**Market data**

EPIC/TKR	YGEN
Price (p)	13.0
12m High (p)	16.0
12m Low (p)	3.6
Shares (m)	459.0
Mkt Cap (£m)	59.7
EV (£m)	58.2
Free Float*	71%
Market	AIM

*As defined by AIM Rule 26

Description

Yourgene Health is an international molecular diagnostics business for research into, and the development and commercialization of gene analysis techniques for pre-natal screening and other clinical applications in the early detection, monitoring and treatment of disease.

Company information

CEO	Lyn Rees
CFO	Barry Hextall
Chairman	Adam Reynolds

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www.yougene-health.com**Key shareholders**

Directors	20.1%
Thermo Fisher	9.0%
S.Myers	7.4%

Diary

Jly'19	Finals
Sep'19	AGM

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YOURGENE HEALTH

Transformed and de-risked

Yourgene Health (YGEN) is an international molecular diagnostics group that uses the latest advances in DNA sequencing technology for non-invasive prenatal screening tests (NIPT). Its flagship IONA test uses complex statistical analyses to determine the likelihood that a fetus is carrying a genetic disorder, such as Down's syndrome. YGEN has been held back by a patent infringement case and a complicated balance sheet. However, settlement of the patent case with Illumina and repayment of debt to Thermo Fisher (TMO) have transformed YGEN, allowing it to focus entirely on the enormous global growth opportunity for prenatal screening tests.

- **Strategy:** Yourgene is focused on the global commercialisation of NIPT, which use the latest DNA analysis technology to predict certain fetal abnormalities. This technology also has the potential for expanded use in other aspects of reproductive health.
- **Illumina:** YGEN has settled its patent infringement case with Illumina by taking out a licence for territories covered by Illumina's patents and agreeing to develop its IONA test to work on the Illumina platform. This has removed the handcuffs from YGN and allow the company to focus on the growth opportunity.
- **Debt-free:** Exercise of 43% of TMO's outstanding warrants and the complete repayment/cancellation of loans have transformed the company's balance sheet. Moving forward, YGEN has a major supportive shareholder in TMO, with 9.0% of the enlarged equity, and net cash of £1.5m (est.) to support operations.
- **Risks:** Both of the uncertainties that have caused the stock to severely underperform have been removed over the last six months, and the company can now focus on the global growth opportunity. Further capital will be required, but this can now be raised from a position of strength.
- **Investment summary:** Despite two years of patent uncertainty, YGEN has continued to expand the availability of its NIPT tests and services. With the handcuffs removed, management can now focus on making these tests available on the two largest sequencing platforms in the world. YGEN looks set to become profitable and cash-generative in fiscal 2021. The stock should command a prospective EV/sales multiple of 5x-10x, suggesting an EV of £60m-£120m.

Financial summary and valuation

Year-end March (£m)	2016	2017	2018	2019E	2020E	2021E
Sales	2.45	3.08	6.15	8.68	12.00	15.50
EBITDA	-5.32	-5.07	-4.72	-3.06	-0.64	1.54
Underlying EBIT	-5.87	-5.80	-5.76	-4.24	-2.13	0.02
Reported EBIT	-11.83	-7.60	-8.60	4.81	-2.38	-0.23
Underlying PBT	-5.96	-6.04	-6.35	-4.69	-2.12	-0.01
Statutory PBT	-12.12	-7.85	-9.54	4.16	-2.37	-0.26
Underlying EPS (p)	-2.71	-2.56	-1.96	-0.99	-0.42	0.00
Statutory EPS (p)	-5.56	-3.34	-2.99	0.89	-0.47	-0.05
Net (debt)/cash	2.20	-6.20	-15.96	1.55	-1.52	0.26
Capital increases	7.72	10.61	0.00	9.64	0.00	0.00
EV/sales (x)	-	18.9	9.5	6.7	4.8	3.8
EV/EBITDA (x)	-	-	-	-19.0	-90.3	36.0

Source: Hardman & Co Life Sciences Research

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Executive summary

Yourgene Health (YGEN, formerly known as Premaitha Health) was incorporated in 2013 for the sole purpose of acquiring the IP and assets of Zoragen Biosciences LLP, a company founded in 2007 to exploit the knowledge that fetal DNA leaks into the maternal bloodstream with a view to developing an improved test to screen for genetic disorders, such as Down’s syndrome. This culminated with the development and CE marking of IONA® in 2015.

IONA®

IONA estimates the risk that a pregnant woman is carrying a fetus with a genetic abnormality...

...IONA is extremely accurate with negligible false positives

IONA is a non-invasive prenatal test (NIPT) for pregnant women that estimates the risk of a fetus being affected by Down’s syndrome or other genetic conditions. The test is performed on a sample of maternal blood extracted after around 10 weeks of gestation, and results are available in three to five days. As it is a molecular diagnostic based on DNA, the test is extremely accurate (>99%) and generates negligible false positives. In contrast, the current ‘combined test’ has detection rates of about 85% and produces false positives at a rate of 3%-4%. Women identified as being high-risk with the combined test need to have an invasive diagnostic test (amniocentesis), which carries a risk of miscarriage. The aim of IONA is to more accurately predict the likelihood of a genetic abnormality, minimise the number of false positives, and reduce the number of invasive confirmatory tests.

Transformational deals

Settlement of the long-running patent dispute with Illumina will allow YGEN to operate freely

Restructuring TMO relationship leaves YGEN debt-free and with estimated net cash of ca.£1.5m...

...and a strategic shareholder locked-in for three years

Over the last six months, YGEN has made two transformational deals that will now permit management to concentrate on its growth strategy. First, it has settled a long-running patent dispute with Illumina, which will allow the company to operate freely in markets in which the Illumina patents are recognised. While there will be some costs involved in settling out-of-court, future investment in Illumina sequencing equipment, and ongoing royalty payments per test, this agreement does remove the considerable uncertainty, cost and management distraction.

Secondly, in order to fund YGEN’s working capital requirements and the considerable court and legal costs in defending the patent infringement claim, YGEN took out a series of loans from the Life Technologies division of its partner, TMO, which, together with accrued interest charges, had reached an estimated £16.5m, accounted for as a combination of long-term liabilities and warrant reserves, severely damaging its balance sheet. The settlement with TMO, largely through the exercise of warrants and debt cancellation, has transformed the balance sheet, left YGEN almost debt-free, and with TMO as a major and supportive shareholder with 9.0% of the enlarged equity, plus warrants that could take it up to 17%. Both these deals will permit YGEN to focus on and accelerate its growth strategy.

