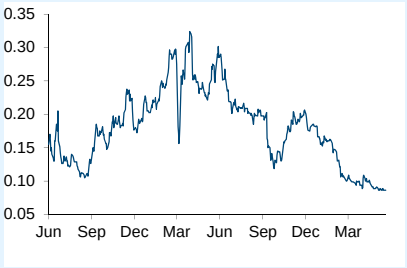
Premaitha Health

2 June 2016

Ticker	NIPT
Price	8.6p
Target Price	20.0p
Upside	132.0%
Market Cap	£19.7m
Index	FTSE All Small
Sector	Pharmaceuticals & Biotechnology
Net Cash	£1.9m
Shares in Issue	228.2m
Next Results	Prelims - July

What's changed	**From**	**To**
Adj. EPS (FD)		-2.0p
Recommendation		Corp
Target Price		20.0p

Share Price Performance



Source: Thomson Reuters

%	1M	3M	12M
Actual	-12.7	-28.9	-62.1
Relative	-11.2	-32.6	-57.7

Company Description
Molecular diagnostics company with an approved non-invasive screening test (IONA) to test fetuses for Down's syndrome and other genetic conditions.

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Right time, right business model

CORP

Initiation of coverage

Premaitha is a molecular diagnostics company that has developed and launched a non-invasive prenatal test (NIPT), targeted initially at ex-US markets; the company is primarily products-based, addressing the needs of its laboratory customers. Differentiated from other NIPTs by a faster turnaround time, a reduced need to re-run tests (failure rate), the fact that the test is CE marked and that it matches the specifications of National screening programmes, Premaitha is well placed to capitalise on an addressable market worth $7.5-20.0bn. First-year revenues of c£2.5m are indicative of early traction in a European market that is underpenetrated compared with the US (c1.4% vs 25%). We initiate coverage with a target price of 20p.

- **Addressable prenatal screening market is worth in excess of $7.5bn.** There are 82m births per annum in countries offering NIPT, a market still very much in its infancy, with the first NIPTs having been introduced in 2011.
- **IONA test**. A screening test for chromosomal abnormalities such as Down's syndrome, marketed as having >99% accuracy and a low false positive rate (<1%); similar to other NIPT results but differentiated by fast time to a result, a much lower failure/repeat rate and the fact that it is a CE marked test.
- **Business model** is differentiated from other NIPT providers, in that it is principally a product-based based business that is readily scalable and addresses the trend for independent laboratories to set up their own NIPT capabilities with a cost-effective solution and a readily visible payback.
- **First-year sales of c£2.5m**. Full-year trading update indicated first-year revenues of £2.5m, 75% of which fell in H2 FY 2016, from principally four customers. With six customers coming on stream in Q1 FY 2017, we see another step up in revenues to £6.7m for FY 2017.
- **Risks.** The key uncertainty is the litigation overhang which is unlikely to be resolved until Q3 2017, but mitigated by the fact that ThermoFisher (a $58bn US life sciences company) invested £5m into the company with this knowledge.
- **Valuation.** There is no directly comparable peer group in the UK. We initiate coverage with a 20p share price target, which implies a calendarised 2017 EV/Sales multiple of 4.2x. This is underpinned by a DCF valuation of 38p.

Year ending March (£m)	2014A	2015A	2016E
Data			
Sales (£m)	0.0	0.0	2.5
Adj EBITDA (£m)	-1.4	-4.1	-4.8
Adj PBT (£m)	-1.5	-4.2	-5.4
Tax rate (%)	nm	0	0
Adj EPS (FD) (p)	-4.1	-2.3	-2.0
DPS (p)	0.0	0.0	0.0
Ratios			
EV/Sales (x)	n/a	n/a	7.3
EV/EBITDA (x)	n/a	n/a	n/a
P/E (x)	n/a	n/a	n/a
Yield (%)	0.0	0.0	0.0
Cash flow yield (%)	-10.1	-31.0	-43.3
EPS growth (%)	n/a	43.5	12.5

Key Financials

Income Statement

Year ending March (£m)	2014A	2015A	2016E
Sales	**0.0**	**0.0**	**2.5**
Gross profit	**0.0**	**0.0**	**0.9**
Operating expenses	-1.4	-4.1	-5.7
Adjusted EBITDA	**-1.4**	**-4.1**	**-4.8**
Depreciation/Amortisation	-0.1	-0.3	-0.6
Adjusted EBIT	**-1.5**	**-4.3**	**-5.4**
Associates/Other	0.0	0.0	0.0
Net interest	0.0	0.1	0.0
Adjusted PBT	**-1.5**	**-4.2**	**-5.4**
Adjustments	0.0	-3.2	-2.6
Reported PBT	**-1.5**	**-7.4**	**-8.0**
Taxation	0.0	0.0	0.0
Tax rate (%)	*nm*	*0*	*0*
Reported earnings	-1.6	-7.4	-8.0
Average no.shares (FD)	38.0	182.4	263.7
Adj. EPS (FD) (p)	**-4.1**	**-2.3**	**-2.0**
DPS (p)	**0.0**	**0.0**	**0.0**

Cash Flow

Year ending March (£m)	2014A	2015A	2016E
EBITDA	**-1.4**	**-4.1**	**-4.8**
Net change in working capital	0.2	0.2	-1.2
Other items	-0.3	-1.4	-0.9
Operating cash flow	**-1.5**	**-5.3**	**-6.9**
Cash interest	0.0	0.1	0.0
Tax paid	0.0	0.3	0.0
Capex	-0.5	-1.2	-1.7
Free cash flow	**-2.0**	**-6.1**	**-8.5**
Disposals	0.0	0.0	0.0
Acquisitions	0.0	1.2	0.0
Dividends	0.0	0.0	0.0
Other	2.0	0.5	3.5
Issue of share capital/(Buyback)	0.0	7.1	7.7
Net Change in cash flow	**0.0**	**2.7**	**2.7**
Opening net (debt)/cash	0.0	0.0	2.7
Closing net (debt)/cash	**0.0**	**2.7**	**5.4**

Balance Sheet

Year ending March (£m)	2014A	2015A	2016E
Tangible assets	0.4	1.3	2.4
Goodwill	0.0	0.0	0.0
Other intangible	0.0	0.0	0.0
Other	0.0	0.0	0.0
Non current assets	**0.4**	**1.3**	**2.4**
Inventories	0.0	0.5	0.8
Trade receivables	0.2	0.3	0.7
Cash	0.0	2.7	5.4
Other	0.3	0.8	1.2
Current assets	**0.5**	**4.3**	**8.1**
Trade payables	-0.4	-1.1	-1.2
Other current liabilities	0.0	0.0	0.0
Short term debt	-0.5	0.0	0.0
Net current assets	**-0.5**	**3.2**	**6.9**
Long term debt	-1.5	0.0	-3.5
Pension	0.0	0.0	0.0
Other/Minorities	0.0	-0.2	-1.7
Net assets	**-1.6**	**4.4**	**4.1**
Net working capital	*-0.2*	*-0.3*	*0.3*
NAV per share (p)	*-4.1*	*2.4*	*1.8*
NTA per share (p)	*-4.1*	*2.4*	*1.8*

Ratio Analysis

Year ending March	2014A	2015A	2016E
Growth			
Revenue growth (%)	n/a	n/a	n/a
EBITDA growth (%)	n/a	182.9	16.6
EPS growth (%)	n/a	43.5	12.5
DPS growth (%)	n/a	n/a	n/a
Returns			
Gross margin (%)	n/a	n/a	38.0
EBITDA margin (%)	n/a	n/a	n/a
EBIT margin (%)	n/a	n/a	n/a
RoE (%)	100.5	n/a	n/a
RoCE (%)	8,553.1	n/a	n/a
Liquidity			
Net debt/equity (%)	3.2	n/a	n/a
Net debt/EBITDA (x)	0.0	0.7	1.1
Interest cover (x)	nm	nm	nm
Net working capital to sales (%)	n/a	n/a	11.9
Cash conversion (%)	138.2	149.8	179.5
Dividend cover (x)	n/a	n/a	n/a

Investment summary

Introduction

Molecular diagnostics company focused on non-invasive prenatal testing (NIPT)

Premaitha Health is a UK-based molecular diagnostic company employing next generation sequencing (NGS) technology (in this case, ThermoFisher Scientific's Ion Proton) to develop, produce and market molecular diagnostics products. While the focus is on the roll-out of a non-invasive prenatal test (NIPT), initially in non-US markets, early development work has shown that there is also applicability in identifying tumour DNA through liquid biopsy (blood samples).

History

Formed to commercialise NIPT, via the reverse into a cash shell

Formed in 2013 to acquire the NIPT technology of Zoragen Biotechnologies LLP, Premaitha was listed on AIM in June 2014 through a reversal into a cash shell, ViaLogy. The company raised £7.2m through a Placing & Open Offer to enable it to CE mark the IONA test and prepare for a European launch. Further funds were raised in July via an £8m Placing after demonstrating early commercial traction in the UK, Switzerland and Poland. In December 2015, ThermoFisher Scientific made a strategic investment in the company by way of a £5m loan facility and issue of warrants (20.3m warrants with exercise price of 24.6p per share).

IONA test – a CE-marked NIPT for Down's Syndrome

IONA: CE-marked, accurate, fast and with lower failure/repeat rate – differentiating it from other NIPTs

IONA is a CE-marked genetic screening test, as opposed to a diagnostic, that detects chromosomal abnormalities such as Down's syndrome, and which either replaces the current blood test as part of the combined test or is used as second level screen, contingent on the first level combined test, which has an accuracy of only c85%. It is marketed as having >99% accuracy and a low false positive rate (<1%); similar/same as other NIPTs. What sets IONA apart is the fast time to a result (3 days vs up to 10 days) and a much lower failure rate. Not only is this advantageous from the laboratory's perspective as it minimises the number of samples that have to re-run (potential margin benefit), but the shorter turnaround time benefits the mother. Like all other NIPTs, if the results suggest that the fetus may have Down's syndrome, the mother will be referred for an invasive procedure, such as amniocentesis, for confirmation.

Addressable market

Total addressable market is considered to be 15-30m tests per annum

Globally there are 137m births per annum, of which 82m are in markets which currently offer NIPTs, with 5.1m in Europe, of which c0.7m are in the UK. The primary focus for companies selling NIPT has been directed towards women considered at higher risk of having a chromosomal abnormality and their child developing Down's syndrome (>35 years amongst other factors), and in markets where there are already screening guidelines and reimbursement, or for women who have the financial capability to self-pay. It is a growing segment of the market as women delay having children, with mothers over the age of 35 currently representing 18.8% of all births in Europe and 20.7% in the UK (up from 6% in 1980), implying a total addressable global market of 15.2m tests (c1m in Europe of which 0.14m in UK).

Implying a potential market of $7.5bn (high risk), rising to $20.5bn

This represents an addressable market of some $7.5bn, based on an average price of c$500. As NIPT has become increasingly accepted by National Screening organisations and clinicians, as well as potential mothers, focus will move towards the next 'at risk' group, women of moderate risk aged 30-35 years. This is a global market of some 20.7m births, 1.4m of which are in Europe, and represents a total addressable market of c$10.3bn. Ultimately we expect first

level NIPT screening to become the standard. NIPT will be used as a first level screen in the Netherlands from 2017. We expect some public health systems and many private payers to adopt this approach as opposed to the contingent one.

Competitive position

A competitive market space but Premaitha differentiates itself by way of business model

First NIPTs were introduced in China in 2011 by BGI Diagnostics. Subsequently, Sequenom, Illumina, Ariosa and Natera launched their NIPTs in the US in 2011, 2012, 2012 and 2013, respectively, during which period we estimate that c60-65% of all high-risk women and c.25-30% of all prenatal screens (0.82m tests) now receive an NIPT.

Premaitha differentiates its IONA test by means of its business model, selling a CE-marked product (reagents and software) to laboratories that wish to provide their own, unlike its competitors which operate either service-based or technology transfer (licensing plus methods) models.

