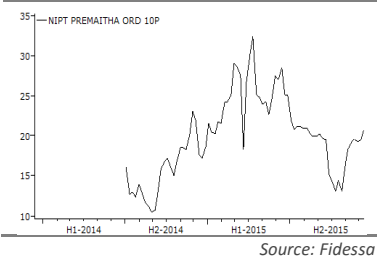


Pharmaceuticals & Biotech



Market data

EPIC/TKR	NIPT
Price (p)	20.0
12m High (p)	34.0
12 Low (p)	11.3
Shares (m)	228.2
Mkt Cap (£m)	45.6
EV (£m)	39.0
Free Float*	53%
Market	AIM

*As defined by AIM Rule 26

Description

NIPT is a molecular diagnostics company using the latest DNA analysis to develop tests for non-invasive pre-natal screening. Its flagship IONA[®] test is the first non-invasive in vitro CE marked diagnostic for pre-natal screening to estimate the risk of a foetus having Down's syndrome or other genetic conditions.

Company information

CEO	Stephen Little
CFO	Barry Hextall
Chairman	David Evans
	0161 667 6865
	www.premaitha.com

Key shareholders

Concert party	39.3%
Helium	6.2%
S&W	3.9%
WB	3.3%
Directors	10.3%

Next event

Jun-16	Trading update
Sep-16	Final results

Analysts

Mark Brewer	020 7148 1434
	mb@hardmanandco.com
Martin Hall	020 7148 1433
	mh@hardmanandco.com

Premaitha Health

Early IONA traction & investment agreement

Premaitha is a molecular diagnostics company that has used the latest advances in DNA technology to develop a non-invasive pre-natal screening test. IONA is its first test, for detection of genetic defects to estimate the risk that a foetus is carrying a disorder, such as Down's syndrome. Although IONA is entering a competitive market, it does have some advantages and is the first test to be regulatory approved via a CE Mark. Interim results show the first signs of commercial traction which are expected to accelerate herein. Also, Premaitha has signed a strategically important partnership with Thermo Fisher which adds considerable credibility.

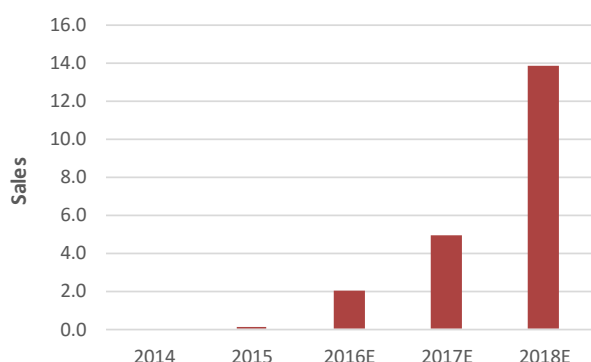
- ▶ **Interims:** 1H'16 results represent the first meaningful set of numbers since the IONA test was approved and launched. With five commercial relationships during the period, sales emerged at £0.6m. The underlying loss was £2.7m as the company built up laboratory testing facilities and commercial infrastructure.
- ▶ **IONA:** This test is a screen for risk assessment that a foetus has a serious genetic disorder. The test is extremely accurate (sensitive) with few false positives and eliminates the need for unnecessary invasive follow-up tests that cause anxiety and stress. An option for gender determination has just been added.
- ▶ **Strategic investment:** Premaitha also announced a strategic partnership with Thermo Fisher Scientific (TMO), that supplies the DNA sequencing instruments for the IONA pre-natal screen. TMO is investing £5.0m to help Premaitha improve its offering and the efficiency of the IONA test.
- ▶ **Risks:** After receiving CE Mark for IONA, Premaitha received notification that Illumina Inc. had filed patent infringement claims against the company. Although Premaitha will put up a vigorous defence and has provided £1.9m for costs, litigation is an expensive and time consuming distraction for management.
- ▶ **Investment summary:** Premaitha has an EV of £39m. The IONA test is the only product for NIPT with regulatory approval in Europe. Although the patent litigation is a distraction, commercial partnerships are being signed and these will drive future revenue growth. Our conservative assumptions, based on signed deals, still suggest that Premaitha will be EBITDA positive in fiscal 2018.