Growth strategy

Yourgene Health’s development pipeline				
2016	2017	2018	2019	2020
	IONA S5 validation	IONA Prime / Plus GeneStudio validation	IONA on new platforms	
	IONA inc. FTCT risk	Extended NIPT menu		
	Sage prenatal screen	Sage Link/ Sage 32 plex workflow		
		Reproductive health menu		
			Oncology menu	
			Future menu	

Source: Yourgene Health

These deals will now allow management to focus on the growth opportunities

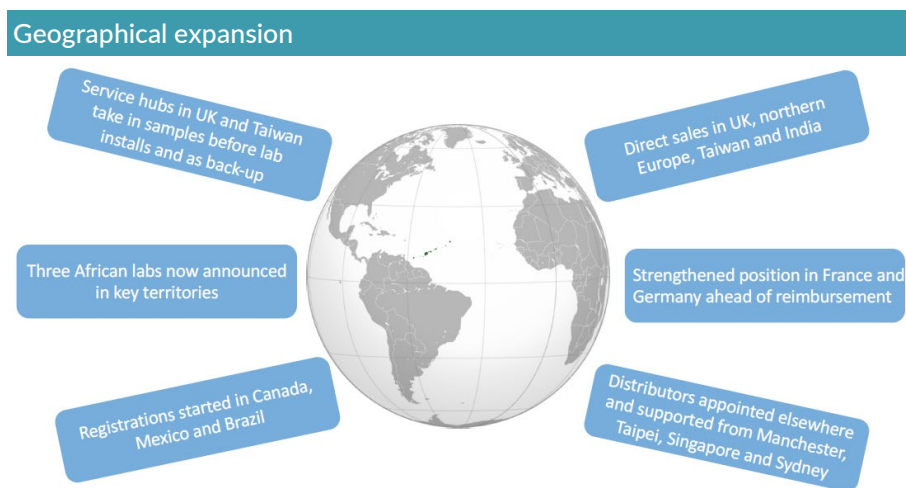
The near-term focus is on expanding the current IONA test and prenatal screening platform (Sage) to improve workflow efficiency. In addition, (and a stated commitment within the Illumina settlement agreement) YGEN will develop the IONA test to run on the Illumina sequencing platform. This will make the IONA test platform-agnostic and open up a considerably larger addressable NIPT market. From Illumina’s perspective, it will be adding a NIPT validated by CE marking for use on its platform, which is available in many clinical laboratories worldwide.

Longer term, YGEN aims to expand its tests/services into other areas of reproductive health and also into oncology.

Geographical expansion

The commercialisation strategy of YGEN is to have partnerships with large clinical laboratories that act as hubs to offer and perform the tests in local geographies. In addition, while such laboratory networks are being established, blood samples can be sent to YGEN’s service centres in either Manchester (UK) or Taiwan.

Since launch, YGEN has established important relationships in the Middle East, Africa and SE Asia, all outside the scope of the Illumina patents. There are a number of geographical opportunities for growth, as illustrated in the following graphic.



Source: Yourgene Health

Conclusion

The announcements with Illumina and TMO have provided a clear forward path for YGEN. The restructured balance sheet is transformational, leaving YGEN debt-free apart from some minor financial leases, and an estimated £1.5m of cash. While the company will still need more capital to fund its operations in fiscal 2020, it will be raised against a background of a fast-growing business, free from legal uncertainty, and with a clean balance sheet, which is likely to be well received by institutional investors. During fiscal 2021, the business is forecast to turn profitable and cash generative.

Given the growth prospects of the business, it would be reasonable to expect YGEN to trade on a prospective EV/sales multiple in the range 5.0x-10.0x for the forecast period. This implies an EV in the range £60m-£100m, even though more capital will be needed to generate the growth forecasts. Comfort should also be garnered from the fact that most of its direct peers have been acquired at very handsome prices by the major players in order to gain access to the novel prenatal testing technologies.

Clear and unhindered path forward...

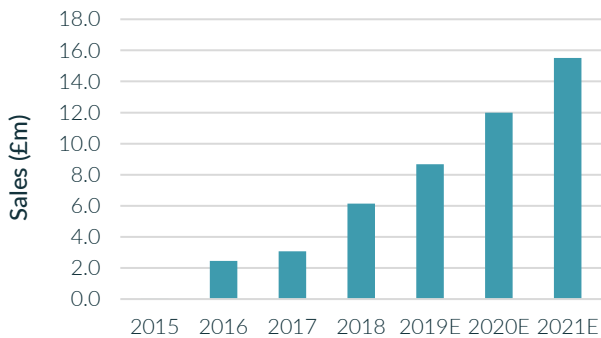
...transformed balance sheet...

...moving fast towards profitability and being cash generative

Compared with global peers, trading on EV/sales of 5.0x-10.0x would not seem unreasonable

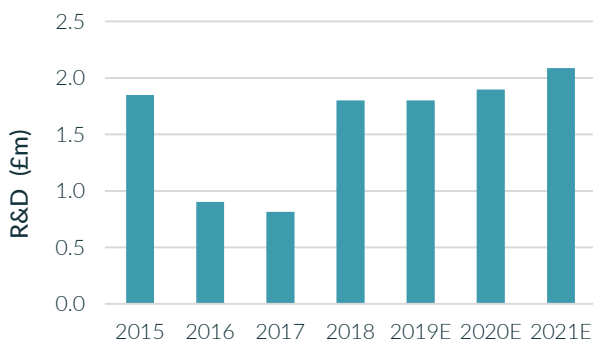
Yourgene Health

Sales



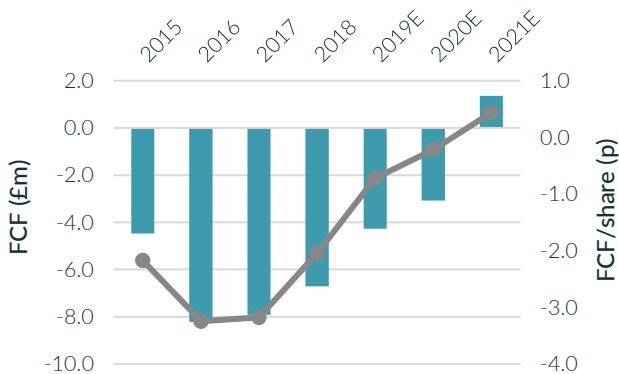
- ▶ Sales are derived from the supply of test kits or a full service for blood samples sent to the company's laboratory for testing
- ▶ Growth will be driven by expanding availability of the prenatal tests into new markets
- ▶ Sales represents the outcome between increasing volumes and price sustainability in different markets
- ▶ The average price per test is an important KPI that can be readily monitored