Business model

Differentiated….

Premaitha's business model is differentiated from the other major players in the NIPT space, in that it has developed a CE-marked *in vitro* diagnostic product which it sells to other laboratories so that they can perform the test themselves. This compares with the competitors which operate with a service-based model (although Premaitha does offer this too), in which samples are sent back to a centralised laboratory, in this case at its Manchester facility, or a technology transfer (licensing plus methods) model as Illumina/Sequenom have done in respect of the patent pool.

…. and readily scalable

The IONA test has been intentionally designed to run on an "easy to use" instrument platform, offering automation and speed of use, enabling laboratory technicians who are not necessarily skilled in the art of running complex gene sequencing instruments, to be able to use the system, rather than sending samples back to centralised facilities. Premaitha was acutely mindful of the trend for independent laboratories (c6,000 globally) to set up their own facilities, consequently addressing the two potential needs of these customers:
Meeting independent laboratories' ROCE metrics

That should appeal to the many independent laboratories wishing to offer NIPT capabilities

- Low cost. A facility that is capable of running 10-12,000 NIPTs, and generating c£3.5-4.2m of revenues per annum, has a set-up cost of c£0.35m. The equivalent cost for an Illumina sequencer is c£1m. Based on a price per test of £350 and an operating margin of c20% (after COGS and opex), payback on the initial investment can be achieved after only around 5,000 IONA tests
- An easy-to-use regulatory-endorsed product. The intention was to create a range of bespoke reagents alongside its proprietary software package that could be approved (CE Mark) and sold as a product to laboratories. Not only does this generate a readily scalable model for Premaitha, but the CE Mark accreditation is a sign of quality

Revenue model

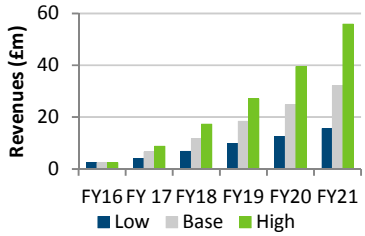
Premaitha has two principal revenue streams:

- Product revenues represent the sale of IONA test kits as a CE Marked IVD to its customer laboratories, with a selling price in the range of £100-150 per test. In some distribution territories, the in-house components are unbundled from low-margin OEM components, which are sold directly to the distributor. The

distributor's margin dilution is therefore neutralised. This is not currently a significant part of the revenue mix but is likely to expand as Premaitha broadens its international footprint.

- Service revenues, generated by the provision of a service (c£350) offered by Premaitha at its central Manchester facility in which blood samples are sent to the company for analysis with a report returned to the clinician within 3-5 days

Revenue scenarios



Source: finnCap

Growth expectations

With a limited trading history and a lack of visibility to future distribution agreements, our revenue forecasts for 2017 and 2018 are based largely on the contracts that have been agreed to date. Premaitha reported in its April trading statement that revenues for the FY ending March 2016 were c£2.5m, c£1.9m (75%) of which was generated in the second half, with revenues principally derived from four customers. A further six customers are expected to come on stream in Q1 FY 2017, which accounts for our expected growth in FY 2017 revenues to £6.7m and £11.8m in FY 2018.

Although we explicitly only forecast to FY 2018, we have looked at a range of potential scenarios, having input different rates of adoption of NIPT in Europe and the consequent potential share of revenues that Premaitha could capture, given the financial attractions afforded to independent laboratories wishing to run their own NIPT screens utilising a CE-marked test.

Strategically aligned with ThermoFisher

Next generation sequencing platform and strategic investment provided by ThermoFisher

Premaitha has aligned itself with ThermoFisher ($58bn US life sciences company), utilising its NGS platform. The decision was driven by the need to have a cost-effective NGS solution fulfilling the profiling needs of the IONA test and business model – namely accuracy, speed, low failure/repeat rates but which is also relatively simple to run. In December 2015, Premaitha signed an agreement with ThermoFisher to provide an investment of £5m in the form of a secured loan facility (£3m received in December 2015 with further milestone payments expected in 2016 and 2017) and the issue of 20.3m warrants, exercisable at 24.6p. Although there are a number of NIPTs available, many of which use the Illumina NGS sequencing platform, the key battleground outside of the US, in our opinion, will be between the following three NIPT/NGS platforms:

Technology providers

Test name	*NIPT originator*	*Sequencing platform*
Verifi/other	*Verinata*	*Illumina*
Harmony	*Ariosa*	*Roche*
IONA	*Premaitha*	*ThermoFisher*

* Illumina acquired Verinata in 2013 for $450m ** Roche acquired Ariosa in 2014 for $650m
Source: finnCap

Litigation risk overhang

Illumina claims Premaitha infringes its IP; however, strategic investment by ThermoFisher is considered supportive of management and Freedom to Operate opinion that this is not the case

Despite a Freedom to Operate (FTO) opinion, disclosed upon AIM Admission, Illumina claims that Premaitha is infringing its IP, namely the use of cell-free DNA for non-invasive prenatal testing and the use of NGS genomic sequencing in diagnosing fetal chromosomal aneuploidy (abnormal number of chromosomes), and is seeking damages and injunctive relief. The UK High Court case is now scheduled for mid-2017. Despite this, however, Premaitha management remains confident in its position that it is not infringing any IP, and this view is also supported by the fact that its IP

estate underwent extensive due diligence prior to ThermoFisher investing in the company in December 2015. Even in a worst-case scenario in which the UK High Court determines that Premaitha and the defendants in a separate but related infringement action in respect of Illumina's IP (Ariosa/Roche, The Doctors Laboratory) did indeed infringe Illumina's patents, there are many territories where the patent landscape is very different to the UK and where there is freedom to operate. Equally, under such a scenario it is quite possible, in our opinion, that the Court could impose a fair and reasonable licence agreement on Illumina in the event that Premaitha is unsuccessful with its invalidity and non-infringement claims.

Valuation and investment conclusion

Initiate coverage with a 20p price target, representing 4.2x calendarised 2017 EV/Sales

We have often written that acquisitions in this sector are based on revenue multiples, not earnings, certainly not in the early stages of product adoption and market penetration. On that basis, we should look at Premaitha Health shares on the basis of revenues and we consider the shares to be undervalued. We set our price target of 20p, equivalent to 4.2x calendarised 2017 EV/Sales.

Over the past nine months Rupert Lywood and his investment vehicles (Animatrix, Loxbridge and Zoragen) have sold over 40% of the company's shares; this has weighed very heavily on the share price, arguably more so than the litigation. With this overhang no longer considered an issue, investors should therefore be able to focus on the fundamental drivers of value.

There is no directly comparable peer group in the UK. However, we include below the quoted companies offering NIPTs in the US.

Comparable companies - peer group

			EV/Sales (x)	
Company	(EV (l/c)	Mkt Cap (l/c)	FY1	FY2
Illumina, Inc.	21,134	21,175	8.2	7.1
Natera, Inc.	489	689	2.7	2.3
Sequenom, Inc.	189	123	1.4	1.3
average	***7,271***	***7,329***	***4.1***	***3.6***
median	***489***	***689***	***2.7***	***2.3***

Source: Factset

Premaitha is entering the European market at the beginning of NIPT adoption

Whereas the broader based integrated platform company Illumina trades on relatively high multiples, despite its recent set back post Q1 2016 results, companies such as Natera and Sequenom have suffered over the past year as a consequence of pricing erosion (prices dropped 17% to $1100 in 2014 and fell again in 2015) in the US market, a maturation of the high risk segment of the market and laboratories moving from a service-based model to a license-based model. Conversely, Premaitha is entering a European market at the beginning of NIPT adoption with a readily scalable business model and a regulatory approved (CE mark) test that should be very attractive to laboratories wishing to set up and provide NIPTs in their local markets. Additionally, the IONA test matches the criteria that many of the national screening bodies are looking for, namely, trisomies 21, 18 and 13.

On this analysis we set our target price at 20p per share, representing an EV/Sales of 4.2x calendarised 2017 forecasts, and an upside to the current share price of 130%. Although a premium to the healthcare sector, we consider this to be justified given the growth opportunity, the fact that additional distribution agreements are likely to see upgrades to forecasts and the strategic relevance of Premaitha within the life sciences sector, where platform companies are seeking to build content (recurring revenues) into their business models.

Acquisition multiples

Supported by 4-6x EV/Sales M&A transaction values

There have been two relevant acquisitions in the NIPT space, albeit both substantially larger and in the US. In February 2013, Illumina bought Verinata for $450m, of which $350m was upfront plus up to $100m in milestone payments through 2015. Although revenues were not disclosed, Illumina's 10K reports proforma revenues for 2013 (as if the acquisition had been included), implying c$12m of acquired revenues and therefore an implied 29x historic EV/Sales multiple or prospective c6x proforma 2014 revenues. In December 2014, Roche acquired Ariosa Diagnostics $625m, of which $400m was upfront plus up to $225m in deferred payments. This represented an historic FY 2013 EV/Sales multiple of 7.5x (excluding deferred consideration) and closer to 4.2x 2014 sales.

Discounted cash flow valuation

Underpinned by DCF valuation of 38p per share in our base case model

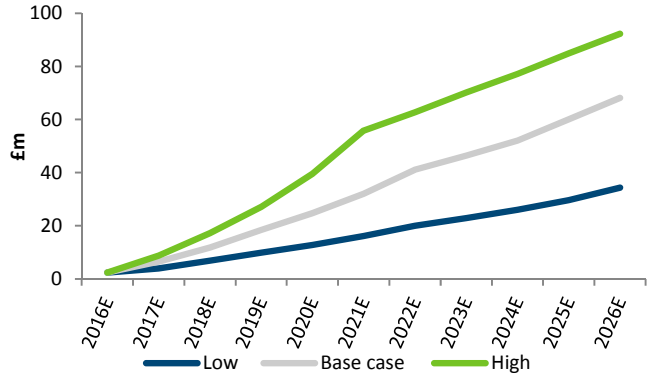
Our target price is underpinned by our DCF valuation. We have modelled three potential scenarios for Premaitha that are driven by different assumptions for NIPTs in Europe and the consequent share of the market that IONA is able to capture. We have looked at the US as a simple proxy for the growth potential in Europe, although it is a little more complex than that. Whereas US reimbursement for NIPT has historically been in the high risk age group, national screening bodies in Europe are looking to recommend that NIPT be made available to all pregnant women or contingent on a positive combined test.

Low, base and high case scenarios in Europe (2020E) vs US (2015E)

	2015E	2020E		
	US	Low	Base	High
Births (m)	3.937	5.161	5.161	5.161
Pre-natal screens (%)	75%	70%	70%	70%
Potential NIPT tests	2.954	3.613	3.613	3.613
NIPT test (m)	0.817	0.411	0.594	0.900
% prenatal screening	28%	11%	16%	25%
IONA test (m)	n/a	0.072	0.149	0.315
IONA market share (%)	n/a	18%	25%	35%
IONA revenues (£m)	n/a	11.3	23.9	51.5

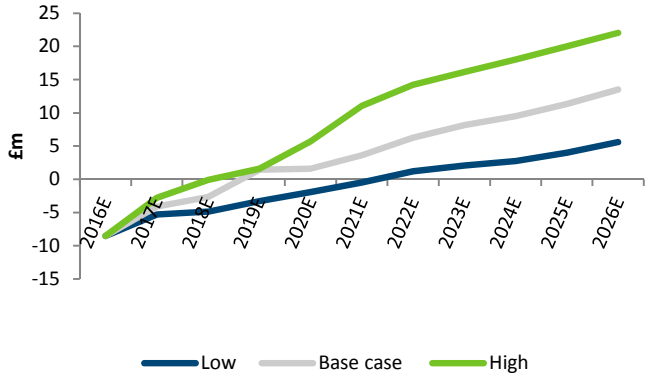
Source: finnCap

Revenues – low, base and high scenarios



Source: finnCap

Free cash flow – Low, base and high scenarios



Source: finnCap

Using these revenue forecasts to 2020, we have looked at the impact that these would have on free cash flows. We have prepared discounted cash flow valuations for our base case scenario. Using a WACC and terminal growth rate of 9% and 2%, respectively the implied equity value is £101m or 38p per share.