Financial summary and valuation

Year end March (£m)	2014	2015	2016E	2017E	2018E
Sales	0.00	0.00	2.00	4.95	13.85
R&D investment	-0.38	-1.85	-1.60	-1.80	-2.00
Underlying EBIT	-1.53	-4.34	-5.02	-4.25	0.00
Reported EBIT	-1.53	-7.54	-7.04	-4.85	-0.60
Underlying PTP	-1.53	-7.45	-6.99	-4.98	-0.85
Statutory PTP	-1.53	-7.45	-6.99	-4.98	-0.85
Underlying EPS (p)	-4.13	-4.89	-3.21	-2.18	-0.37
Statutory EPS (p)	-4.13	-4.07	-2.52	-1.73	-0.29
Net (debt)/cash	-1.99	2.71	3.93	-3.34	-5.71
Shares issued	0.00	7.48	7.72	0.00	0.00
EV/sales (x)	nm	nm	nm	8.1	2.9
EV/EBITDA (x)	nm	nm	nm	-11.3	42.8

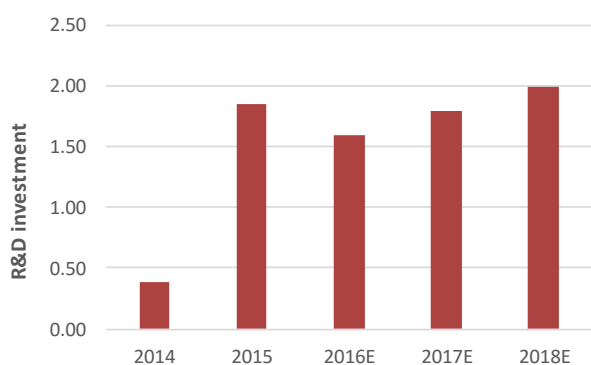
Source: Hardman & Co Life Sciences Research

Sales development



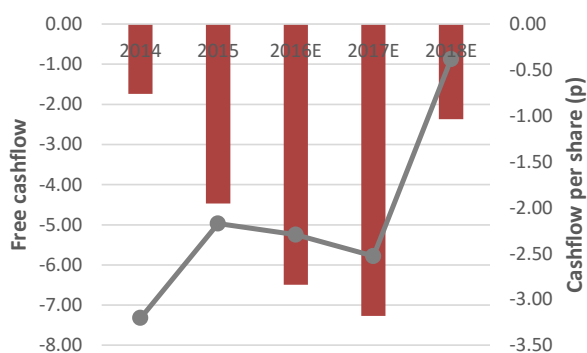
- ▶ Sales will mostly be derived from the supply of IONA kits or a full service for blood samples sent to the company's laboratory for testing
- ▶ Some 'pass through' sales will be derived from strategic clients whose clinical labs are funded initially by Premaitha
- ▶ After signing contracts, there is an initial set-up/validation phase after which sales develop quite rapidly
- ▶ Monitoring 'sales/client' ratio will be a useful future guide (KPI) to sales growth

R&D investment



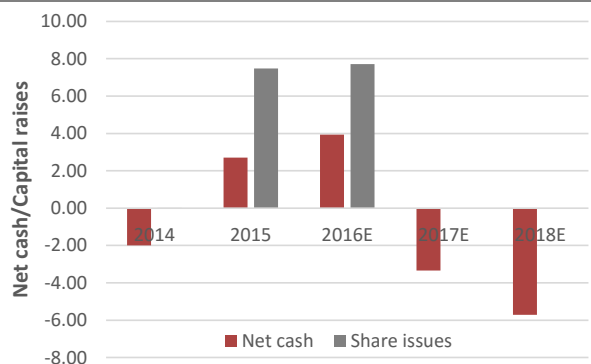
- ▶ An estimated £5m has been invested in R&D to get IONA to where it is today
- ▶ Further development to improve IONA functionality and increase the Premaitha offering will continue in future
- ▶ Management also intends to enhance the workflow efficiency of the test
- ▶ Liquid biopsies (early test for cancer) is an option in the future

Free cashflow



- ▶ Our forecasts for Premaitha are conservative, largely based on contracts/distribution agreements already announced
- ▶ Given that IONA has only been on the market for about six months, it is too early to predict uptake of the test
- ▶ Even on these cautious assumptions, Premaitha would approach cashflow breakeven towards the end of fiscal 2018
- ▶ Profitability and cashflows are extremely sensitive to small changes in sales forecasts

Net cash at 30th March



- ▶ At the end of September, Premaitha had cash of £6.6m
- ▶ This has been boosted by the £3.0m cash injection from TMO but, being in the form of a loan, it does not alter the net cash position
- ▶ Given sensitivity of forecasts to sales, announcements of new contracts would improve the the year-end net cash position
- ▶ In the event that Premaitha has to initially fund the establishment of strategic clinical labs, so a further capital injection might be required

Source: Company data; Hardman & Co Life Sciences Research

Interim results

Commercialisation of IONA has started...with 8 agreements to date

These interim results represent the first set of numbers to be reported since the regulatory approval and launch of Premaitha's non-invasive pre-natal screening test (NIPT) which estimates the risk of a pregnant woman having a foetus with Down's syndrome or other serious genetic disorders. Despite entering a relatively competitive market place, the IONA test has made substantial progress, with five (currently eight) supply/distribution agreements having been signed by Premaitha and generating sales of £0.6m. With further agreements on the horizon, this augurs well for future commercial traction of the test.