R&D investment



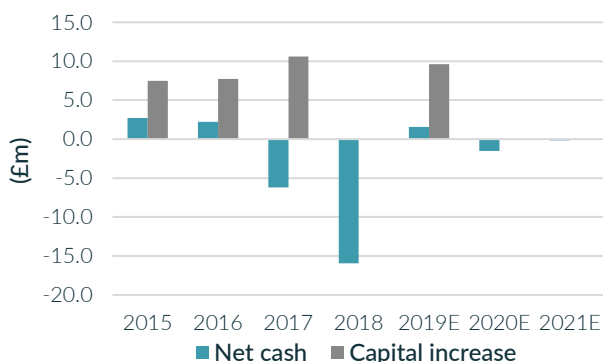
- ▶ An estimated £8m has been invested in R&D to get IONA to where it is today – widely available with CE marking
- ▶ Further development to improve IONA functionality and increase YGEN's offering will continue in future
- ▶ As part of the patent settlement, YGEN will need to invest to make IONA available on the Illumina NGS platform
- ▶ Longer-term, YGEN intends to develop liquid biopsies for early detection of cancer

Cashflow



- ▶ Excluding the litigation costs, the average monthly cash burn has been £435k over the last five years – for fiscal 2020 it is forecast to fall to £185k
- ▶ Cashflow over the next 18 months will be impacted by the necessary capex on Illumina sequencing equipment as part of the patent settlement
- ▶ Profitability and cashflows are quite sensitive to small changes in sales forecasts
- ▶ YGEN is forecast to turn cashflow-positive in fiscal 2021

Balance sheet



- ▶ Following the debt/warrant restructuring, YGEN is forecast to end fiscal 2019 with net cash of ca.£1.5m
- ▶ To provide a comfortable base and allow for contingencies in the run-up to cashflow-breakeven, our forecasts suggest that YGEN needs to raise £5.0m of new capital for fiscal 2020 and 2021

Source: Company data; Hardman & Co Life Sciences Research

Illumina settlement

Background

IONA was the first NIPT to receive validation through CE marking in 2015

YGEN launched its IONA test in the UK following receipt of CE marking in February 2015. In March 2015, Illumina Inc and its wholly-owned subsidiary, Verinata Health Inc, filed a patent suit in the UK asserting that its assigned patents EP0994963 (Non-invasive prenatal diagnosis, ISIS Innovation Ltd) and EP1981995 (Non-invasive digital fetal genetic screening by digital analysis, Stanford University) had been infringed. Based upon legal opinion, patent infringement was vigorously denied by YGEN, and the company decided to defend itself in the courts.

Judgement in the patent infringement case went against YGEN, and the whole experience was a time-consuming and costly distraction that damaged the share price

Following some pre-trial hearings, this complex patent infringement case was heard in the High Court in July 2017. Unexpectedly, in November 2017, the judgement was made in favour of Illumina, although YGEN was granted a right to appeal. For a small company like YGEN, this whole experience turned out to be an extremely time-consuming and expensive distraction, which has been reflected in the performance of its shares. Therefore, even though management and its legal advisors believed that YGEN had a strong case, in September 2018, the decision was made to settle out of court.

An out-of-court settlement with Illumina was considered by the Board to be the best option...

The agreement

...and allows the company to move forward

- ▶ Under the terms of the legal settlement with Illumina, YGEN has taken out a licence on the patent pool for NIPT in territories where Illumina holds relevant granted patents, which includes, amongst others, countries of the European Patent Convention.
- ▶ The IONA test will be developed further to run on Illumina sequencing equipment. YGEN has committed to submitting documentation to a notified body for obtaining CE-IVD certification in Europe for the Illumina-compatible IONA test within nine months of signing the agreement, with a view to launching the product in 2020.
- ▶ In countries where the IONA test is already available, and covered by the agreement, YGEN will assist customers with the migration from TMO sequencing equipment to Illumina sequencing equipment.
- ▶ Once launched, Premaitha will pay Illumina a royalty per sample tested using the IONA test based on Illumina sequencing technology.

Financial impact

YGEN to make a series of payments up to £1m...

...plus investing in developing IONA for use on the Illumina NGS platform

- ▶ With respect to the UK litigation, YGEN will make a series of payments to Illumina in a full and final settlement, which the directors have estimated to be a maximum of £1m.
- ▶ YGEN will need to invest in Illumina sequencing equipment in order to establish a service laboratory in Manchester (UK) in which it will develop the new version of the IONA test. Hardman & Co estimates the cost of this at ca.\$1m/£0.75m.
- ▶ In situations where YGEN has a close working relationship with existing clinical laboratories in territories covered by the patent licence, YGEN will need to subsidise the cost of purchasing Illumina sequencing equipment for them to run the new IONA test. Hardman & Co estimates the cost of this at ca.\$2m/£1.5m.
- ▶ The total cost of defending itself against the patent infringement challenge will, therefore, be ca.£10m, plus upcoming capital expenditure of ca.£2.25m. In addition, YGEN will be paying ongoing royalties on IONA tests performed on Illumina sequencing equipment, which might be significant based on the \$75 that Illumina wanted to charge Great Ormond Street Hospital in 2017.

Revised Thermo Fisher relationship

Financial support from TMO had resulted in long-term liabilities of ca.£16.5m...

...which stretched the balance sheet and put off potential investors

As part of the debt structure, TMO had accumulated 95.7m warrants at an average exercise price of 13.4p

As a direct consequence of the uncertainty caused by the patent litigation with Illumina, raising working capital for the growth in its operations has been extremely difficult for YGEN. Therefore, in order to fund working capital and provide the funds needed to support its legal defence, management agreed a loan facility with TMO, the supplier of sequencing equipment for the original IONA test. Management had always stated its intention to review the funding structure with TMO once the Illumina patent case had been resolved. The announcement that YGEN and TMO have restructured their financial and commercial relationship, eliminating all the loans and accrued interest due to TMO, is transformational for YGEN's balance sheet. In addition, a new commercial arrangement provides TMO with a three-year exclusivity period for YGEN's NIPT products.

TMO loans and warrants

Over the last three years, YGEN has made three separate loan agreements with TMO. These, together with accrued interest at 6%, had reached an estimated £16.5m debt to TMO at 31 January 2019, accounted for as long-term liabilities and warrant reserve, resulting in a particularly stretched balance sheet. This debt was due for repayment in 2023. Each time the loan facility was drawn down, an issue of warrants was triggered, which is summarised below. Prior to the announcement, TMO had 95.7m warrants at an average exercise price of 13.4p.