DCF valuation - base case

Year end March (£m)	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026
Sales	6.6	11.8	18.4	24.7	32.1	41.1	46.4	52.1	60.0	68.1
EBITDA	-3.3	-0.9	2.1	4.7	7.6	11.2	13.0	14.8	17.6	20.4
change in working capital	-0.1	0.0	0.2	-1.3	-1.1	-1.3	-0.8	-0.9	-1.2	-1.2
Cash tax	1.2	0.4	0.0	-0.5	-1.4	-2.1	-2.5	-2.8	-3.3	-3.9
Capital Expenditure	-0.8	-0.9	-0.9	-0.9	-1.0	-1.0	-1.1	-1.1	-1.2	-1.3
Other	-1.1	-1.3	0.0	-0.4	-0.4	-0.5	-0.5	-0.5	-0.5	-0.6
Group Free Cash Flow	**-4.1**	**-2.7**	**1.4**	**1.6**	**3.6**	**6.3**	**8.1**	**9.5**	**11.3**	**13.5**
Discount factor	0.9	0.8	0.8	0.7	0.7	0.6	0.5	0.5	0.5	0.4
Discounted Cash Flow	**-3.7**	**-2.2**	**1.1**	**1.1**	**2.4**	**3.7**	**4.5**	**4.8**	**5.2**	**5.7**

	Current	Yr+1
Sum of Discounted Cash Flows	23	29
Terminal Value	77	84
Enterprise Value	**100**	**113**
PV of DCF as % of EV	23%	25%
PV of TV as % EV	77%	75%
add cash	5	2
minus debt	-4	-5
Implied Equity Value	**101**	**115**
number of shares in issue (f. dil)	264	264
Implied share price	**38**	**44**

Source: finnCap estimates

We have included a sensitivity analysis of the base case scenario to both WACC and terminal growth, which generates a 29-56p price range.

Sensitivity analysis of base scenario - terminal growth rate and WACC

Discount rate	Net Debt/(Cash)	Equity value (£m)			Price per share (p)		
		Terminal growth			Terminal growth		
		1%	2%	3%	1%	2%	3%
8.0%	-2	111	126	147	42	48	56
8.5%	-2	100	113	130	38	43	49
9.0%	-2	91	101	115	35	**38**	44
9.5%	-2	83	92	103	32	35	39
10.0%	-2	76	83	93	29	32	35

Source: finnCap estimates

We have generated the following DCF valuations from the three scenarios.

DCF valuations under different scenarios

	Europe (2025)					
	Births (m)	Prenatal screens (m)	NIPTs (m)	IONA (m)	DCF valuation (p)	Upside/ Downside
Low	5.186	3.63	0.595	0.104	11	19%
Base case	5.186	3.63	0.955	0.277	38	327%
High	5.186	3.63	1.176	0.482	69	668%

Source: finnCap

In the low case, a DCF value of £28m or 11p is generated. This assumes Premaitha undertakes c01.1m screens in 2025. Given that the revenues (excluding pass-through sales) in FY 2016 amounted to c£2.1m and represented c15k tests, we considered this scenario to be unlikely and would imply poor execution and/or significant new competitors entering the market.

Our base case generates a DCF value of £101m or 38p per share, and implies that Premaitha undertakes c0.28m tests in 2025.

Our high case generates a DCF value of £182m or 69p per share, implying 0.48m NIPT screens in 2025, which represents around 13% of the c3.63m prenatal screens currently undertaken in Europe. Over time, we would anticipate NIPTs to be used as a first-level screen in all prenatal categories – the question remains how much and over what period? The market will inevitably apply a discount factor to the DCF valuation, given that Premaitha has yet to resolve the litigation case with Illumina.

Although Illumina is seeking an injunction, in our opinion we consider it highly unlikely that Premaitha would be forced to withdraw IONA from the market, thereby depriving patients of choice. Under such circumstances, we would envisage some form of licensing/cross-licensing arrangement would be agreed or for the Court to impose a fair and reasonable license arrangement on Illumina. Premaitha has the time until the mid-2017 UK High Court hearing to strengthen its defence further and de-risk the company where possible through international expansion, as well as to introduce an anti-trust angle into the UK proceedings to put Illumina's tactics under the spotlight.

Prenatal screening

Combined test – fetal ultrasound and maternal blood test

Traditional screening offered during the first trimester of pregnancy is called the combined test, used to detect for chromosomal abnormalities (aneuploidies) such as Down's syndrome, Edwards' syndrome and Patau's syndrome. This is a test that combines information from an ultrasound scan of the baby (measuring the small collection of fluid at the back of the fetus' neck – nuchal translucency test) and a blood test from the mother (measuring the level of two hormones – pregnancy associated plasma protein-A (PAPP-A) and free (B-human chorionic gonadotrophin (B-hCG).

The combined test, however, is not sufficiently accurate (a sensitivity of 85-90% implying 10-15% of Down's syndrome babies are not picked up by this test) and a specificity of 95.0-97.5% (implying 2.5-5.0% of results are false positive).

High risk patients offered invasive amniocentesis

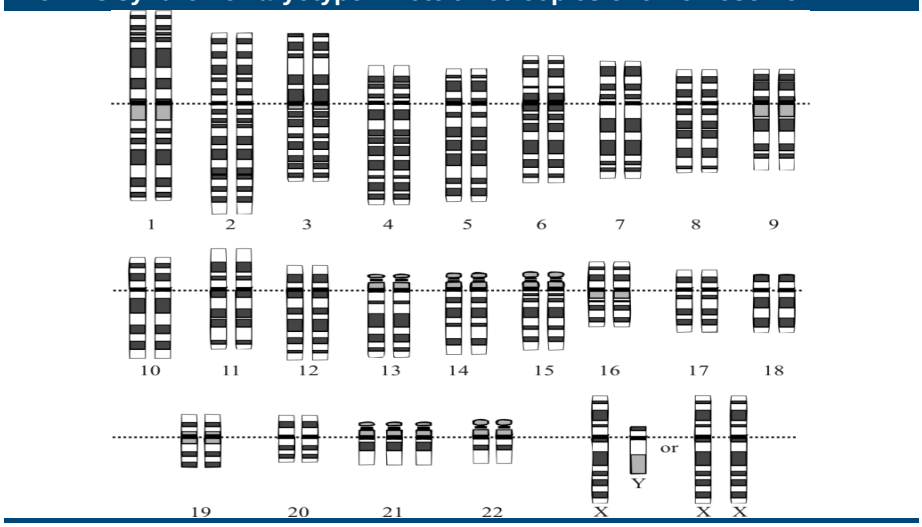
The risk of Down's syndrome following the combined test is based upon a combination of (i) age, (ii) ultrasound measurement, (iii) blood test levels and (iv) the length of the fetus. If deemed to be high risk, invasive procedures are offered to give a clearer indication if the fetus has Down's syndrome or not (amniocentesis – needle to withdraw and test a small amount of amniotic fluid and cells from the sac surrounding the fetus) or chorionic villus sampling (placental cells taken). However, these tests carry a risk of miscarriage of around 1% above the usual risk of miscarriage.

Non-invasive prenatal testing (NIPT)

Non-invasive DNA-based test introduced in 2011with superior accuracy and lower false positives

A non-invasive prenatal test, using DNA in the mother's blood to estimate the risk of a fetus having a chromosomal abnormality, was introduced in 2011 for women considered to be at higher risk of developing trisomies (>35 years old) – a chromosomal abnormality when three copies of a chromosome are present, the most prevalent of which are trisomy 21, 18 and 13.

Down's syndrome karyotype – note three copies of chromosome 21



Source: Human Genome Project

To be clear, NIPT is a screen for chromosomal abnormalities rather than a confirmatory diagnostic test, which would be offered to the woman if the NIPT suggested she was at high risk of having a chromosomal abnormality.

Comparison of screening and diagnostic		
	Screening test	Diagnostic test
Purpose	To detect potential disease indicators	To determine presence/absence of disease
Sensitivity	High, so as not to miss potential disease	High, to identify healthy people as having disease
Specificity	Low	High, to identify healthy people as not having disease
Patient population	Asymptomatic patients, although high risk	Symptomatic patients to identify disease
Test method	Simple	Accuracy but it may be invasive test
Cost	Typically low as in large number of patients	Typically higher

Source: finnCap

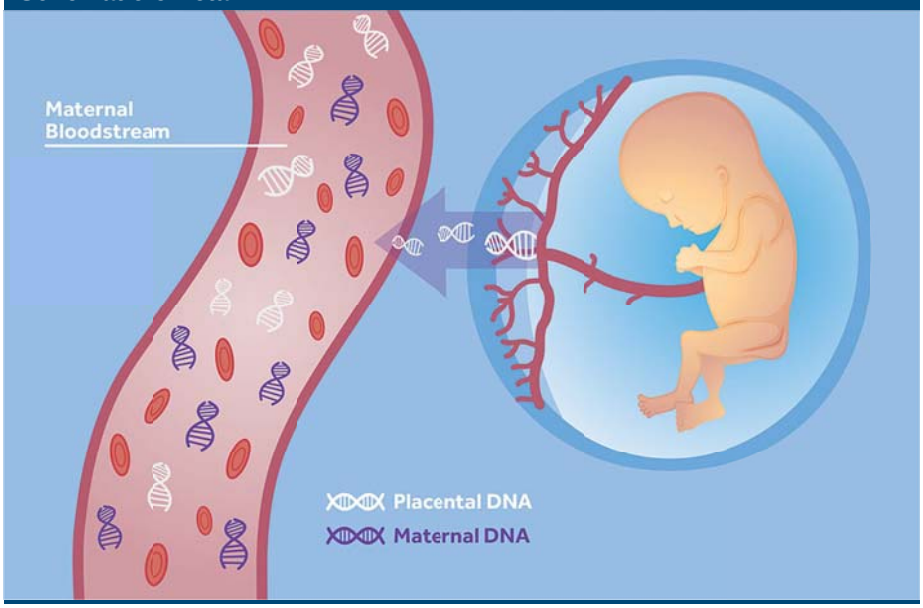
The advantages of NIPT are that there is no risk to pregnancy; it is a highly sensitive test and provides reassurance to the mother that their child is very unlikely to have chromosomal abnormality. The disadvantages are that some NIPTs (less in the case of Premaitha) have an indeterminate result, usually due to low proportion of fetal DNA in the sample; they are not always fully reimbursed by national healthcare systems and, for self-pay patients, the test is relatively expensive.

Comparison of NIPT to combined test and amniocentesis			
	NIPT	Combined test	Chorionic villus sampling/ amniocentesis
Risk to pregnancy	No	No	Yes (0.5-1.0%)
Detection rate for trisomies 21, 18, 13	High (>99.5%)	Moderate (c85%)	High (>99.9%)
False positive rate (healthy who are incorrectly identified)	Low	Low	Low (diagnostic)
Other aneuploidies	Yes	No	Yes

Source: finnCap

From 10 weeks gestation, a blood sample can be taken from the mother, which contains both maternal as well as fetal DNA as the placenta leaks fetal cell-free DNA (cfDNA) during pregnancy.

Schematic of fetal DNA



Source: Premaitha Health

NIPTs measure the amount of cell-free DNA and can detect small changes in the DNA ratio between the maternal and cell-free DNA when a fetal trisomy 21, 18 or 13 is present. The NIPTs will typically screen for the following chromosomal abnormalities:

Chromosomal abnormalities

Syndrome	Chromosome	Description	Prevalence (live births)
Down's	Trisomy 21	Extra copy of chromosome 21	1 in 700
Edwards'	Trisomy 18	Extra copy of chromosome 18	1 in 6,000
Patau's	Trisomy 13	Extra copy of chromosome 13	1 in 5,000 to 1 in 29,000
Turner	Monosomy X	One complete X sex chromosome	1 in 2,500

Source: finnCap

Down's syndrome (trisomy 21)

Down's syndrome occurs when there is an extra copy of chromosome 21 present. 50% of all babies born with Down's syndrome are also born with a congenital heart defect. Detection with NIPT is >99%.

