expenditure is forecast at £0.9 million a year over the forecast period, with depreciation at 25% of property, plant and equipment. Inventory levels are expected to grow in line with sales growth, with 60 days of inventory kept on hand. Similarly, receivables and creditors are forecast to grow in line with total revenues.

DCF Analysis

In our DCF analysis we have chosen to use a discount rate of 8% as we believe this adequately reflects the equity risk premium, especially given the way Yourgene has significantly de-risked its business over recent years as described in this note. For our terminal value calculation we assume a long-term growth rate of 5%, a figure which is arguably conservative given the forecast growth rates of the molecular diagnostics industry as a whole and Yourgene's potential for growth from a relatively small base.

The findings of our DCF analysis are presented in the table below.

	2021	2022	2023	2024	2025
Revenues	21,342,000	28,302,880	36,064,247	41,911,724	47,401,856
COGS	-8,323,380	-11,038,123	-14,065,056	-16,345,573	-18,486,724
Gross profit	**13,018,620**	**17,264,757**	**21,999,191**	**25,566,152**	**28,915,132**
Admin expenses	-10,741,537	-12,435,691	-13,829,260	-15,122,186	-16,539,904
EBITDA	**2,277,083**	**4,829,066**	**8,169,931**	**10,443,966**	**12,375,227**
Interest	-25,000	-25,000	-25,000	-25,000	-25,000
Depreciation	-717,326	-762,995	-797,246	-822,935	-842,201
PRE-TAX PROFIT	**1,534,757**	**4,041,071**	**7,347,685**	**9,596,032**	**11,508,027**
Tax	-291,604	-767,804	-1,396,060	-1,823,246	-2,186,525
NET PROFIT	**1,243,153**	**3,273,268**	**5,951,625**	**7,772,786**	**9,321,501**
Adjusted for:					
Capex	-900,000	-900,000	-900,000	-900,000	-900,000
Depreciation	717,326	762,995	797,246	822,935	842,201
Change in inventories	-215,919	-446,259	-497,578	-374,879	-351,970
Change in receivables	-1,608,077	-2,360,530	-2,631,986	-1,982,959	-1,861,779
Change in creditors	1,401,979	2,057,994	2,294,659	1,728,815	1,623,165
TOTAL	**-604,691**	**-885,800**	**-937,659**	**-706,090**	**-648,383**
Free cash flow to equity	**638,462**	**2,387,468**	**5,013,966**	**7,066,696**	**8,673,119**
Year	1	2	3	4	5
Discount rate	0.08	0.08	0.08	0.08	0.08
Discount factor	1.08	1.1664	1.259712	1.36048896	1.469328077
NPV	**591,169**	**2,046,869**	**3,980,248**	**5,194,232**	**5,902,779**

5 year NPV	17,715,296
NPV of terminal value	206,597,259
TOTAL of 5 year + terminal	224,312,555
Shares in issue	719,509,950
Value per share (p)	**31.18**
Diluted share capital	842,189,288
Value per share (p)	**26.63**

Our analysis shows that Yourgene has a highly profitable and cash generative business which benefits from a strong operational gearing. Should our forecasts be met then we see no need for an additional fundraise, except in the case of funds being needed to pay for any further acquisitions. Our valuation for the company comes out at £224.3 million, with the majority of this (£206.6 million) being attributed to the terminal value. Divided by the current number of shares in issue results in a valuation of 31.18p per share. **However, adding in warrants and share options outstanding and the fully diluted valuation is 26.63p, which we have chosen to adopt as our target price.**

Peer analysis

To support our DCF valuation we have conducted a peer analysis of certain London listed companies operating in the diagnostics field which we believe have broadly similar (if not identical) operations, risks and business models as Yourgene and are at the stage of ramping up their product sales. Given that Yourgene is yet to reach profitability at the operating level we choose to adopt the enterprise value to sales multiple as an additional valuation metric. We identify three companies for the analysis; **Omega Diagnostics (ODX),** the medical diagnostics company focused on CD4, infectious diseases and food intolerance testing; **EKF Diagnostics (EKF),** the point-of-care diagnostics and central laboratory assay manufacturer; and **Diaceutics (DXRX),** a diagnostic commercialisation company for global pharmaceutical companies.

Company	Price (p)	Market cap (£m)	Net cash (£m)	Sales (£m)	EV/Sales
Omega Diagnostics	0.6	106.92	-0.78	9.82	10.97
EKF Diagnostics	0.55	250.03	16.30	44.90	5.21
Diaceutics	1.7	142.92	29.80	13.40	8.44
				AVERAGE	**8.20**

The three peers currently trade on an average EV/Sales multiple of 8.2 times. Applying this multiple to our 2022 revenue and current net cash forecasts implies a market cap of £215.8 million for Yourgene. **On a diluted basis, this equates to a value of 25.62p per share.**

COVID upside potential

While news of the launch of COVID-19 related products and services has caught the market's attention, Yourgene's management have held back on guiding towards any potential in terms of sales volumes or revenue figures, particularly in terms of its Clarigene™ SARS-CoV-2 diagnostic test and laboratory testing services. This is understandable given the current market dynamics and uncertainties over how long current levels of demand will hold. As stated above, management have committed to updating shareholders on a quarterly basis on the commercial take up. However, prior to this, we attempt to highlight some of the benefits of the company's own test and to quantify some of the potential.