Summary of Thermo Fisher loans and warrants			
Warrants	Number	Price	Value
11 December 2015	20,325,204	24.6p	£5.00m
22 September 2016	17,094,018	11.7p	£2.00m
31 March 2017	16,913,319	11.825p	£2.00m
12 July 2017	28,938,797	10.625p	£3.07m
12 February 2018	12,417,368	5.775p	£0.72m
@31 December 2018	95,688,706	13.37p	£12.79m
12 February 2019	-41,356,165	9.2p	-£3.80m
Balance	54,332,541	16.6p	£9.00m

Source: Company reports, Hardman & Co Life Sciences Research

Revised agreement

Repayment/cancellation of debt

TMO has exercised 43% of its warrants, raising £3.8m to be used to reduce the debt...

...plus all the remaining debt and accrued interest has been written off...

...and the remaining warrants could raise a further £9m in the future

The announcement that YGEN and TMO have agreed to restructure these loans is very important for YGEN. Effectively, TMO has exercised ca.43% of its warrants at 9.2p, raising £3.8m of new capital for the company, which has been used concomitantly by YGEN to repay/cancel all the debt and accrued interest. This has completely changed the shape of YGEN's balance sheet and brought TMO onto the share register as a major shareholder, with 9.0% of the enlarged share capital.

As part of the revised agreement, TMO will retain the balance (54.3m) of its warrants, at the adjusted weighted average exercise price of 16.6p per warrant, which could generate £9m of additional capital for YGEN in the future, and increase TMO's shareholding in YGEN to 17.0% on a fully-diluted basis.

New commercial arrangement

As part of the agreement to restructure the debt, YGEN has entered into a new commercial deal whereby TMO has been granted a three-year period of exclusivity for YGEN's NIPT products in certain international markets not covered by the Illumina patent deal.

- ▶ TMO will have commercial exclusivity in certain international markets, notably SE Asia.
- ▶ Once YGEN is cashflow-positive, the company will pay royalties to TMO on sales made in these markets until a cap threshold is reached.
- ▶ These royalty payments will be offset against any gains made by TMO on its shareholding and warrant positions.
- ▶ There is an additional £6.5m contingent liability, which would crystallise if the company is sold or enters into insolvency. This can also be eroded by share price gains.

YGEN will still need more capital for fiscal 2020...

...but this will be against a transformed balance sheet and strong operating position

Need for more capital

Following this announcement, YGEN will have no debt on its balance sheet, apart from some minor financial leases, and an estimated £1.5m of cash. While the company will still need more capital to fund its operations in fiscal 2020, it will be raised against a background of a fast-growing business, free from legal uncertainty, and with a clean balance sheet, which is likely to be well supported by institutional investors. During fiscal 2021, the business is forecast to become profitable and turn cash-generative.

Operational update

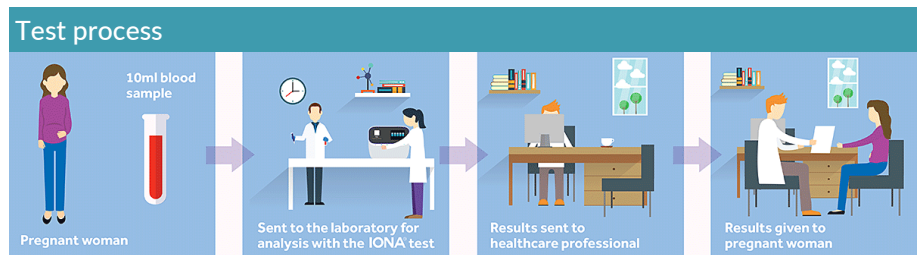
Non-invasive prenatal testing (NIPT)

IONA®

The IONA test estimates the risk that a pregnant woman is carrying a fetus with a genetic abnormality. The test is performed on a sample of maternal blood extracted after around 10 weeks of gestation and results are available in 3-5 days.



Source: Yourgene Health



Source: Yourgene Health

IONA estimates the risk that a pregnant woman is carrying a fetus with a genetic abnormality...

...it is extremely accurate, with negligible false positives

When developed on the Illumina platform, the test will be more widely available and would be platform-agnostic

The test estimates the risk of a fetus carrying an extra chromosome. Usually, cells contain 46 chromosomes – a child inherits 23 from each parent. In some circumstances, all or some of the cells in the fetus contain 47 chromosomes. Trisomies occur when three copies of a chromosome are present, instead of the normal two, which occurs in Down's syndrome (Trisomy 21) and, more rarely, in Edwards' syndrome (Trisomy 18) and Patau's syndrome (Trisomy 13). Published independent trials indicate that the test is >99% accurate, with negligible (or zero) false positives.

The test has been developed and validated on sequencing equipment supplied by Thermo Fisher Scientific and has CE marking. As part of the previously mentioned legal settlement between YGEN and Illumina, the test will now be developed and validated on sequencing equipment supplied by Illumina, so that it can be sold and performed in countries covered by Illumina's NIPT patents.

Sage™ prenatal screen

One of the benefits derived from the acquisition of Yourgene Biosciences in 2017 was the broader menu of NIPT test features, as well as non-NIPT content such as pre-implantation genetic screening (PGS) and oncology (liquid biopsies). Marketed under the Sage trademark, the prenatal screen differs from the IONA test by offering a service for a wider range of clinical conditions, while still offering trisomy 21, trisomy 18 and trisomy 13, and sex chromosome aneuploidies. 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 32 plex is designed to improve test efficiency for clinical laboratories

In January 2019, YGEN officially launched the Sage 32 plex test, a new high-throughput NIPT and analysis solution for clinical laboratories. Sage 32 plex uses the latest technology to improve efficiency over the basic Sage screen, enabling up to 32 samples to be processed in one sequencing run, compared with just 12 samples previously. This updated screen will provide laboratories with enhanced flexibility, scalability and cost-effectiveness. Sage 32 plex uses a combination of workflow improvements and upgraded analysis methodology to obtain this improved performance. The screen is being run on Thermo Fisher's Ion Torrent sequencing technology and will be available internationally.