Edwards' syndrome (trisomy 18)

Edwards' syndrome occurs when there is an extra copy of chromosome 18 present. NIPT detects elevated levels of chromosome 18 DNA sequences, suggestive that the fetus has Edwards' syndrome. Detection is as accurate as for Down's syndrome (>99%). Key clinical features include kidney malformations, structural heart defects at birth, intestines protruding outside the body and intellectual disability.

Patau's syndrome (trisomy 13)

Patau's syndrome occurs when there is an extra copy of chromosome 13 present. NIPT detects elevated levels of chromosome 13 DNA sequences, which would suggest the baby has Patau's syndrome. The identification of Patau's syndrome is as accurate as for Down's syndrome. Many fetuses never survive until term, are stillborn or spontaneously abort. Key features are similar to Edwards' and include intrauterine growth restriction, congenital heart defects, cleft lip, neural tube defects and urogenital abnormalities

Turner syndrome

Turner Syndrome occurs when there is only one copy of the X chromosome present in a female baby. NIPT detects a reduced level of X chromosome sequences and no Y chromosome sequences, indicating that the baby is likely to have Turner syndrome. Detection of Turner syndrome is not as accurate as for the other aneuploidies. Women with this condition tend to be shorter than average and are usually infertile because of an absence of ovarian function.

Prenatal screening is recommended by fetal and maternal medicine associations (ESHG/ASHG, FIGO, SMFM), all of which support prenatal screening for Trisomy 21, Trisomy 18 and Trisomy 13. However, they strongly advocate caution in including and reporting micro-deletions and sex-chromosomal abnormalities, which can reduce the overall effectiveness of an NIPT and brings with it ethical considerations, for example sex determination in some markets where parents seek to have male children.

Sequencing technology used in NIPT

Currently, two broad categories of NGS are being used to provide plasma cell-free DNA-based NIPT clinical services for patients as well as Ariosa/Roche's microarray platform:

- Shotgun sequencing (for example ThermoFisher/Premaitha and Illumina), in which DNA molecules contained in maternal blood samples are sequenced at random. The proportional representation of DNA molecules sequenced from the chromosome of interest (for example, chromosome 21) is compared with those sequenced from elsewhere in the genome. The key advantage is that the sequencing steps are essentially the same irrespective of the genomic locations of the chromosomal targets. One disadvantage of this approach is that genomic regions that are not directly relevant to NIPT are also analysed as the sequencing is random. Premaitha has been able to lower the costs and time of performing this test on ThermoFisher's Ion Proton NGS sequencer.
- Targeted sequencing (for example SNP analysis by Natera), in which genomic regions containing the chromosomes at risk of the aneuploidy, as well as a selected group of reference regions, are selectively targeted for sequencing. The principal advantage is that the sequencing power can be focused solely on genomic regions of interest rather than other areas of the genome. The downside, however, is that targeting steps are tailor made for each test panel and cannot be changed if one wants to increase the number of test targets to include targets not relevant in a particular test.
- Ariosa has developed a microarray platform for NIPT that it claims has a faster turnaround time and greater accuracy, while also reducing the number of patient samples needed for an economical run.

IONA test

Premaitha has developed a proprietary NIPT called IONA, which is based on NGS technology, using ThermoFisher Scientific's benchtop Ion Proton System; designed to simplify the process to a level at which laboratory technicians can routinely run the tests. The test detects trisomies by analysing placental derived cell-free DNA (cfDNA) extracted from the mother's plasma. The relative amount of chromosomes 13, 18 and 21 are then used to calculate a likelihood ratio, which the software then uses in conjunction with the prior risk of the mother at the time of sampling to calculate a risk score for each trisomy.

Clinical performance

The IONA test has a higher detection rate than the combined test and similar to other NIPTs.

IONA clinical performance

	Detection rate (sensitivity)	False Positive rate
Trisomy 21 (Down's)	>99%	<1%
Trisomy 18 (Edwards')	>99%	<1%
Trisomy 13 (Patau's)	>99%	<1%

Source: Premaitha Health

In a recent independent study of 242 patients, performed at Kings College, London, the IONA test detected 100% of the trisomies, with 0% false positives.

How is IONA test performed?

The healthcare provider will take a small sample of blood from the mother which is sent to the laboratory performing the test. Here the test is performed and a simple report is produced indicating whether the mother is low risk or high risk, in which case an invasive test (eg amniocentesis) is required to confirm trisomy.

Workflow – results in 3 days

Step	Description
Step 1	Blood sample (10mL) collected from pregnant woman at least 10 weeks pregnant and sent to laboratory
Step 2	Circulating DNA fragments isolated, analysed and counted using shotgun whole genome sequencing
Step 3	IONA software uses the relative amount of chromosomes 21, 18 and 13 to generate risk scores for each trisomy
Step 4	IONA test report produced – clear, easy to interpret
Step 5	High risk results should be confirmed with a diagnostic test (amniocentesis)

Source: finnCap

Key benefits of IONA test

The following five criteria are considered important for commercial uptake. The three most relevant are considered to be CE marking (quality), turnaround time and ease of use.

Benefits of IONA test	
Criteria	Description
Performance	Clinical validation data to demonstrate >99% detection
Ease of use	Suitable for trained laboratory technicians
Throughput	> 200 samples per week
Cost	50-60% of the price of tests from other NIPT providers, allowing lab. customers to achieve typical profit margins
Turnaround time	3 days. Performed in a local laboratory
Regulatory status	CE marked IVD

Source: Company reports, finnCap

Key processes involved in IONA test

Premaitha has partnered with leading suppliers of technology for DNA extraction, library preparation, PCR and NGS. Premaitha has developed a range of proprietary reagents used in sample preparation and proprietary software to complete the IONA test, which has been CE marked.

IONA test – key processes involved and instrument suppliers/partners

Test Element	Description	Premaitha	Instrument platform	Partner/ Supplier
DNA extraction	Isolates a mixture of maternal and fetal DNA from blood samples		QIA Symphony	Qiagen
Library preparation	Prepares the isolated DNA for sequencing and adds barcodes to allow multiplex testing and subsequent decoding	IONA reagents	Sciclone	PerkinElmer
Emulsion PCR	Creates millions of clonal copies of each DNA molecule so that the sequencing reactions can generate sufficient signal to allow detection		Ion Chef	ThermoFisher Scientific
DNA sequencing	Identifies the DNA sequence of each of the molecules from the previous step		Ion Proton	ThermoFisher Scientific
Data interpretation	Counts the numbers of molecules derived from each chromosome and calculates whether this is consistent with an affected or unaffected pregnancy	IONA software		

Source: Company reports, finnCap estimates

How are the IONA results reported?

The IONA test is like other NIPTs in that it is a screening test rather than a confirmatory diagnostic. A woman with a high risk result will be advised to follow up with a confirmatory invasive procedure.

Report output	
Report output	Comment
Low risk	Very unlikely that the pregnancy is affected by T21, 18 or 13
High risk	Increased risk for T21, 18 or 13. The result should be confirmed by a follow up invasive procedure such as amniocentesis
No result	Insufficient placental/fetal DNA in the sample to obtain a result. Women may be asked back for a further blood sample.

Source: finnCap

Addressable market

Global birth rate

Global birth rate of c137m, of which 82m births are in countries offering NIPT screening

Globally, there are an estimated 137m babies born a year. Of these, c82m (60%) are in countries that offer NIPTs. Since its introduction to clinical practice in Hong Kong in 2011, NIPT uptake around the world has been rapid, with an estimated 60% of high risk women receiving NIPT in the US.

Live births

Births	m
World	137.4
US	3.9
EEA 28 +	5.2
EU 28	5.1
France*	0.8
Germany	0.7
Italy	0.5
Poland*	0.4
Spain	0.4
UK*	0.7
Turkey	1.3
Russia*	1.9
India*	24.4
China	17.2

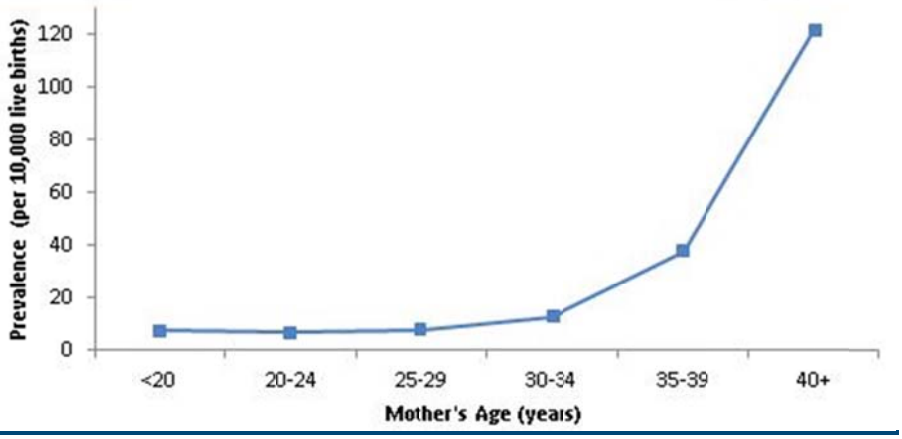
Source: CIA Handbook, Eurostat, ONS
* countries in which Premaitha already has a distribution/supply agreement

Initial target market

NIPT initially targeted at women over 35 years considered to be high risk

NIPT is initially targeted at women over the age of 35 years, at which point the prevalence of Down's syndrome exponentially increases, doubling between 35 and 40 years, as illustrated in the following chart.

Prevalence of Down's syndrome with mother's age



Source: CDC

Although NIPTs are not a fertility test, the risk of trisomies can be explained perhaps by the very fact that fertility rates decline as a function of age which can

be attributed to two main factors: (i) a decline in the actual number of eggs in the ovary post 35 years; and, perhaps more relevant, (ii) a decline in the number of genetically normal eggs.

4m births in US

- In the US, there were 3.932m births in 2014, of which 0.617 were to women over 35 years old and considered high risk (15.5%) and where NIPT is currently reimbursed. Sequenom suggests that the number of high risk patients (age and other factors) is around 0.75m (18.75% of births). Currently, c75% of all pregnant women receive a prenatal screening test (combined test or NIPT), implying that there are c3m prenatal screening tests. Of this we estimate that c15% were NIPT (c0.55m NIPTs). We estimate 60% of high risk women received NIPT in 2015, with the balance in lower risk women.

5.1m births in EU28

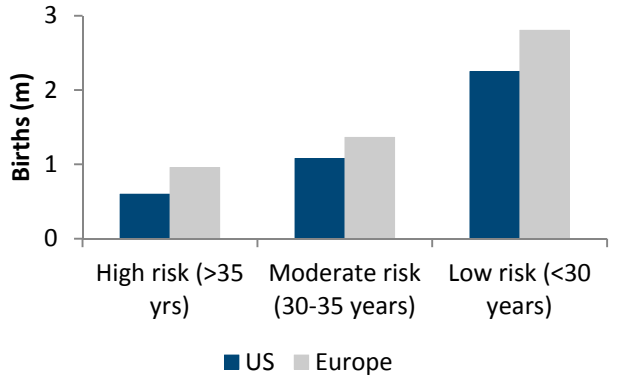
- In Europe, there were 5.131m births in 2014, of which 0.96m women (18.8%) were over 35 years old or high risk. According to Premaitha, around 3.6m screening tests are currently performed annually (c70% of all births), of which only 1.4% were NIPT (c50,000 NIPTs), implying c5% penetration of high risk women or less if being used in lower risk women. Unlike the US, the European market is currently self-pay, although guideline recommendations, when they are enacted, are likely to advocate NIPT use for all women or contingent on the combined test. BGI Diagnostics claims to have performed over 20,000 NIFTY tests in the three years to end 2013.