Premaitha will defend itself vigorously against Illumina...now with added support from TMO

Being the only approved, 'fully regulated' test outside China, IONA is clearly a threat to the competition, as evidenced by Illumina/Verinata Health claiming that the test infringes three of its patents. Premaitha is defending this challenge vigorously and has received further support from a major player – Thermo Fisher Scientific – whose sequencing instruments are tied in to the IONA test. Management is clearly aware of the distraction and potential cost of defending itself as evidenced by an increased litigation provision from £0.5m (March 2015) to £1.9m (at September 2015). Moreover, the TMO strategic investment announced today frees up more resource with which to fund the litigation costs.

Net cash at end of Sept was £6.6m...now boosted by TMO agreement

Following receipt of CE Mark for its IONA test, Premaitha raised £8.0m gross (£7.7m net) funds to support the commercial development of the IONA pre-natal screen. At the end of September, the company had £6.6m net cash in its balance sheet. This has been boosted by £3.0m as the initial tranche from the strategic investment being made by TMO, albeit in the form of a loan.

Summary half-year analysis						
Year end March (£m)	1H'15	2H'15	2015	1H'16	2H'16E	2016E
Sales	0.00	0.00	0.00	0.62	1.38	2.00
COGS	0.00	0.00	0.00	-0.37	-0.56	-0.92
Gross margin	nm	nm	nm	41.4%	45.6%	44.0%
SG&A	-2.35	-2.12	-4.47	-2.95	-3.15	-6.10
Other income (grants)	0.08	0.04	0.13	0.00	0.00	0.00
Underlying EBIT	-2.27	-2.07	-4.34	-2.69	-2.33	-5.02
EBIT margin	nm	nm	nm	nm	nm	nm
Share-based costs	-0.12	-0.22	-0.35	-0.32	-0.28	-0.60
Exceptionals	-2.05	-0.80	-2.85	-1.41	0.00	-1.41
Reported EBIT	-4.44	-3.09	-7.54	-4.42	-2.62	-7.04
Net financials	0.08	0.01	0.09	0.00	0.05	0.05
Underlying pre-tax	-2.19	-5.26	-7.45	-4.42	-2.57	-6.99
Reported pre-tax	-4.37	-3.08	-7.45	-4.42	-2.57	-6.99
Weighted average shares			151.89	208.05	228.16	217.42
Underlying EPS (p)			-4.89	-2.13	-1.09	-3.21
EBITDA			-4.08	-3.43	-1.11	-4.54
Operating cashflow			-3.30	-2.94	-3.45	-6.39
Cap-ex			-1.17	-0.88	-0.62	-1.50
Free cashflow			-4.47	-3.82	-4.07	-7.89
Share issues			7.48	7.72	0.00	7.72
Change in net debt			4.70	3.90	-1.09	2.80
Net cash/(debt)			2.71	6.61	2.53	2.53

Source: Hardman & Co Life Sciences Research

Commercialisation of IONA

Premaitha has three possible revenue streams from sales of IONA

Premaitha derives three sales streams from its IONA pre-natal screen:

- ▶ IONA test kit – sales of the kit to clinical testing labs and overseas distributors for an estimated £100-150 per kit
- ▶ Full service sales – where blood samples are sent to Premaitha’s labs to be analysed for an estimated £200-250 per test
- ▶ Pass through sales – Premaitha pays for the equipment required to set up a clinical testing facility and recovers this cost. The margin on this will essentially be zero, with Premaitha making money out of the subsequent supply of test kits

The majority of Premaitha sales will come from either the supply of kits (and reagents) to perform the IONA test, or providing a full test service to clients that send blood samples to the company’s laboratory. In some circumstances, Premaitha will fund strategic clients by paying the cost of setting up their laboratories and recover this outlay through leases, reagent rental, or profit share.

Commercial agreements

Five commercial agreements signed in 1H’16...currently eight...and expected to rise to 10 by end March...and 20 by end fiscal 2017

Since receipt of CE Mark in February 2015, Premaitha has signed eight supply and distribution agreements, five of which were during this reporting period. We anticipate that this will rise to 10 by the end of the current financial year (March 2016) and double again during fiscal 2017.