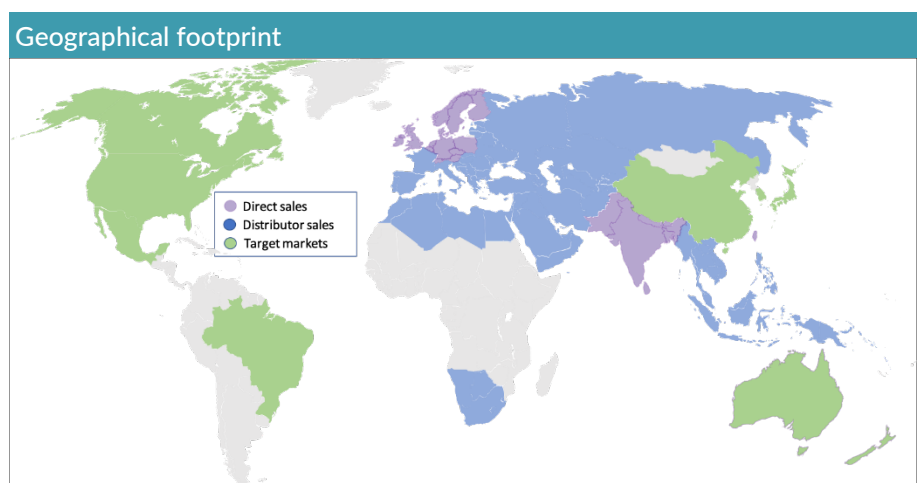
Comparison of products		
Feature	The IONA® test (CE-IVD)	Sage™ prenatal screen
Clinical content:		
• Trisomy 21, 18, 13	✓	✓
• Sex chromosomal aneuploidies		✓
• Autosomal aneuploidies		✓
• Microdeletions		✓
• Fetal sex determination – optional	✓	✓
CE-IVD	✓	
Fully automated workflow with workflow manager	✓	
NIPT service available from Yourgene Laboratory Services (Manchester and Taipei)	✓	✓
MyNIPT® sample tracking and reporting portal	✓	
Suitable for low to high throughput laboratories	✓	
Minimum fetal fraction required	≥ 2%	≥ 3.5%
Technical support and lab installation	✓✓✓	✓

Source: Yourgene Health

Geographical footprint

Despite the patent issues, the IONA geographical footprint has continued to expand

While the initial focus of YGEN was to make NIPT, through IONA, more readily available in the relatively under-developed markets of Europe, management always recognised the potential for NIPT in Asia. The acquisition of Yourgene Biosciences accelerated YGEN’s long-term goals in Asia, providing a number of existing relationships in several countries and delivering an important springboard into China and India. These two markets represent an enormous growth opportunity that is best served by a test approved through the Chinese regulators (CFDA). To foster this opportunity at a faster rate, the company appointed Keng Hsu as COO (Asia).



Source: Yourgene Health

- ▶ **Service hubs:** In the UK (Manchester) and in Taiwan to perform tests and support new laboratories (territories) while sequencing equipment is being installed and validated.
- ▶ **Europe:** Tests mostly being performed by large laboratories, currently on TMO platform, but will change to Illumina platform in the future when test is ready,

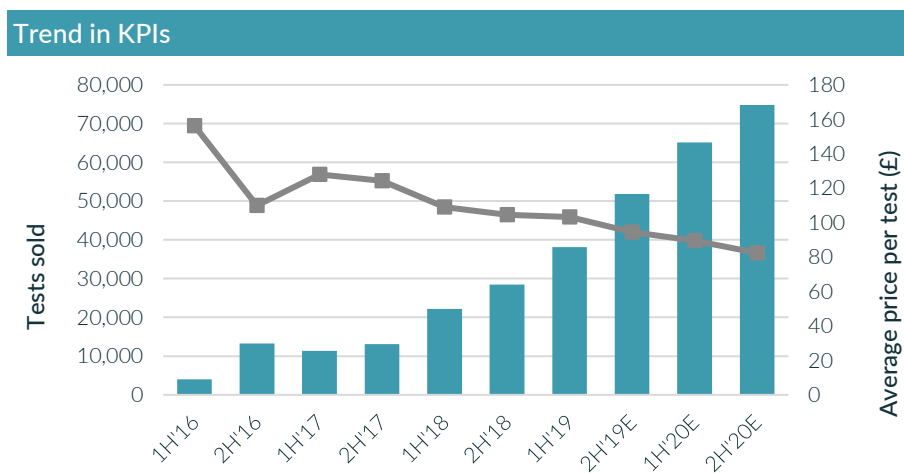
validated and has CE marking. Reimbursement for NIPT is expected in Germany and France during 2019.

- ▶ **SE Asia:** Direct selling with sequencing results sent to Taiwan service hub for analysis.
- ▶ **India:** Established as a leading provider of NIPT, with representation in 10 of the 15 most populous states and several of the largest nationwide pathology laboratory groups. Currently, there are seven laboratories with installed NIPT solutions, which have an extensive network of hospitals feeding samples into them.
- ▶ **China:** The company is wisely approaching the Chinese market carefully and continues to evaluate its options for this important market.
- ▶ **Middle East:** This represents a substantial opportunity for YGEN, given that the region readily adopts new technologies in the medical device/diagnostic field. Currently, three active laboratories are processing samples sent from all countries in the region, with the potential to generate 10,000 samples p.a.
- ▶ **Africa:** Laboratories in three key countries – South Africa, Kenya and Egypt.
- ▶ **RoW:** The registration process is underway in Canada, Brazil and Mexico, and the Illumina settlement also opens up Australia, New Zealand and Japan.

Trend in KPIs

Volume of tests versus average price of the tests provides a simple assessment of performance

A simple model has been established that only requires knowledge of the number of tests performed/sold on a half-yearly basis, in order to assess performance. This provides KPIs in the form of growth in the number of tests and the average price obtained per test, as shown in the following chart.



Source: Yourgene Health, Hardman & Co Life Sciences Research

The average price per test is expected to trend modestly downwards, due to expansion in the offering, and making a cheaper test available for some markets, e.g. India

On historical data, from the number of tests being sold/used, coupled with the sales data, the average price achieved per test can be calculated. This, in turn, can then be used to generate a future sales forecast. Although there is a modest downward trend in the average sales per test, there are a number of reasons for this:

- ▶ The average price per test achieved by Yourgene Biosciences was less than the price achieved for IONA.
- ▶ India represents a high volume market, but at lower pricing levels, thereby reducing the group average price per test.
- ▶ Mimicking what has happened in the US market for NIPT, where test prices received by the manufacturer halved between 2014 and 2018.

Commercial opportunity

Global market opportunity

The UN estimates that there are ca.130 million live births p.a. globally

There is an overwhelming quantity of statistics available on birth rates around the world, which, ultimately, equates to the target market. Given that the United Nations states that there were 130.0 million live births globally in 2016, the market opportunity is enormous. Statistics for the key markets where NIPT is available are shown in the following table. However, the focus should be on the number of births to mothers over 35 years of age, where the risk of abnormality is much higher.