0.7m births in UK

- In the UK, there were 0.695m births in 2014, of which 144,181 (20.7%) were to women over 35 years old.

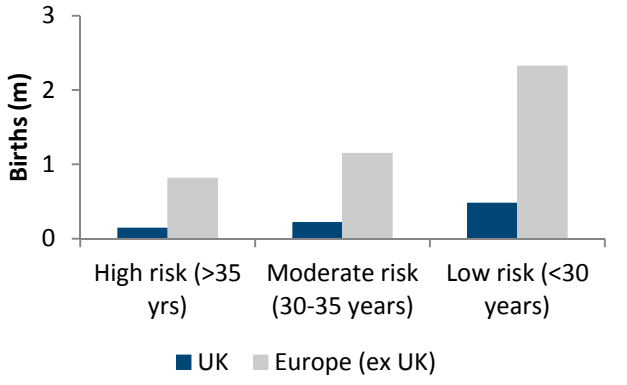
The following charts illustrate the breakdown of births for women considered to be at high risk, moderate risk and low risk of having a chromosomal abnormality. What is clear is that the European market is about 20% larger than the US but is very much in the early stages of NIPT adoption. Whereas c15% of all prenatal screens in the US use NIPT, it is a more modest 1.4% in Europe.

Births in Europe and USA (2014)



Source: Eurostat, CDC

Births in UK and Europe (ex-UK) 2014

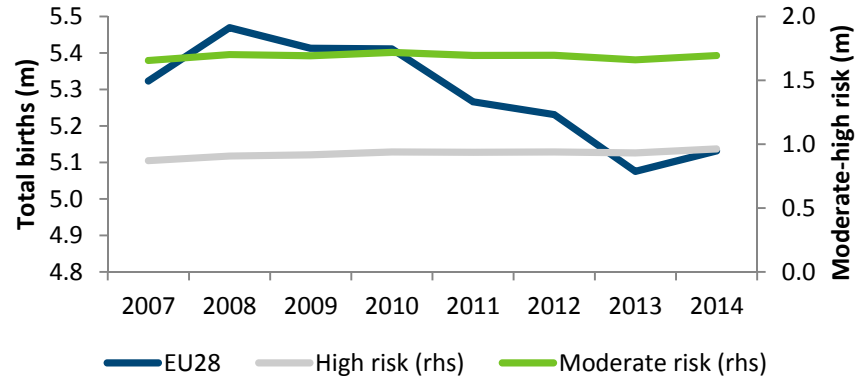


Source: ONS, Eurostat

Europe

Premaitha has determined initially to focus on non-US markets, with the majority of its distribution and commercial agreements signed to date being in Europe. Although the birth rate in Europe has fallen over the past 50 years from c8m to c5.1m in 2014, the number of high risk births (>35 years) has risen over the past decade from 0.85m to 0.96m in 2014 as women have delayed having children.

Number of live births, EU28 1961-2014

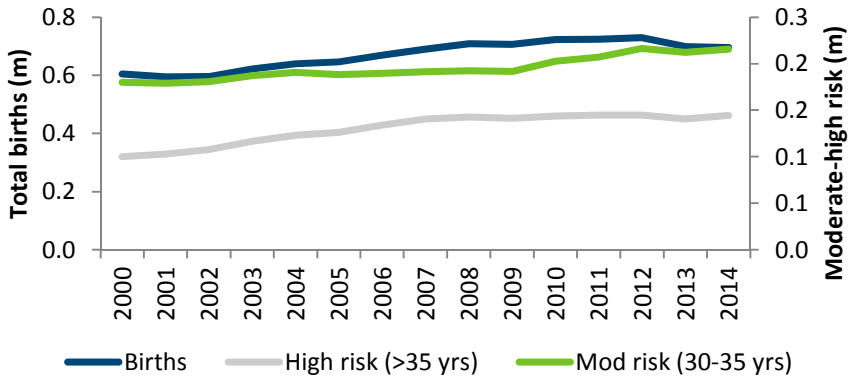


Source: Eurostat

UK

As in Europe, the number of births to women over 35 years has increased over the past decade despite a gradual decline in the number of births. In 2014, there were 144,181 'high risk' babies born, with 215,642 births to women of 30-35 years (moderate risk). Premaitha supplies the IONA test kit to St Georges Hospital, London and the Wolfson Institute, the first two centres in the UK to have set up independent testing facilities using IONA.

UK births (2000-2014)



Source: ONS

Pricing and reimbursement

The price of NIPTs ranges from c$800 (Harmony) to $2,700 (MaterniT21) in the US, although reimbursement in high risk women is around $1,100. In Europe, the price of NIPTs ranges from €600 to €800. In the UK, the price of a test ranges from £400 to £900.

The pricing difference is partly to do with the sequencing methods that the tests employ; both Harmony and Natera use a targeted approach, focusing on DNA from the chromosomes of interest, whereas the other players, including Premaitha, sequence the full genome (massive shotgun sequencing).

Premaitha is able to offer a NIPT at c£250/$375. Alternatively, it will sell the IONA kit (reagents and software) to a customer laboratory for c£125/$180, thus enabling the laboratory to generate acceptable operating margins.

NIPT addressable market

	Births (m)	High risk (>35 years)	Moderate risk (30-35 years)	Low risk (<30 years)
US	3.9	0.6	1.1	2.3
Europe	5.1	1.0	1.4	2.8
o/w UK	0.7	0.1	0.2	0.5
ROW	72.9	13.5	18.2	41.2
Total births	**82.0**	**15.2**	**20.9**	**46.7**
Cumulative value of market ($bn)				
Price per test ($)		500	350	250
US		301	589	983
Europe		480	814	1,283
o/w UK		72	126	174
ROW		6,747	11,105	18,234
Market size ($)		**7,599**	**12,633**	**20,500**

Source: finnCap

Assuming an average price of c$500 per NIPT, the addressable market for NIPT in high risk women is considered to be as much as $7.5bn. If one was to consider penetration of the moderate risk group, the total addressable market is c$18bn.

Given the pricing/reimbursement differential in global markets it is perhaps more relevant to look at the number of births amongst high risk women where there is reimbursement or the likelihood of reimbursement as well as those births that are considered moderate risk but where women will self-fund an NIPT. In this case there is an estimated market for c15-36m NIPTs, of which 1-2.4m tests are possible in Europe. Given that there were an estimated 50,000 NIPTs undertaken in Europe in 2015, the opportunity is considered significant.

From Premaitha's perspective, based on the assumption that it sells the IONA test at £125 to independent laboratories:

- the European market is valued at up to $1.28bn, assuming 5.1m births
- the UK alone is worth up to $174m, assuming 0.7m annual births

Drivers of NIPT adoption

Drivers of adoption are considered to be:

- Guideline recommendations in Europe. Leading medical associations in Europe recently recommended that NIPT can now be used as primary screening for fetal trisomy 21 in all pregnant women of any age or risk, although this has yet to translate into national screening guidelines, the timing of which is unclear and the resultant impact to NIPT uptake therefore being rather lumpy.
- UK National Screening Committee recommendation in January 2016 that NIPT is made available through the NHS to all women who are considered high risk.

- This trend is likely to continue as several other European health services are planning to offer testing to high risk groups on a contingent basis (Netherlands, Belgium, Switzerland). The Netherlands is expected to offer NIPT as a first level screen from 2017. Ultimately, we expect first level NIPT screening will become standard practice.
- Insurance coverage for all risk groups increased in the US after guideline changes in September 2015, in which The American Congress of Obstetricians and Gynecologists (ACOG) recommended that the use of NIPT in women at increased risk of aneuploidy or as a follow-up test for women with a positive first- or second-trimester maternal serum screening result (combined test).
- New laboratories setting up NIPT capabilities.

Growth of the NIPT market has primarily been in the high risk population; partly due to medical utility but also because this is the population group which can in some territories obtain reimbursement for the test. Our model looks at three scenarios in which the number of NIPTs in Europe rises from c50k to c1m tests in 2020, which would imply c65% of high risk prenatal screening (similar to that seen in the US) and c28% of the total prenatal screening market. However, we do expect the market to develop further into 'all risk' populations over the next decade, which would increase the number of NIPTs to perhaps 2-3m per annum.

Regulatory path

Within the US, all NIPTs fall under the title Laboratory Developed Tests (LDT), which are overseen by the Centres for Medicare & Medicaid Services (CMS) through set standards imposed by the Clinical Laboratory Improvement Act (CLIA), rather than regulated by the FDA as an approved test. When CLIA came into being in the 1980s, genetic testing was in its infancy and the need for regulatory approved products was considered unnecessary. However, there is an on-going debate as to whether such tests should be FDA regulated. The prospect of Illumina and Roche pursuing a stringent and costly pre-market approval (PMA) with the FDA is a good reason, in the short term, why Premaitha is not seeking to enter the more developed and competitive US market. Premaitha could enter the market once the dust has settled, with a clearer regulatory path to market, most likely then by a 510(k) route; its USPs being lower failure/test repeat rate and lower pricing.

Competition

Competitive global market but level playing field in Europe

BGI Diagnostics was the first to launch an NIPT in China in 2011, followed by Sequenom's launch in late 2011 in the US. Since then, the market has become increasingly competitive and a number of NIPTs have been launched.

The major competitive platforms, from Premaitha's perspective, in Europe, however, can be considered to be based around either the Illumina/Sequenom platform in which laboratories have licensed the technology to perform tests in their own laboratories (or have samples sent to the US for processing in the CLIA-approved laboratories) or the Ariosa platform which, similarly, is based on a service-driven business model. In the US, where Premaitha does not have a presence, the key players are considered to be Illumina, Sequenom, Natera and Ariosa.

IONA designed to address competitors' shortcomings

The main difference between Premaitha's test and the competition is the fact that it has been intentionally designed to run on an "easy to use" instrument platform, offering automation and speed of use (particularly in the time consuming sample preparation phase -– IONA reagents -– as well as traceability) which will enable laboratory technicians who are not necessarily skilled in the art of running complex gene sequencing instruments, to be able to use the system, rather than sending samples back to centralised facilities. Premaitha was also acutely mindful of the trend for independent laboratories to set up their own facilities, and was keen therefore to ensure that it could provide a cost-effective solution. Sequenom, for example, claims that there are now 46 participants (ie licensees) in the Illumina/Sequenom patent pool. The IONA test consequently addresses the two potential needs of the independent laboratory:

Meeting independent laboratories' financial metrics of ROCE

- Low cost. The laboratory can set up a facility that is capable of running 10-12,000 NIPTs, capable of generating c£3.5-4.2m of revenues per annum, for c£350,000. The equivalent cost for an Illumina sequencer is c£1m. Based on a price per test of £350 and an operating margin of c20% (after cost of goods and opex), payback on the initial investment can be achieved after only around 5,000 IONA tests

Scalable business model for Premaitha

- An easy-to-use regulatory-endorsed product. The intention was to create a range of bespoke reagents alongside its proprietary software package, that could be approved (CE Mark) and sold as a product to laboratories. Not only does this generate a readily scalable model for Premaitha, but the fact that it has been awarded external accreditation via the CE Mark should be a major positive with purchasers

The following table summarises the key competitors in the market:

NIPT screening – key competitors

Company	Test name	Conditions screened for	Regulatory Path	Technology/ NGS Platform	Launch
Sequenom	MaterniT21	Trisomies 22, 21, 18, 16, 13, fetal sex aneuploidies and microdeletions	Lab-developed test	MPS (Illumina)	2011
Natera	Panorama	Trisomies 21, 18, 13, sex chromosome triploidy, monosomy X, and microdeletions	Lab-developed test	SNP/ PCR multiplex	2013
BGI Diagnostics	Nifty	Trisomies 21, 18, 13, aneuploidies and microdeletions	Lab-developed test	MPS	2011
Roche (Ariosa)	Harmony	Trisomies 21, 18, 13, sex chromosome triploidy and monosomy X	Lab-developed test; future FDA submission expected; software is CE marked in Europe	Microarray (Affymetrix)	2012
Illumina (Verinata)	Verifi	Trisomies 21, 18, 13 and monosomy X	Lab-developed test; future FDA submission expected	MPS (Illumina)	2012
LabCorp	InformaSeq	Trisomies 21, 18, 13 and monosomy X	Lab- developed test	MPS (Illumina)	2014
Quest Diagnostics	QNatal Advanced	Trisomies 21, 18, 13 and monosomy X	Lab-developed test	MPS (Illumina)	2015
LifeCodexx AG	PrenTest	Trisomies 21, 18, 13, sex chromosome triploidy and monosomy X	CE marked in Europe, not available in US	qPCR	2012
Berry Genomics	Chromate	Trisomies 21, 18, 13 and monosomy X	CFDA approval (China)	MPS (Illumina)	2015
Premaitha Health	IONA	Trisomies 21, 18, 13	Reagents and software are CE marked in Europe; not yet available in US	MPS (ThermoFisher)	2015

Source: Company reports, finnCap estimates * MPS - massively parallel shotgun sequencing

Business model

Differentiated business model

Premaitha's business model is differentiated from the other major players in the NIPT space, in that it has developed a CE-marked *in vitro* diagnostic product which it sells to other laboratories so that they can perform the test themselves. This compares with competitors which operate with a service-based model (although Premaitha does offer this too), whereby samples are sent back to a centralised laboratory, in this case at its Manchester facility, or a technology transfer (licensing plus methods) model as Illumina/Sequenom have done in respect of the patent pool.

We believe that the technology transfer model preferred by Illumina, Ariosa and Natera leads to greater variability in test performance and extended launch times due to the necessary additional validation required in setting up these systems. This is unlike the 2-3 months in Premaitha's cases, in which it has pre-validated the product (CE Mark) to save the laboratory operator time and hassle.

Technical help provided to set up and run IONA on the instrument platform

Premaitha will provide laboratories with the technical help needed to set up and run IONA on the instrument platform, the capital cost of which is c£350,000. Whilst the IONA test is perhaps not as broad (in fact most national screening associations advocate a narrower specification that excludes microdeletions and sex aneuploidies) as some of the other NIPTs (determining the risk of a fetus having trisomies 13, 18 and 21) it is able to use the CE Mark as a selling point to persuade doctors and payers that the IONA test is perhaps the most reliable.

Service offered to customers as they install and verify instrument platform

In addition, Premaitha can offer those customers wishing to establish their own NIPT laboratories an interim service in which samples, collected from mothers, are sent to Premaitha's facilities in Manchester.

Revenue model

Early adoption drives 10-month sales to £2.5m

Premaitha launched IONA in April 2015. In the April trading update, the company stated that full-year revenues to 31 March 2016 are expected to be c£2.5m. We estimate, excluding pass-through sales on instruments, that c£2.0-2.1m of revenues will have been derived from product sales and service sales, implying that the company had sold sufficient product to run c15,000 NIPT screens.

Three revenue streams

There are the following revenue streams:

- Product revenues. These revenues represent the sale of IONA test kits as a CE Marked IVD to its customer laboratories, with a selling price in the range of £100-150 per test.
- Service revenues, generated by the provision of a service (c£250) offered by Premaitha at its central Manchester facility, in which blood samples are sent to the company for analysis with a report returned to the clinician within 3-5 days.
- Pass through revenues. These relate to sales of instruments (sourced from its partners such as Qiagen, Perkin Elmer and ThermoFisher) to its customers intending to set up laboratory to run tests. We expect this revenue stream to cease in 2017.
- Other – these are minimal and related to service-based revenues.

This is unlike Premaitha's competitors offering Laboratory Developed Tests (LDTs) in the US which also sell their testing services in Europe. In these cases the samples must be shipped to the US – or, in one case, China – for processing.

Premaitha's principal revenue stream will be through the sale of a product, in this case called IONA (reagents and software for analysis), rather than a service.

With such limited history and a lack of visibility to future distribution agreements, our revenue forecasts for 2017 and 2018 are based on the contracts that have been agreed to date, plus the expectation that an additional ten contracts are signed up in the remainder of 2016 and 2017.

Since April 2015, Premaitha has announced the following agreements, although we understand that it serves other NHS trusts and private UK clinics that have not been individually announced:

- 10 product-based agreements
- 7 service agreements

We anticipate further announcements over the course of 2016.

Product and service agreements

Country	Date	Description
Product/IONA kit agreements		
Switzerland	Mar-15	Genoma SA to provide screening service under Tranquility brand
UK	Mar-15	St Georges Hospital, London, to offer in-house screening test
Poland	Mar-15	Centrum Badum to offer in-house screening service
UK	Oct-15	Wolfson Institute, London, to offer In-house screening capability. Previously NIPT samples were sent to the US
France	Dec-15	Adgenix (distributor) who signed with LaboSud Laboratories in Montpelier to provide in-house screening
Russia	Mar-16	GeNext. Central lab to be set up with interim service agreement (samples to Manchester). 2m annual births
Middle East - 3	Mar-16	Laboratories to be set up in three M. East markets with annual birth rate of c2m
France	Mar-16	Adgenix (distributor) who signed new lab in central France (acting as regional hub)
Service agreements		
This is My Limited	Jun-15	Clinics in Leeds, Manchester, Liverpool, Hull, Coventry, Halifax, Durham and London
Chile	Sep-15	Service contract with Servicos Geneticos OriGen. Samples sent to Premaitha's Manchester facility
Greece	Oct-15	Antisel, initially as distributor to hospitals, but longer term to set up screening service
Armenia	Jan-16	Service contract
Republic of Moldova	Jan-16	Service contract
India	Feb-16	Service contract with Visional Medical
UK	Feb-16	Service contract with Leeds Teaching Hospital Trust

Source: Company reports, finnCap estimates

Intellectual property and patent litigation

IP-protected technology with Freedom to Operate opinion

Premaitha has five key patents, the most significant of which is WO/2014/033455. This patent describes:

"a method of detecting chromosomal abnormalities, in particular, the diagnosis of fetal chromosomal abnormalities such as trisomy 21 (Down's syndrome) which comprises sequence analysis of cell-free DNA molecules in plasma samples obtained from maternal blood during gestation of the fetus".

Illumina patent challenge

The big elephant in the investment room is Illumina's lawsuit brought against Premaitha for allegedly infringing its patents, despite the fact that Premaitha has a FTO opinion. It will most likely remain an overhanging issue to the share price pending the UK High Court case, scheduled for mid-2017. Despite this, however, Premaitha management remains confident in its position, supported also by the recognition that its IP estate underwent extensive due diligence prior to ThermoFisher investing into the company in December 2015 via a loan and warrants.

Illumina is claiming that Premaitha is infringing its assigned IP, namely the use of cell free DNA for non-invasive prenatal testing and the use of NGS genomic sequencing in diagnosing fetal chromosomal aneuploidy (abnormal number of chromosomes) and is seeking damages and injunctive relief. The key Premaitha patents as well as those allegedly being infringed are highlighted in the following table:

Key patent information

Patent	Description	Country	Proprietor	Filing date	Expiry
Premaitha patents:					
WO 2014/033455	Pre-natal counting for detection of trisomy and other chromosomal abnormalities	PCT*	Zoragen/ Premaitha	Aug-13	Aug-23
US13/996303	Pre-natal testing/diagnosis using nanopore sequencing	US	Loxbridge/ Premaitha	Dec-11	Dec-21
EP1180.44760	Pre-natal testing/diagnosis using nanopore sequencing	Europe	Premaitha/ Premaitha	Dec-11	Dec-21
US11/909557	Nucleic acid detection	US	Zoragen/ Premaitha	Mar-06	Mar-26
US11/036833	Nucleic acid detection	US	Zoragen/ Premaitha	Jan-05	Jan-26
Patents that are alleged to be infringed:					
EP 218 3693 B1	Diagnosing fetal chromosomal aneuploidy using genomic sequencing	Europe	Chinese Univ. of Hong Kong	Jul-08	Jul-28
EP 0994 963 B2	Non-invasive prenatal diagnosis	UK	Sequenom	Mar-98	Mar-18
EP 1981 995 B1	Non-invasive fetal genetic screening by digital analysis	UK	Leland Stanford Junior Univ	Feb-07	Feb-27

Source: Company reports, finnCap estimates * *PCT - International patent application under the Patent Cooperation Treaty*

The patents asserted are European Patent (UK) 0 994 963, European Patent (UK) 1 981 995 and European patent (UK) 2 183 693, which are said to be exclusively licensed to Illumina from Sequenom, The Board of Trustees of Leland Stanford Junior University, and The Chinese University of Hong Kong, respectively.

Timetable of patent litigation in the UK

Date	Comment
3 July 2017	Start of trial window
25 May 2016	Illumina to present arguments as to why actions are not anti-competitive and why counterclaim should not be accepted
21 April 2016	Illumina initiated patent infringement proceedings in Switzerland against Genoma SA, a Premaitha customer
20 April 2016	Case Management Conference (CMC) determinations: ‣ Rejected Illumina's application to change which patents would be determined at scheduled trial in October 2016 ‣ Accepted counter-proposal for a combined trial on all three patents to take place in July 2017 ‣ Trial to be held in conjunction with proceedings brought by Illumina against TDL Genetics, The Doctors Laboratory and Ariosa Diagnostics ‣ Ariosa Diagnostics and Premaitha are to cooperate on their invalidity attacks in respect of European Patent (UK) EP 0 994 963 ‣ Premaitha proposed an anti-trust defence and counterclaim which alleges Illumina's actions to be anti-competitive. On 25 May 2016 Illumina will present its arguments as to why this defence and counterclaim should not be accepted. On 13-15 June a hearing will be held to determine whether Premaitha's defence and counterclaim will be part of the patent litigation
8 January 2016	Illumina filed two patent infringement suits in Europe, against Premaitha's Polish customer as well as Ariosa Diagnostics (a Roche subsidiary) and their UK customer, The Doctors Laboratory
30 September 2015	Illumina added a 3rd patent (European patent (UK) 2 183 693) to the two previously asserted in a UK patent suit against Premaitha in the UK
16 March 2015	Illumina filed a patent infringement suit against Premaitha in the High Court of Justice, Patents Court in the United Kingdom. The patents asserted are European Patent (UK) EP 0 994 963 and European Patent (UK) EP 1981 995

Source: Company reports, finnCap estimates

Whilst impossible for us to judge the outcome of this case, we would point to the following factors that give confidence to management's claims that they do not infringe:

- Given the litigation within the NIPT market in the US, Premaitha commissioned a Freedom to Operate (FTO) analysis in 2014/15, in which legal opinion determined that there were no IP restrictions on commercialisation of the IONA test within Europe;
- ThermoFisher is understood to have undertaken extensive due diligence on the IP position, in the knowledge that Illumina had already brought an action against Premaitha and some of its customers, prior to its investment in Premaitha;
- At the Case Management Conference (CMC) in April 2016, the Judge ruled against Illumina's proposed ordering for the hearings on each patent in suit, deciding instead that a trial be heard that encompasses the claims made in respect of all three patents sought to be enforced against Premaitha as well as the proceedings brought by Illumina against Ariosa, TDL Genetics and The Doctors Laboratory;
- Ariosa Diagnostics will work together with Premaitha in its invalidity attacks against European Patent (UK) EP 0 994 963; and
- Claims of infringement, brought by Illumina against Sequenom in the US, were ultimately settled in December 2014, with an agreement to pool their patents regarding non-invasive prenatal testing. Illumina paid Sequenom $50m upfront, in addition to other significant ($64m minimum) payments/royalties pertaining to the pooled patent agreement through 2020. According to Sequenom (Q1 2016 earnings release) there are now 46 participants (licensees) in the "patent pool", up from 39 at 31 December 2015.

