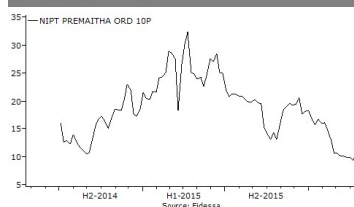


Pharmaceuticals & Biotech



Source: Fidessa

Market data

EPIC/TKR	NIPT
Price (p)	10.0
12m High (p)	34.0
12m Low (p)	8.0
Shares (m)	228.2
Mkt Cap (£m)	22.8
EV (£m)	16.2
Free Float*	74%
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 fetus 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

Directors	10.9%
Helium	12.8%
Hargreave Hale	8.0%
Calculus Capital	5.6%
IS Partners	4.5%

Next event

Sep-16	Final 2016 results
Oct-16	AGM

Analysts

Martin Hall	020 7148 1433	mh@hardmanandco.com
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Premaitha Health

Solid first year IONA sales; positive litigation update

Premaitha uses the latest advances in DNA sequencing technology for non-invasive prenatal screening tests. IONA[®] uses complex statistical analysis to determine the likelihood that a fetus is carrying a disorder such as Down's syndrome or other prenatal genetic abnormalities. Although IONA has entered a competitive and litigious market, it has some advantages, is CE Marked, and was first to win UK NHS contracts. Early signs of commercial traction for IONA were evident in the trading update. Also, a recent court hearing has positive outcomes: amalgamating all the defences against patent infringement brought by Illumina, delaying the potential start of the trial, and joining Premaitha up with Roche.

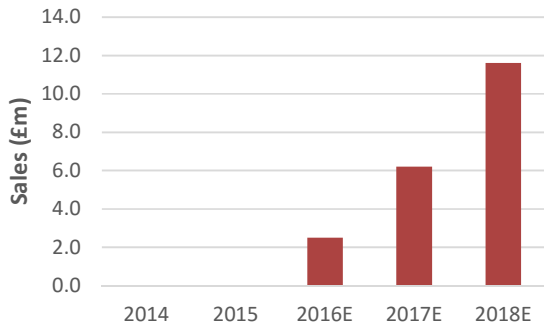
- **Strategy:** Premaitha is using the latest DNA analysis technology for non-invasive prenatal screening (NIPT). Management is focused on the commercialisation of its flagship IONA test worldwide. This diagnostic technology could be developed and used also for the early detection of other diseases, such as cancer.
- **Trading update:** Premaitha has announced that 2016 sales were towards the top-end of market expectations at £2.5m, most of which will be directly related to its IONA test. This suggests that the 1H:2H KPI of sales/active client was £145k:£165k. The period-end cash position was below expectations at £5.4m.
- **Valuation:** Similar quoted companies are more mature and have considerable sales from the US market. Companies looking for access to NGS technology have paid handsome prices, again for more mature companies. Now that sellers within the Concert Party have been cleared, the share price should recover.
- **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 £16.2m. The IONA test is the only complete NIPT with regulatory approval in Europe. Although patent litigation is a distraction, commercial partnerships are being signed and these are driving revenue growth. Our conservative assumptions, based on signed deals only, still suggest that Premaitha will be EBITDA positive in fiscal 2018.

Financial summary and valuation

Year end Dec (£m)	2014	2015	2016E	2017E	2018E
Sales	0.00	0.00	2.51	6.21	11.61
EBITDA	-1.44	-4.08	-4.19	-2.64	0.08
Underlying EBIT	-1.53	-4.34	-4.70	-3.40	-0.92
Reported EBIT	-1.53	-7.54	-6.71	-4.00	-1.52
Underlying PBT	-1.53	-7.45	-6.66	-4.17	-1.79
Statutory PBT	-1.53	-7.45	-6.66	-4.17	-1.79
Underlying EPS (p)	-4.13	-4.89	-3.07	-1.83	-0.79
Statutory EPS (p)	-4.13	-4.07	-2.40	-1.44	-0.62
Net (debt)/cash	-1.99	2.71	2.43	-3.23	-6.64
Capital increase	0.00	7.48	7.72	0.00	0.00
EV/sales (x)	nm	nm	nm	3.0	1.6
EV/EBITDA (x)	nm	nm	nm	nm	nm

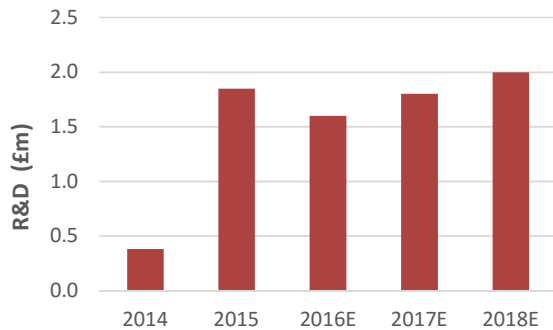
Source: Hardman & Co Life Sciences Research

Sales development



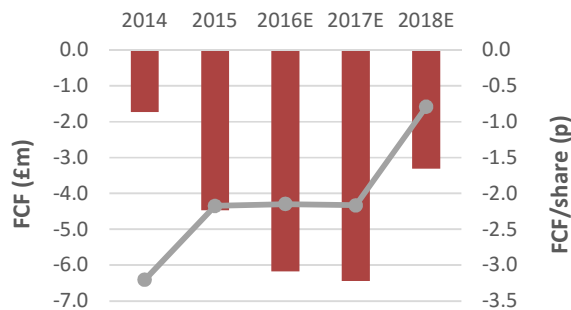
- ▶ Sales will mostly be derived from the supply of IONA kits or a full service for blood samples sent to the company's laboratory for testing
- ▶ Some 'pass through' sales will be derived from strategic clients whose clinical labs are funded initially by Premaitha
- ▶ After signing contracts, there 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