Live birth statistics – 2016					
(m)	World	India	China	Europe	US
Live births	130.0	25.5	17.9	5.1	3.9
Mother >35 years	-	-	-	1.4	0.6

Source: United Nations, Statistica, Eurostat, CDC

High-risk women

In the developed world, around 20% of live births are to 'high-risk' women aged 35 years and above

Using the statistic that about 20% of live births in countries offering prenatal care are in high risk women over 35 years of age, the potential opportunity in countries where NIPT is available is 15.6 million tests p.a. At an average price of \$350, this gives a global market opportunity of \$5.5bn. Tracking the number of tests being performed annually has become more difficult since the smaller NIPT providers were taken over by the large diagnostic players. However, based on information publicly available, Hardman & Co estimates that the number of NIPT tests performed in 2018 was 1.2 million, suggesting that the market has only been penetrated ca.7%-8%.

US

Although YGEN is not pursuing the US market, given that it is the most mature for NIPT, it is interesting to see how the opportunity has developed. There are routinely around four million live births in the US each year with 0.6 million of these to high-risk women over the age of 35. NIPT was first launched in the US in late 2011 by Sequenom as a Laboratory Developed Test (LDT), and it remains the case today that no test has been formally approved by the FDA for the US market. In our opinion, the US represents the lion's share (ca.75%) of the global market for tests performed. However, since launch the price achieved per test has more than halved to ca.\$350.

Europe

Given its larger number of births, the European market is potentially twice as large as the US market. Despite this, the use of NIPT is still in its infancy in Europe. As the IONA test will be available on both the major sequencing platforms in the future, and as more countries, notably Germany and France, set reimbursement levels, so the level of market penetration should increase.

SE Asia

YGEN's strong presence in Taiwan positions it very well to open up important markets in SE Asia, notably China and India

Given YGEN's presence in Taiwan and existing relationships in SE Asia, it is well positioned to benefit from the opportunities that exist in these territories, notably China and India. Both these markets have attractive birth statistics. Government strategy in China is to decentralise the provision of healthcare, from which YGEN would benefit, with its provision of localised technical support and by having linguistic capability in this area. Precisely how this market is to be addressed is still to be ascertained but, among various options, it might be through some form of joint venture with a Chinese partner. The aim will also be to offer a test that has been approved by the CFDA. Meanwhile, YGEN has become an established provider of NIPT in India, for which it is developing a slightly lower cost option.

Financials and investment case

Profit & Loss

- ▶ **Sales:** Sales are based on the number of tests performed and an estimate of the average price achieved per test. Fiscal 2019 forecasts are based on a 75% increase in the number of tests sold/performed at a modestly reduced average price.
- ▶ **COGS:** Increasing volumes are expected to result in lower GOGS, hence improving gross margins.
- ▶ **SG&A:** Management is expected to keep tight control of sales and marketing and the corporate overhead, such that this should remain fairly flat during the forecast period.
- ▶ **Exceptional items:** As a direct consequence of the revised financial agreement with TMO, the excess loans and accrued interest, totalling £9.3m, are being written back through the P&L in fiscal 2019.

Profit & Loss						
Year-end March (£m)	2016	2017	2018	2019E	2020E	2021E
Test sales	2.08	3.08	5.40	8.68	12.00	15.50
Research income	0.00	0.00	0.75	0.00	0.00	0.00
Pass-through sales	0.37	0.00	0.00	0.00	0.00	0.00
Total sales	2.45	3.08	6.15	8.68	12.00	15.50
COGS (Test)	-1.38	-1.80	-2.97	-4.03	-5.21	-6.42
% sales	66.3%	58.3%	48.4%	46.4%	43.4%	41.4%
Reported COGS	-1.75	-1.80	-2.97	-4.03	-5.21	-6.42
SG&A	-5.67	-6.26	-7.17	-7.09	-7.02	-7.02
% sales	nm	nm	nm	81.7%	58.5%	45.3%
R&D	-0.90	-0.82	-1.80	-1.80	-1.90	-2.05
% sales	43.4%	26.5%	29.3%	20.7%	15.8%	13.2%
EBITDA	-5.32	-5.07	-4.72	-3.06	-0.64	1.54
Depreciation	-0.56	-0.72	-1.05	-1.18	-1.48	-1.53
Amortisation	0.00	-0.01	-0.16	-0.16	-0.16	-0.16
Other income	0.00	0.00	0.03	0.00	0.00	0.00
Underlying EBIT	-5.87	-5.80	-5.76	-4.24	-2.13	0.02
EBIT margin	nm	nm	nm	-48.9%	-17.7%	0.1%
Share-based costs	-0.12	-0.33	-0.14	-0.25	-0.25	-0.25
Exceptional items	-5.83	-1.47	-2.69	9.30	0.00	0.00
Statutory EBIT	-11.83	-7.60	-8.60	4.81	-2.38	-0.23
Net interest	-0.08	-0.25	-0.58	-0.45	0.00	-0.03
Net financials	-0.08	-0.25	-0.94	-0.65	0.00	-0.03
Underlying pre-tax profit	-5.96	-6.04	-6.35	-4.69	-2.12	-0.01
Extraordinary items	-0.20	0.00	0.00	0.00	0.00	0.00
Statutory pre-tax profit	-12.12	-7.85	-9.54	4.16	-2.37	-0.26
Tax payable/credit	0.04	-0.01	0.06	0.05	0.04	0.00
Underlying net income	-5.92	-6.05	-6.29	-4.65	-2.08	-0.01
Statutory net income	-12.13	-7.88	-9.60	4.21	-2.33	-0.26
Ordinary 0.1p shares:						
Period-end (m)	228.16	321.22	321.22	492.33	492.33	492.33
Weighted average (m)	218.11	236.28	321.22	470.94	492.33	492.33
Fully-diluted (m)	277.10	326.83	452.43	562.38	583.77	583.77
Underlying basic EPS (p)	-2.71	-2.56	-1.96	-0.99	-0.42	0.00
Statutory basic EPS (p)	-5.56	-3.34	-2.99	0.89	-0.47	-0.05
U/I fully-diluted EPS (p)	-2.14	-1.85	-1.39	-0.83	-0.36	0.00
Stat. fully-diluted EPS (p)	-4.38	-2.41	-2.12	0.75	-0.40	-0.04
DPS (p)	0.00	0.00	0.00	0.00	0.00	0.00

Source: Hardman & Co Life Sciences Research

Balance sheet

The new financial and commercial agreement with TMO has resulted in a number of changes directly to the balance sheet.

- ▶ **Capital increase:** Exercise of the tranche of TMO warrants has resulted in a £3.8m rise in the capital increases for fiscal 2019 from £6.0m to £9.8m.
- ▶ **Warrant reserve:** This represented the accrued interest on the TMO loans, which has been written-off along with the excess of loans over the £3.8m generated through the exercise of the warrants.
- ▶ **Loans:** The outstanding TMO loan capital, together with the warrant reserve (accrued interest), has all been paid back or written-off. The only debt remaining on the balance sheet represents some modest financial leases.
- ▶ **Cash:** At the period-end, YGEN is forecast to have only a modest amount of cash (ca.£1.5m). Further capital will be required for fiscal 2020, but this can now be raised against the backdrop of a freedom-to-operate, strong operating performance, and a transformed balance sheet, which represents a very different proposition.