Even in a worst-case scenario in which the UK High Court determined that Premaitha and its co-defendants did indeed infringe Illumina's patents, there are many territories where the patent landscape is very different to the UK and where there is freedom to operate; for example, the US, where Illumina's challenge against Natera and Sequenom failed, and Asia.

In this situation, we consider it highly unlikely that Premaitha would be forced to remove its test from the market, thereby depriving patients of choice. Instead, we would envisage some form of licensing/cross-licensing arrangement to be agreed or for the Court to impose a fair and reasonable licence agreement on Illumina, thus mitigating the risk of an outright defeat.

In the meantime, it provides the company with a window of opportunity to build out the business without imminent court action. On balance, this recent ruling by the CMC should be seen positively, the downside being that it leaves open the fact that there is a longer-term overhang of patent litigation, but the upside being that it gives Premaitha the time to strengthen its defence and de-risk the company where possible through international expansion, as well as introduce the anti-trust angle to put Illumina's tactics under the spotlight.

Technology partner

IONA test run on leading manufacturers' instrument platforms…..

Premaitha has aligned itself with larger life science companies which provide the instrument platform(s) on which the IONA test is run. A laboratory customer for the IONA test is potentially a customer for ThermoFisher, Perkin Elmer or Qiagen. In the case of next generation sequencing platforms (NGS), Premaitha is using ThermoFisher's Ion Proton system.

… utilising ThermoFisher's next generation sequencing platform, Ion Proton

Both ThermoFisher and Illumina are intent on building content into their instrument platforms. The two companies have the leading NGS platforms that have reduced the costs of sequencing a genome from $3m twenty years ago to less than $1,000 today and the strategic imperative, having sold instruments to researchers, is to build out potential clinical applications. To that extent, Illumina, having originally sued Verinata for allegedly infringing its patents, acquired the company in 2012, moving into prenatal genetic testing.

ThermoFisher also provided a £5m investment

In December 2015 Premaitha signed an agreement with ThermoFisher to provide an investment of £5m in Premaitha in the form of a secured loan facility with £3m received in December 2015 and further milestone payments expected in 2016 and 2017:

- Interest will accrue at 6% per annum payable quarterly in arrears or capable of conversion to loan principal;
- Repayable between 14 December 2022 and 14 December 2023, with option to repay earlier; and
- Premaitha issued warrants to ThermoFisher over 20.3m new ordinary shares at an exercise price of 24.6p per share representing 8.2% of the so-enlarged issued share capital (7.1% on a fully diluted basis). The warrants will expire after 8 years.

Equally, ThermoFisher will benefit from the simple fact that for each laboratory that wants to set up a NIPT capacity utilising the IONA test, the laboratory will have to buy an NGS Ion Proton system. From Premaitha's perspective, it should be able to benefit from ThermoFisher's experience selling the combined test, in which it has a leading market position with clinical testing laboratories that already use the Kryptor prenatal assays (part of the combined test). This was part of BRAHMS AG, which was acquired by ThermoFisher in 2009 for c$470m (c$105m revenues).

From an investor's perspective, we suggest that they draw a high degree of comfort from the fact that ThermoFisher is understood to have undertaken extensive due diligence into the IP position before making this investment.

Revenue and costs

Revenue

We have modelled revenues based on the contracts announced to date (10 laboratory contracts and 7 service agreements) together with the expectation that the company is able to secure an additional 10 contracts over the next 2 years (2016-17), with further new customers in other geographic territories thereafter.

- We estimate IONA kit sales to be £1.9m in FY 2016, which implies c15,000 tests were sold, which can be attributed largely to the first four laboratory contracts (Switzerland, St Georges, London, Poland and the Wolfson Institute). We forecast this to rise to £5.09m, implying c40,000 kits in FY 2017 with full 12-month operations for these four centres as well as the 6 additional contracts that were signed prior to 31 March 2016. This is expected to rise to c£9.5m (76,000 tests) in FY 2018 and £14.9 (120,000 tests) in FY 2019. Given that each laboratory has the capacity to run c10-12,000 tests per annum, it implies that our forecasts for FY 2019 could theoretically be achieved if all 10 existing laboratory contracts are running at full capacity. Thus with 20 contracts (10 existing and 10 forecast), our forecasts are assuming that these laboratories are running at only 50% capacity, with the prospect, therefore of seeing the outer year forecasts rising as a consequence of increased capacity utilisation.
- We assume revenue from service-based contracts to build over the next few years, rising from c4,000 tests in FY 2017 to a maximum annualised capacity of c12,000 tests by end 2017, implying revenues of c£3m in FY 2019. Should demand on the service side rise beyond this level, Premaitha has the capacity to add an addition NGS and accompanying instrumentation for c£0.35m.
- Pass through revenues of £0.4m in FY 2016 relate to the sales of instrumentation from ThermoFisher and Qiagen when Premaitha assisted St Georges hospital with the set-up of its NIPT laboratory, for which we assume no gross margin contribution.

Revenue model

Year end March (£m)	2014A	2015A	I	II	2016E	2017E	2018E	2019E
IONA kit sales	0.00	0.00	0.52	1.21	1.74	5.43	9.49	14.89
% growth						212%	75%	57%
Service revenue	0.00	0.00	0.10	0.12	0.22	1.00	2.00	3.00
% growth						355%	100%	50%
Pass through revenue	0.00	0.00	0.00	0.40	0.40	0.00	0.00	0.00
Other income (incl. service contracts)	0.00	0.00	0.00	0.10	0.10	0.15	0.35	0.53
Total product revenue	**0.00**	**0.00**	**0.62**	**1.83**	**2.46**	**6.58**	**11.84**	**18.42**
% growth						167%	80%	56%
Grant income	0.10	0.13	0.00	0.00	0.00	0.00	0.00	0.00
Total revenue	**0.10**	**0.14**	**0.62**	**1.83**	**2.46**	**6.58**	**11.84**	**18.42**

Source: finnCap estimates

Cost of goods and gross profit

We forecast FY 2016 cost of goods to be c59% of revenues, comprising the costs of producing IONA kits, the costs of running IONA tests at its Manchester facility and the cost of purchasing equipment that was passed on at cost to St George's hospital. Looking to the future, we expect gross margins for move from the 38% expected in FY 2016 towards 50% by FY 2018 driven by improving service

margins as volume throughput increases towards 10,000 tests per annum, and economies of scale in the supply chain. As to the long term, we would anticipate gross margins of c50% for IONA test kits with competing pressures holding them at around that level; downwards pressure on price as IONA moves into 1st-level screening programmes offset by improvements in product/instrumentation developments and economies of scale in the supply chain.

It is possible that reagent rental deals will occur in future years with either explicit income reported or implicitly rolled up into higher reagent pricing.

Operating costs

Year end March (£m)	2014	2015	2016E	2017E	2018E	2019E
Cost of Goods	0.00	0.00	-1.52	-3.41	-6.01	-9.32
% of sales			*62.0%*	*51.8%*	*50.7%*	*50.6%*
Gross profit	**0.00**	**0.00**	**0.94**	**3.17**	**5.83**	**9.10**
Gross margin %			*38.0%*	*48.2%*	*49.3%*	*49.4%*
Administrative expenses	-1.25	-2.62	-4.46	-5.35	-5.72	-6.01
% growth			*70%*	*20%*	*7%*	*5%*
Research & Development	-0.38	-1.85	-1.85	-1.87	-1.89	-1.90
% growth			*0%*	*1%*	*1%*	*1%*
Share based payments	0.00	-0.35	-0.60	-0.60	-0.60	-0.60
Exceptional cost	0.00	-2.35	-0.04	0.00	0.00	0.00
Litigation provision	0.00	-0.50	-2.00	0.00	0.00	0.00
Total costs	**-1.63**	**-7.67**	**-8.94**	**-7.81**	**-8.21**	**-8.51**

Source: finnCap

Administration expenses

We expect administration expenses to have ramped up significantly, rising 70% to c£4.5m in FY 2016. We assume that these expenses rise by a further 20% in FY 2017 as Premaitha builds its sales and support teams, especially in Europe and Asia. Thereafter, we expect a more modest growth rate.

Research & Development expenses

Research & Development costs are expected to have been c£1.85m in FY 2016, in line with FY 2015E. Our forecasts assume only modest growth (1% per annum) over the period to FY 2019 and relate to ongoing development work with ThermoFisher to improve further the efficiency of the IONA test. This would change if the company is to develop a new cancer screening programme.

Litigation expenses

We expect stated EBITDA to be affected by two non-recurring items in FY 2016, namely £35k related to share issue expenses and a provision against future litigation expenses. Given the litigation timetable, outlined earlier, we have assumed that the company will have provided for additional legal expenses beyond the £1.4m indicated at the interim results. This is expected to take the provision for future litigation costs to c£2m at 31 March 2016.

Taxation and tax credit

We do not forecast any tax payments over the period to FY 2019, given accumulated losses to FY 2019 of c£23.5m. Our forecasts assume a tax asset of £1.2m at 31 March 2016, having risen to £0.9m at 30 September 2015. We assume that future R&D tax credits are lower (c£0.4m vs £0.8m) in subsequent years, given that Premaitha has now launched IONA and that any additional credits will relate to the development of next generation NIPTs.

Capital expenditure

Capital expenditure in FY 2016 is expected to be c£1.6m and relates to the work undertaken at its Manchester facilities. We expect future capital expenditure to be running at around £0.8-1.0m per annum, comprising largely replacement costs as well as modest reagent rental deals.

Loan facility and interest

ThermoFisher provided an initial £3m loan facility in December 2015. We have anticipated that some milestones will have been met and that Premaitha, consequently, will have drawn down c£0.5m of the remaining £2m facility as at 31 March 2016. The TMO loan is accruing interest at 6% pa annum, which we have rolled up into our forecasts for year-end (31 March 2016) debt of £3.55m. Looking to the future, we forecast that this loan facility rises to £4.5m in FY 2017 and £5m in FY 2018. With interest accumulating at 6% pa, the loan on the balance sheet rises to c£7m in FY 2019.

Net cash

Premaitha ended the year 31 March 2016 with cash of c£5.4m, and a loan facility that we estimate to have been c£3.5m provided by ThermoFisher, with the capacity to drawdown an additional £1.5m over 2017 and 2018. As a consequence, we consider the company to have working capital headroom to fund the business through to at least the end of FY 2017.