Following the signing of a commercial agreement there is typically a period of time (ca. 3 months) where laboratories are fitted out with the equipment required to run the IONA test, and validated. Therefore, contracts do not tend to be generating sales immediately. Should the signatory wish to offer the test to pregnant women immediately, they can send blood sample to Premaitha to run the service in its laboratories in Manchester. This has been the case with the St George’s Hospital, London contract. However, St George’s new lab is now fully functional and, in future, it will be running the screen independently using IONA kits supplied by Premaitha.

Key KPI going forward...sales of £155k per active client for 1H 2016

As the sales model becomes better developed and more commercial agreements get signed, we expect to use sales/contract as a key performance indicator (KPI), which will provide an objective method of growth. For 1H 2016, this ratio was £155k per active client.

Commercial agreements to date

Date	Country	Partner	Agreement type	Comment
5 Feb 2015	CE Mark Europe			
16 Mar 2015	Switzerland	Genoma SA	Clinical testing lab	Under TRANQUILITY brand
23 Mar 2015	UK	St George’s NHS Trust	NHS clinical testing lab*	First availability free on NHS
31 Mar 2015	Poland	Centrum Baden	Clinical testing lab	Private screening availability
22 Jun 2015	UK	“This is My”	Service agreement	Private screening availability
22 Sept 2015	Chile	Servicios Genéticos OriGen	Service agreement	Samples to UK for analysis
2 Oct 2015	Greece	Antisel SA	Distributor	Supplies network of clinical labs
13 Oct 2015	UK	Wolfson Institute	Clinical testing lab*	Charitable (part NHS) screening service
2 Dec 2015	France	Adgenix	Exclusive distributor	
2 Dec 2015	France	LaboSud	Private testing lab	Minimum 3-year contract

**Initially samples sent to Premaitha for service testing
Source: Company announcements; Hardman & Co Life Sciences Research*

**About 140m live births annually
...with 80m in countries offering
NIPT**

Commercial market opportunity

There is an overwhelming quantity of statistics available on birth rates around the world, which, ultimately, equates to the target market. Given that the World Health Organisation states that there were 136.8 million live births globally in 2013, the market opportunity is enormous. However, we believe that it is more sensible to focus on a potential market that is more realistically achievable.

Live birth statistics — 2013					
	Global	China	Europe	US	UK
Total births	136,800,000	18,500,000	5,075,380	3,932,181	778,800
Mother >35yrs	-	-	1,139,471	601,529	156,723

Source: WHO; Eurostat; ONS

**About 20% of births are to women
classified as 'high risk (age >35
years at birth)**

Using the statistic that about 20% of live births in countries offering pre-natal care are in high risk women over 35 years of age, the potential opportunity in countries where NIPT is available is 16m tests per annum. At an average price of \$500, this gives an end-user global market opportunity of \$8.0bn. In 2014, there were an estimated 1m NIPT tests performed, suggesting that the market has only been penetrated ca.6%.

- ▶ **Global market:** \$8.0bn based on 20% of live births to high risk women in countries where NIPT is available
- ▶ **US market:** \$300m for the high risk category based on average price of \$500 per test; some penetration of the average risk category which is expected to become routine over the next 25 months if prices are reduced to \$250-500 per test. No products formally approved by FDA
- ▶ **European market:** High risk market valued at \$550m and currently a very low uptake of NIPT – opportunity for IONA as the only product with CE Mark
- ▶ **UK market:** 'High risk' maternity market valued at \$80m – decision by UK National Screening Committee expected by end of 2015

**Apart from its CE Mark, IONA has a
number of advantages over other
tests**

Competitive landscape

At present, one of the most attractive features of IONA compared to the competing products is that it has received full external quality accreditation and CE Mark. This gives purchasers, whether they are clinical service labs (e.g. St George's NHS Trust) or kit purchasers, comfort that the product has been fully validated.

Comparison of tests		
Brand	Supplier	Approach
Harmony	Ariosa/Roche	Digital analysis of selected regions in an attempt to reduce time to result and cost by limiting sequencing to chromosomes of interest
IONA	Premaitha	Massively parallel sequencing (MPS) of whole DNA using ionosphere to amplify >100k times
Maternit21	Sequenom	Uses MPS (shotgun) to examine more genetic material which is time consuming and expensive
Panorama	Natera	Single nucleotide polymorphism (SNP) technology which isolates and eliminates the maternal genotype thereby theoretically making the test on foetal DNA more accurate
Verifi	Illumina	Uses MPS (shotgun) of 36/72 sequences and uses fixed primers and light fluorescence for only four base pairs making the test more time consuming and expensive to run