Balance sheet						
@31 March (£m)	2016	2017	2018	2019E	2020E	2021E
Shareholders' funds	-0.28	2.78	-6.68	15.88	13.55	13.29
Cumulated goodwill	0.00	0.00	0.00	0.00	0.00	0.00
Total equity	-0.28	2.78	-6.68	15.88	13.55	13.29
Share capital	31.17	32.27	32.27	49.23	49.23	49.23
Reserves	-31.46	-29.49	-38.95	-33.35	-35.68	-35.94
Provisions/liabilities	5.55	3.50	0.96	0.46	0.46	0.46
Deferred tax	0.00	0.29	0.26	0.00	0.00	0.00
Long-term loans	3.13	7.38	16.18	0.25	0.25	0.25
Short-term debt	0.00	0.12	0.06	0.06	0.06	0.06
less: Cash	5.34	1.30	0.28	1.86	-1.21	0.57
less: Deposits	0.00	0.00	0.00	0.00	0.00	0.00
less: Non-core invests.	0.00	0.00	0.00	0.00	0.00	0.00
Invested capital	3.06	12.76	10.50	14.79	15.54	13.50
Fixed assets	1.94	2.89	1.92	1.64	2.16	0.93
Intangible assets	0.00	1.54	1.38	1.38	1.38	1.38
Capitalised R&D	0.00	0.00	0.00	0.00	0.00	0.00
Inventories	0.46	0.43	0.28	0.33	0.46	0.59
Trade debtors	0.96	0.90	0.89	0.54	0.75	0.97
Other debtors	0.70	2.39	1.66	1.74	1.83	1.92
Tax liability/credit	1.09	1.10	1.15	1.44	0.38	0.41
Trade creditors	-1.10	-2.32	-2.20	-2.54	-3.28	-4.04
Other creditors	-0.99	-1.17	-1.59	3.24	4.85	4.32
Debtors less creditors	0.66	0.89	-0.09	4.43	4.53	3.58
Invested capital	3.06	12.76	10.50	14.79	15.54	13.50
Net cash/(debt)	2.20	-6.20	-15.96	1.55	-1.52	0.26
Net debt/equity	-7.8%	-2.2%	2.4%	0.1%	-0.1%	0.0%
NAV/share (p)	-0.13	1.17	-2.08	3.37	2.75	2.70
Stock days	81	51	19	14	14	14
Debtor days	85	111	61	30	20	20
Creditor days	183	348	278	215	204	208

Source: Hardman & Co Life Sciences Research

Cashflow

- ▶ **Operational cashflow:** There is a noticeable downward trend in the cash burn from operations, until the company becomes cash-generative in fiscal 2021.
- ▶ **Capex:** The increase in capital expenditure over the forecast period reflects the purchase of sequencing equipment from Illumina to satisfy the terms of the legal settlement with that group.
- ▶ **Capital increases:** YGEN raised £2.9m (net) in April 2018, and a further £2.9m (net) in October 2018 to fund working capital requirements. In addition, the £3.8m raised through the exercise of the TMO warrants is included, even though it was used immediately to repay part of the outstanding loans, and no cash was actually moved between the companies.
- ▶ **'Acquired' cash:** This simply reflects the write down by TMO of the excess loans and accrued interest, and is replicated in the P&L account under exceptional items.

Cashflow						
Year-end March (£m)	2016	2017	2018	2019E	2020E	2021E
Underlying EBIT	-5.87	-5.80	-5.76	-4.24	-2.13	0.02
Depreciation	0.56	0.72	1.05	1.18	1.48	1.60
Amortisation	0.00	0.01	0.16	0.16	0.16	0.16
Inventories	-0.01	0.12	0.15	-0.06	-0.13	-0.13
Receivables	-1.37	0.18	0.08	0.35	-0.21	-0.22
Payables	1.01	0.45	0.30	0.33	0.74	0.76
Change in working capital	-0.38	0.75	0.53	0.62	0.41	0.41
Exceptionals/provisions	0.04	-2.05	-2.53	-1.00	-1.00	0.00
Disposals	0.00	0.01	0.00	0.00	0.00	0.00
Other	-1.44	-1.16	0.00	0.00	0.00	0.00
Company op. cashflow	-7.10	-7.52	-6.56	-3.28	-1.08	2.18
Net interest	0.01	0.01	-0.02	-0.10	0.00	-0.03
Tax paid/received	0.00	-0.01	0.03	0.00	0.00	0.00
Operational cashflow	-7.08	-7.51	-6.55	-3.38	-1.08	2.16
Capital expenditure	-1.15	-0.41	-0.16	-0.90	-2.00	-0.80
Sale of fixed assets	0.00	0.00	0.00	0.00	0.00	0.00
Free cashflow	-8.23	-7.92	-6.72	-4.28	-3.08	1.36
Dividends	0.00	0.00	0.00	0.00	0.00	0.00
Acquisitions	0.00	-9.54	0.00	0.00	0.00	0.00
Disposals	0.00	0.00	0.00	0.00	0.00	0.00
Other investments	0.00	-2.36	0.00	0.00	0.00	0.00
Cashflow after investments	-8.23	-19.82	-6.72	-4.28	-3.08	1.36
Share repurchases	0.00	0.00	0.00	0.00	0.00	0.00
Share issues	7.72	10.61	0.00	9.64	0.00	0.00
Currency effect	0.00	0.00	0.00	0.00	0.00	0.00
Acquired cash/(debt)	0.00	0.80	-3.04	12.72	0.00	0.00
Change in net cash/(debt)	-0.51	-8.40	-9.76	18.08	-3.08	1.36
Hardman& Co FCF/share (p)	-3.25	-3.18	-2.04	-0.72	-0.22	0.44
Opening net cash	2.71	2.20	-6.20	-15.96	1.55	-1.52
Closing net cash	2.20	-6.20	-15.96	1.55	-1.52	-0.17

Source: Hardman & Co Life Sciences Research

Valuation

Comparative valuation

YGEN is trading on an EV of ca.£60m, compared with a total investment of ca.£42m to get the company where it is today. Whether this is a true reflection of valuation is difficult to say. First, there are now only two other quoted companies that specialise in molecular diagnostic NIPT products, both of which are considerably more mature companies and with much larger sales, derived from the large, but competitive US market. In contrast, YGEN will derive the vast majority of its sales from developing regions, particularly SE Asia, and from the less developed markets of Europe, under the agreement from Illumina.