Income statement

Year end March (£m)	2014	2015	2016E	2017E	2018E	2019E
Revenue	**0.00**	**0.00**	**2.46**	**6.58**	**11.84**	**18.42**
revenue growth			*nm*	*167.5%*	*80.0%*	*55.6%*
Cost of Goods Sold	0.00	0.00	-1.52	-3.41	-6.01	-9.32
Gross Profit	**0.00**	**0.00**	**0.94**	**3.17**	**5.83**	**9.10**
gross margin			*38.0%*	*48.2%*	*49.3%*	*49.4%*
Administrative expenses	-1.25	-2.62	-4.45	-5.35	-5.72	-6.01
Research & Development	-0.38	-1.85	-1.85	-1.87	-1.88	-1.90
Share based payments	0.00	-0.35	-0.60	-0.60	-0.60	-0.60
Exceptional cost	0.00	-2.35	-0.04	0.00	0.00	0.00
Litigation provision	0.00	-0.50	-2.00	0.00	0.00	0.00
Total costs	-1.63	-7.67	-8.94	-7.81	-8.20	-8.51
Other income	0.10	0.13	0.00	0.00	0.00	0.00
Company Stated EBIT	**-1.53**	**-7.54**	**-8.00**	**-4.64**	**-2.37**	**0.59**
EBIT margin	*nm*	*nm*	*-325.5%*	*-70.6%*	*-20.1%*	*3.2%*
Exceptional costs	0.00	2.85	2.04	0.00	0.00	0.00
Share based payment	0.00	0.35	0.60	0.60	0.60	0.60
Adjusted' EBIT	**-1.53**	**-4.34**	**-5.37**	**-4.04**	**-1.77**	**1.19**
EBIT margin	*nm*	*nm*	*-218.3%*	*-61.5%*	*-15.0%*	*6.5%*
add back depreciation	0.08	0.26	0.61	0.72	0.83	0.92
add back amortisation	0.00	0.00	0.00	0.00	0.00	0.00
Adjusted' EBITDA	**-1.44**	**-4.08**	**-4.75**	**-3.32**	**-0.95**	**2.11**
'Clean' EBITDA margin	*nm*	*nm*	*-193.3%*	*-50.5%*	*-8.0%*	*11.5%*
Finance income	0.00	0.09	0.04	0.04	0.01	0.01
Finance expense	0.00	0.00	-0.05	-0.25	-0.32	-0.39
Profit Before Tax	**-1.53**	**-7.45**	**-8.01**	**-4.86**	**-2.69**	**0.21**
Adjusted PBT	**-1.53**	**-4.25**	**-5.37**	**-4.26**	**-2.09**	**0.81**
Taxation	-0.04	0.00	0.00	0.00	0.00	0.00
Net Profit	**-1.57**	**-7.45**	**-8.01**	**-4.86**	**-2.69**	**0.21**
Adjusted Net Profit	**-1.57**	**-4.25**	**-5.37**	**-4.26**	**-2.09**	**0.81**
Year End shares in issue (m)	38.0	181.7	228.2	228.2	228.2	228.2
Average shares in issue (m)	38.0	151.9	218.1	228.2	228.2	228.2
Fully diluted shares in issue (m)	38	182.4	263.7	263.7	263.7	263.7
Earnings per Share (EPS) p	-4.13	-4.89	-3.67	-2.13	-1.18	0.09
EPS growth		19%	-25%	-42%	-45%	-108%
Adjusted Earnings per Share (Adj EPS) p	**-4.13**	**-2.78**	**-2.46**	**-1.87**	**-0.91**	**0.36**
Adj EPS growth		-33%	-12%	-24%	-51%	-139%
Adjusted Earnings per Share (Fully Dil.) p	**-4.13**	**-2.32**	**-2.04**	**-1.61**	**-0.79**	**0.31**
Adj EPS growth		-44%	-12%	-21%	-51%	-139%
Dividend per Share (p)	0.0	0.0	0.0	0.0	0.0	0.0

Source: Company reports, finnCap estimates

Cashflow statement

Year end March (£m)	2014	2015	2016E	2017E	2018E	2019E
Cash from operating activities						
Profit before tax	-1.53	-7.45	-8.01	-4.86	-2.69	0.21
Finance income	0.00	-0.09	-0.04	-0.04	-0.01	-0.01
Finance expense	0.00	0.00	0.05	0.25	0.32	0.39
Deemed cost of reverse acquisition	0.00	1.62	0.00	0.00	0.00	0.00
Depreciation and amortisation	0.08	0.26	0.61	0.72	0.83	0.92
Loss on disposals	0.00	0.10	0.00	0.00	0.00	0.00
Increase in litigation provision	0.00	0.50	2.00	0.00	0.00	0.00
Share option & warrant exercise	0.00	0.40	0.60	0.60	0.60	0.60
Foreign exchange movements	0.00	-0.01	0.00	0.00	0.00	0.00
R&D tax credit	-0.25	-0.80	-0.40	-0.40	-0.40	-0.40
Provisions	0.00	0.00	-0.50	-0.70	-0.92	0.00
Cash flow from operations	**-1.70**	**-5.47**	**-5.69**	**-4.42**	**-2.27**	**1.71**
(Increase)/decrease in inventories	0.00	-0.45	-0.31	-0.36	-0.42	-0.49
(Increase)/decrease in receivables	-0.19	-0.05	-0.40	-0.77	-0.97	-1.01
Increase/(decrease) in payables	0.42	0.70	-0.47	1.03	1.43	1.71
Decrease in deferred income	0.00	0.00	0.00	0.00	0.00	0.00
Cash generated from operating activities	**-1.47**	**-5.28**	**-6.87**	**-4.52**	**-2.23**	**1.92**
R&D tax credit received	0.00	0.25	0.00	1.20	0.40	0.40
Net cash flow from operating activities	**-1.47**	**-5.03**	**-6.87**	**-3.32**	**-1.83**	**2.32**
Acquisition, net of cash acquired	0.00	1.23	0.00	0.00	0.00	0.00
Purchase of property plant & equipment	-0.52	-1.17	-1.70	-0.80	-0.85	-0.90
Purchase of intangible assets	0.00	0.00	0.00	0.00	0.00	0.00
Finance income	0.00	0.09	0.04	0.04	0.01	0.01
Net cash used in investing activities	**-0.52**	**0.15**	**-1.66**	**-0.76**	**-0.84**	**-0.89**
Net cash flow before financing	**-1.99**	**-4.88**	**-8.53**	**-4.08**	**-2.66**	**1.43**
Financing						
Issue of ordinary share capital	0.00	7.07	7.72	0.00	0.00	0.00
Net proceeds from borrowing	2.04	0.46	3.50	1.00	0.50	0.00
Dividends paid	0.00	0.00	0.00	0.00	0.00	0.00
Net cash flow from financing	**2.04**	**7.54**	**11.22**	**1.00**	**0.50**	**0.00**
Increase in cash and cash equivalents	**0.05**	**2.66**	**2.69**	**-3.08**	**-2.16**	**1.43**
FX changes impact on cash	0.00	0.00	0.00	0.00	0.00	0.00
Cash and cash equivalents at beginning of year	0.00	0.05	2.71	5.40	2.31	0.15
Cash and cash equivalents at end of year	**0.05**	**2.71**	**5.40**	**2.31**	**0.15**	**1.58**
Represented by:						
Cash in hand and at bank	0.05	2.71	5.40	2.31	0.15	1.58
Bank Overdrafts	-0.54	0.00	0.00	0.00	0.00	0.00
Other	-1.50	0.00	-3.55	-4.84	-5.96	-6.97
Net cash/(debt)	**-1.99**	**2.71**	**1.85**	**-2.53**	**-5.81**	**-5.39**

Source: Company reports, finnCap estimates

Balance sheet						
Year end March (£m)	2014	2015	2016E	2017E	2018E	2019E
Non-current assets						
Goodwill	0.00	0.00	0.00	0.00	0.00	0.00
Property, plant & equipment	0.44	1.35	2.43	2.51	2.53	2.51
Intangible assets	0.00	0.00	0.00	0.00	0.00	0.00
Non-current assets	**0.44**	**1.35**	**2.43**	**2.51**	**2.53**	**2.51**
Current assets						
Cash & cash equivalents	0.05	2.71	5.40	2.31	0.15	1.58
Inventories	0.00	0.45	0.76	1.12	1.54	2.03
Trade and other receivables	0.20	0.34	0.74	1.51	2.49	3.50
Tax Asset	0.25	0.80	1.20	0.40	0.40	0.40
Current assets	**0.50**	**4.30**	**8.10**	**5.34**	**4.57**	**7.51**
Total assets	**0.94**	**5.65**	**10.53**	**7.85**	**7.10**	**10.02**
Capital & Reserves						
Share capital	0.01	28.17	32.17	32.17	32.17	32.17
Share premium	0.00	23.31	27.02	27.02	27.02	27.02
Merger reserve	0.00	0.95	0.95	0.95	0.95	0.95
Reverse acquisition reserve	0.00	-39.95	-39.95	-39.95	-39.95	-39.95
Foreign exchange translational reserve	0.00	0.02	0.02	0.02	0.02	0.02
Retained earnings	-1.57	-8.61	-18.02	-22.28	-24.36	-23.55
Shareholder Funds	**-1.56**	**3.90**	**2.21**	**-2.05**	**-4.14**	**-3.32**
Non-controlling interest	0.00	0.00	0.00	0.00	0.00	0.00
Capital & Reserves	**-1.56**	**3.90**	**2.21**	**-2.05**	**-4.14**	**-3.32**
Long term liabilities						
Interest bearing liabilities	1.50	0.00	3.55	4.84	5.96	6.97
Provision	0.00	0.12	1.62	0.92	0.00	0.00
Deferred tax	0.04	0.04	0.04	0.04	0.04	0.04
Non-current liabilities	**1.54**	**0.16**	**5.20**	**5.80**	**6.00**	**7.01**
Current liabilities						
Bank overdraft	0.54	0.00	0.00	0.00	0.00	0.00
Obligations under finance leases	0.00	0.00	0.00	0.00	0.00	0.00
Trade and other payables	0.42	1.09	1.21	2.89	4.95	6.04
Deferred income	0.00	0.00	0.00	0.00	0.00	0.00
Litigation provision		0.50	1.91	1.21	0.29	0.29
Current liabilities	**0.95**	**1.59**	**3.12**	**4.10**	**5.24**	**6.33**
Total equity and liabilities	**0.94**	**5.65**	**10.53**	**7.85**	**7.10**	**10.02**

Source: Company reports, finnCap estimates

Key Shareholders

	%
Helium Rising Stars	12.8%
Directors	11.0%
Hargreave Hale	8.0%
Calculus Capital	5.6%

Management Summary

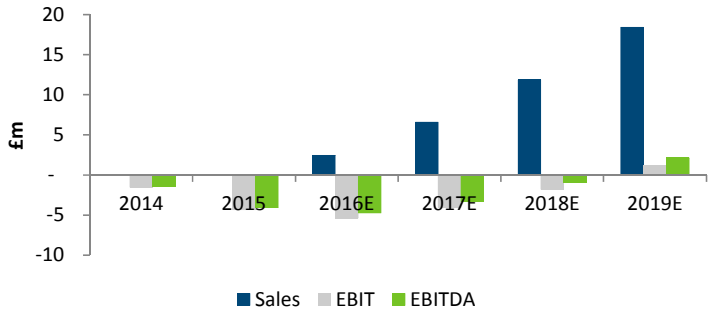
Name	Description
David Evans	Chairman
Dr Stephen Little	Chief Executive Officer
Barry Hextall	Chief Financial Officer
Peter Collins	Chief Business Officer
Dr William Denman	Chief Medical Officer
Nicholas Mustoe	Non-Executive Director
Adam Reynolds	Non-Executive Director
Dr Charles Roberts	Non-Executive Director

Source: Premaitha

Company Description

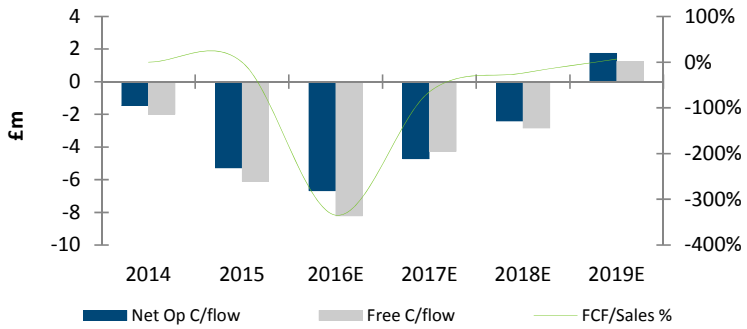
Premaitha is a molecular diagnostic company that has developed the IONA Test, an in vitro diagnostic non-invasive pre-natal screening test for fetal chromosomal abnormalities such as Down's syndrome. The IONA Test is based on the analysis of circulating fetal DNA in the maternal bloodstream, an approach that has been used since 2011 by several pre-natal screening companies, principally in the US. The IONA Test is the first and only regulated CE marked in vitro diagnostic non-invasive pre-natal screening product to market.

Sales and profits



Source: finnCap estimates

Cashflow



Source: finnCap estimates

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