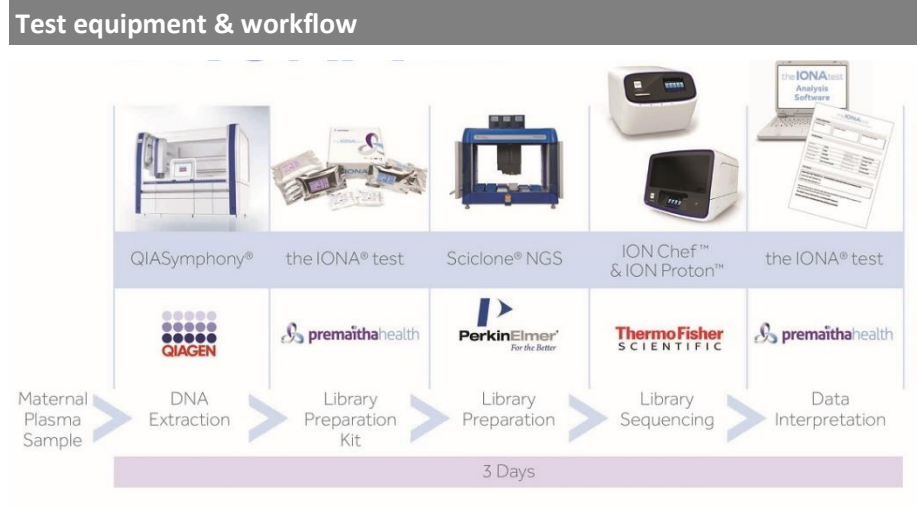
Source: Corporate websites; Hardman & Co Life Sciences Research

Investment agreement

Thermo Fisher Scientific (TMO)

Important strategic partnership announced with Thermo Fisher to support further development of the test

Along with its interim results, Premaitha also announced that it has signed a long-term investment agreement with one of its core suppliers – Thermo Fisher Scientific. The DNA library sequencing process within Premaitha’s IONA test is run on TMO’s Ion Torrent Proton and Ion Torrent Chef sequencing instruments which, unlike some of the reagents, cannot be substituted readily by instruments from an alternative manufacturer. Therefore, there is an inherent link between Premaitha and TMO. The aim of this agreement will be to support the further development of the IONA test through product extensions and to improve the workflow efficiency of the IONA screen.



Source: Premaitha Health

As part of this agreement, TMO has agreed to invest £5.0m into Premaitha in the form of a staged long-term loan and warrants over 20.325m ordinary shares at an exercise price of 24.6p per share.

Terms of the agreement

- ▶ Staged £5.0m loan to Premaitha attracting a coupon of 6%, with the first tranche of £3.0m received on signing the agreement
- ▶ Further tranches will be released as required over the next two years to fund Premaitha’s litigation costs in its patent infringement case with Illumina/ Verinata Health
- ▶ The loan is repayable between 14th December 2022 and 13th December 2023, with the option of being repaid earlier
- ▶ Warrants for £5.0m over Premaitha ordinary shares at a price of 24.6p per share (the price at close of business on day before signature), which expire on the eighth anniversary – 13th December 2023
- ▶ On exercise, the warrants would represent 7.1% of the fully diluted share capital of Premaitha

Importance of the agreement

In our opinion, this investment relays a number of important messages:

- ▶ Consolidation of the importance of TMO instruments to the IONA test
- ▶ Strengthens Premaitha's financial position in its court battle with Illumina
- ▶ TMO is unlikely to have made this investment without carrying out its own independent Freedom-to-Operate report, adding further validity to Premaitha's strong defence
- ▶ Increasing the ties between the IONA test and TMO's instruments could provide a potential exit strategy

***Partnership adds credibility,
financial support...and a possible
future exit route***

This agreement provides immediate financial support for Premaitha to continue the successful commercialisation of its IONA pre-natal screen and to provide resource towards its continual development. In addition, it frees up more financial resources to support Premaitha's litigation costs in proving non-infringement of Illumina's patents and sends a strong message to Illumina that it is no longer dealing with a cash-strapped minnow. From a shareholder's perspective, increasing the ties between Premaitha and Thermo Fisher might provide a long-term exit strategy.

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*Hardman & Co Research Limited (trading as Hardman & Co)
11/12 Tokenhouse Yard
London
EC2R 7AS
T +44 (0) 207 929 3399*

Follow us on Twitter @HardmanandCo

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Hardman & Co

11/12 Tokenhouse Yard
London
EC2R 7AS
United Kingdom

Tel: +44(0)20 7929 3399
Fax: +44(0)20 7929 3377

www.hardmanandco.com