Comparative valuation			
Company Ticker	Invitae NTVA	Natera NTRA	Yourgene YGEN
Currency	\$	\$	£/p
Share price*	16.1	16.6	13.0
Shares (m)	74.6	61.8	459.0
Market cap	1,198.4	1,023.2	59.7
Net cash/(debt) (m)	70.7	42.0	1.5
EV (m)	1,127.7	981.2	58.2
Sales (m)	140	240	12.0
EV/sales	8.1	4.1	4.9

*Prices taken at close of business on 15 February 2019

Source: Hardman & Co Life Sciences Research

M&A activity

An alternative way to determine value looks at the prices that acquirers have been prepared to pay for similar breakthrough technologies and assets. All the major players have secured the latest prenatal testing technology by buying smaller competitors in order to access their products. There are few instances where M&A activity has been used to garner geographical expansion. However, it is again difficult to make a direct comparison with YGEN because the targets have been more advanced and generating sales largely from the US market. However, this does provide readers with a guide about value when NIPT/molecular diagnostic products have gained sales traction.

Recent M&A activity –prenatal testing						
Date	Target	Acquiror	Consideration (\$m)	Cash/(debt) (\$m)	EV	
Feb'13	Verinata Health	Illumina	450	9	441	
Jan'15	Ariosa	Roche	565	14	551	
Jan'17	Multiplicom	Agilent Tech.	62	0	62	
Aug'17	Sequenom	LabCorp	249	-130	379	
Aug'17	Good Start Genetics	Invitae	17	-24	41	
Nov'17	CombiMatrix	Invitae	31	1	30	

Source: Hardman & Co Life Sciences Research

Company matters

Registration

Incorporated in the UK with company registration number: 3971582

Company information

Registered Office

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www.yourgene-health.com

Board of Directors

Board of Directors			
Position	Name	Nominations/ Remuneration	Audit
Chairman	Adam Reynolds	C	M
Chief Executive Officer	Lyn Rees		
Chief Financial Officer	Barry Hextall		
Chief Operating Officer (Asia)	Keng Hsu		
Chief Scientific Officer	Dr Bill Chang		
Group Commercial Director	Hayden Jeffreys		
Vice-Chairman	Dr Stephen Little		
Non-executive director	Nicholas Mustoe	M	C

*M = member; C = chair
Source: Company reports*

Capital increases

Since its IPO in 2014, YGEN has undertaken three additional capital increases to fund its working capital requirements, together with the issue of shares to the vendors of Yourgene Biosciences. In total, the company has raised £42.4m of capital to get the company to where it is today. This excludes the write-down of the excess loans and accrued interest by TMO, just announced.

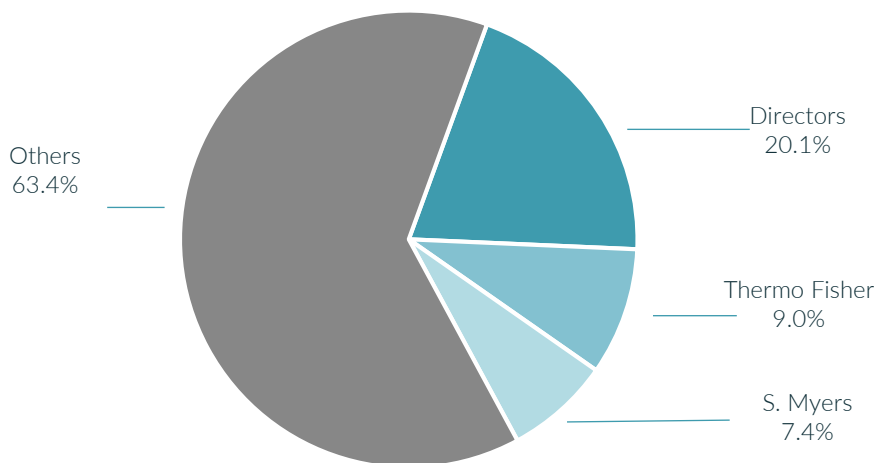
YGEN capital increases						
Date	Shares (m)	Price (p)	Raised £m)	Shares o/s (m)	Valuation (£m)	Comment
Pre-IPO				26.89		
Jly-14	95.45	11.0	10.5	122.35	13.5	Consideration shares for reverse take-over
Jly-14	65.81	11.0	7.24	188.16	20.7	Placing & Open offer
Jly-15	40.00	20.0	8.00	228.16	45.6	Placing
Jan-17	76.05	9.0	6.84	321.22	28.91	Acquisition of Yourgene Bioscience
May-18	65.63	4.5	2.95	386.84	17.41	Share issue
Oct-18	30.80	10.0	3.08	417.64	41.76	Placing and subscription
Feb 2019	41.36	9.2	3.80	459.00		Exercise of TMO warrants and repayment or cancellation of all debt and accrued interest
Total			42.42	459.00	59.7	

Source: Company reports, Hardman & Co Life Sciences Research

Share capital

The company presently has 459.00m shares in issue. In addition, there are 34.11m options outstanding. TMO still retains 54.33m warrants @16.6p which, on exercise, would increase TMO's shareholding to 17.0% (fully-diluted basis) and raise a further £9.0m of new capital for YGN.

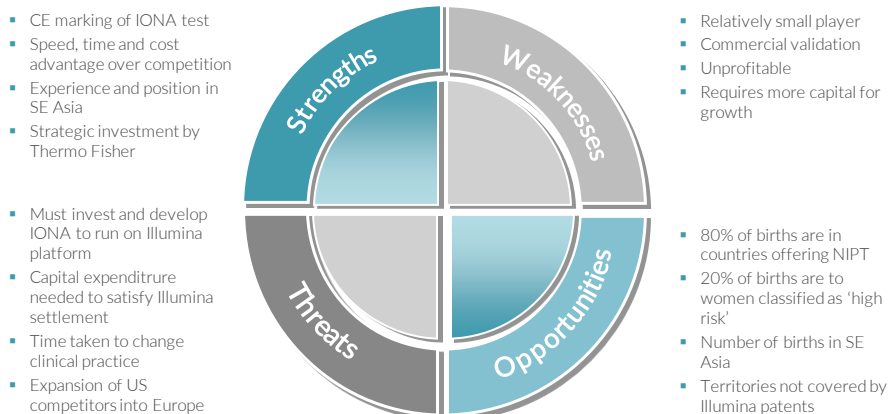
Shareholders



Source: Hardman & Co Life Sciences Research

SWOT analysis

SWOT analysis



Source: Hardman & Co Life Sciences Research

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