According to website 360dx.com's Coronavirus Test Tracker report, as at 11th August 2020 there were exactly 100 commercially available CE marked COVID-19 diagnostic tests. Despite the competition, Yourgene has entered the market having learned from the shortcomings of some earlier tests and so has designed its own to counter these.

For example, a recent study from the University of Bristol[1] found that a systematic review of the accuracy of COVID-19 tests reported false negative rates (wrongly telling someone they are not infected) of between 2% and 29%. While no test will ever deliver 100% accuracy in the long-term, clinical validation of Yourgene's test has shown >99.9% accuracy with no false positive or false negative results (there were 48/48 positive and 24/24 negative when compared to a "gold standard" reference). Further studies on Clarigene™ have shown 100% repeatability data and an average >99.7% reproducibility.

Additionally, Clarigene™ SARS-CoV-2's use of dual viral targets and assay controls provides a more reliable result, while also making it more desirable across several European regions, including France, which require dual viral targets for reimbursement. What's more, inadequate sample collection has been an issue in the global pandemic and the Clarigene™ test kit has an internal control that detects poor-quality samples to give an invalid result, allowing greater confidence in negative results.

[1] *Watson, J. , Whiting, P. F., & Brush, J. E. (2020). Practice pointer: Interpreting a covid-19 test result. BMJ, 2020, [369]. https://doi.org/10.1136/bmj.m1808*

Potential figures

We feel we have enough basic information to give some broad figures on the potential of the firm's testing services only (not sales of Clarigene™ kits) and have made some assumptions using data from several sources. Firstly, we believe that in the medium term Yourgene has the potential to build up testing capacity at its laboratories to 10,000 a month. Caxton's website is currently pricing the tests for employers, administered by a health professional provided by Yourgene, at between £130 and £150 per test, dependent on volumes.

Taking the mid-range of £140 we assume that Caxton takes a 50% cut of the sales price. At a typical margin of 60% Yourgene would then be making a net contribution from each test of £42. Multiplied by the 10,000 a month testing capacity gives the potential for an additional £420,000 contribution to operating profits on a monthly basis, or just over £5 million if annualised. **Adding this into our DCF model from 2022 onwards (keeping all other assumptions consistent) would add an additional 13.04p to our target price.**

A scenario on the low side, assuming 5,000 tests a month would see additional annualised operating profits of £2.52 million, which added to the model as above gives another 6.52p of value per share. Alternatively, a high side scenario of 15,000 tests a month gives additional annual profits of £7.56 million and adds 19.55p per share to the valuation.

We point out that these figures are illustrative only, with concrete data on demand levels currently unavailable. It is also unclear as to how demand for COVID testing will play out over the next few years. While the finding of a viable vaccine may reduce demand, we expect that testing will continue to be needed in many contexts, especially employment, to identify individuals who are currently infected and to help reduce the spread of the virus.

Conclusion

Following the debt restructuring with Thermo Fisher, the licensing agreement with Illumina, the acquisition of Elucigene and the recent fundraisings, Yourgene has significant de-risked its business and put itself in an excellent position for future growth. Our analysis suggests that the funds are in place for the company to continue its growth throughout the current financial year and beyond, with 2021 and 2022 in particular set for strongly rising sales on the back of the launch of the IONA® Nx test - without even considering the venture into COVID-19 related products and services.

We set our target price for Yourgene at 26.63p, based on our DCF valuation. Once again, we point out that the analysis is based on organic growth only and ignores the company's stated strategic aim of expansion by acquisition. With the potential for further earnings enhancing deals to be done, we see significant further upside potential to our target price in the medium to long-term. This view is backed by the company's excellent track record of deal making, with revenues having grown rapidly following the (relatively modestly sized) acquisitions of Yourgene Bioscience and Elucigene. Indeed, the acquisition of/merger with a more medium-sized player in the range of Yourgene's current market cap could be truly transformational. We also note that all of the company's major acquisitions, those of Yourgene Bioscience, Elucigene, AGX-DPNI and Coastal Genomics, have involved some form of equity element, either as part of the initial consideration or the earn-out payments. This approach shows that Yourgene is aligning the interests of the acquired companies with that of the group as a whole and that vendors are willing to take a long-term stake in the business. **We initiate coverage of Yourgene Health with a target price of 26.63p and stance of Conviction Buy.**

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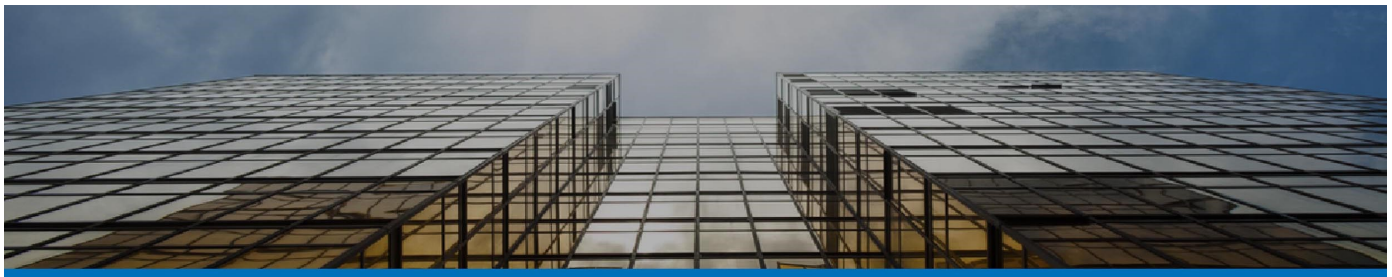

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