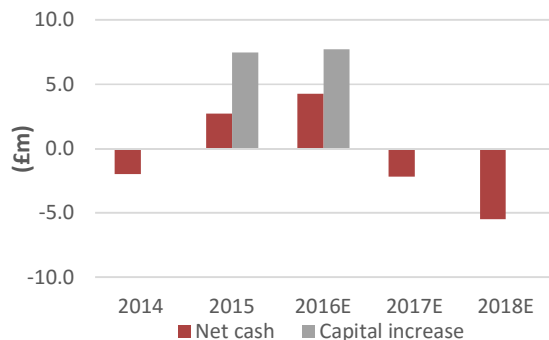
- ▶ An estimated £5m has been invested in R&D to get IONA to where it is today
- ▶ Further development to improve IONA functionality and increase Premaitha's offering will continue in future
- ▶ Management also intends to enhance the workflow efficiency of the test
- ▶ Liquid biopsies (early test for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

Free cashflow



- ▶ Our forecasts for Premaitha are conservative, largely based only on contracts/distribution agreements already announced
- ▶ Given that IONA has only been available for 12 months, it is too early to predict accurately the 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 March, Premaitha had cash of £5.4m
- ▶ This was boosted by the £5.0m (first tranche: £3.0m) cash injection from TMO but, being in the form of a loan, it does not alter the net cash position
- ▶ The year-end net cash position is sensitive to unpredictable items such as the timing of receipt of tax credits
- ▶ 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

Trading update

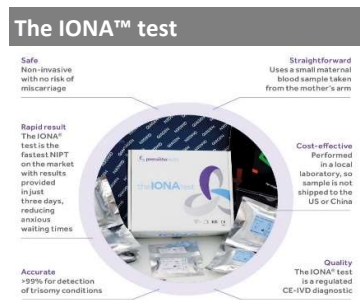
Following the period end, Premaitha has issued a trading update to the market for its fiscal year ending March 2016. The key points in the statement are as follows:

- ▶ Sales of £2.5m which “are at the upper end of revenue expectations”
- ▶ Revenues were mainly from four contracts with some additional sales from smaller customers using Premaitha’s testing service
- ▶ The cash balance at the period end was £5.4m – below expectations

The IONA test is a non-invasive prenatal test (NIPT) for pregnant women which estimates the risk that their fetus might have trisomy of one or more of chromosomes 13 (Patau’s syndrome), 18 (Edwards’ syndrome) and/or 21 (Down’s syndrome). The test is performed on a sample of maternal blood extracted after around 10 weeks of gestation and results are available in 3-5 days.

IONA® – the first year

IONA, Premaitha’s non-invasive pre-natal test, received regulatory approval via CE Mark on 5th February 2015, since when it has been made available to the market in two ways. First, clinical laboratories can purchase the complete IONA kit and run the service themselves. Alternatively, for small throughput providers, blood samples can be sent to Premaitha’s testing laboratory which will provide the service for a combined fee. The main focus during the first year has been to establish relationships with distributors and/or clinical laboratories in different countries that will then offer the test.



Source: Premaitha Health

Commercial strategy

Although a number of deals have been announced by Premaitha over the last year, it is difficult to state exactly how many countries where the IONA test is available. This is because, for example, Premaitha’s partner in Switzerland is testing samples from other European countries, making it more widely available than would appear from the number of individual country deals. In addition, Premaitha announced recently a deal to establish three strategically positioned clinical laboratories that will provide the service for all the territories in the Middle East. On a simplistic basis, IONA is available potentially in 10 countries plus the Middle East.

Availability of the IONA test

Announced deals

UK (NHS & private)	Armenia	France	Greece
Moldova	Poland	Russia	Switzerland
Chile	India	Middle East	

Source: Premaitha Health

Commercial opportunity

Given that there are about 140 million births globally each year and that ca.60% of these are in countries that offer NIPT screening, the commercial opportunity is enormous. The statistics readily available in Europe and the US indicate that 20% of these births are to ‘high risk’ women over the age of 35 years at parturition, the initial target market for the IONA test.

Around 20% of live births in Europe and the US are to ‘high risk’ women over 35 years of age...

...the key target for the IONA test

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

Accuracy of NIPT has been demonstrated to reduce by 80% the need for invasive confirmatory tests

Apart from peace of mind, where the data is available, the accuracy of NIPT tests has been shown to cause a near 80% reduction in the use of confirmatory amniocentesis and chorionic villus sampling, saving significant sums of money and reducing the risk of miscarriage.

Key performance indicator

As the sales model becomes better developed and more commercial agreements get signed and become active, we expect to use IONA sales per contract as a key performance indicator (KPI), which will provide an objective method of growth.

Based on initial sales reported in the recent interim results, this ratio was £155k per active client for 1H 2016. Premaitha has announced that sales for FY 2016 were approximately £2.5m, which suggests IONA sales of £2.1m after taking account of pass-through sales (eg setting up the lab at St Georges Hospital). This implies that 2H'16 sales were £1.49m. Although most of these will be from the four established clinical labs, there were estimated to be nine active labs during the second half, which gives a sales/client for 2H'16 of £165k.

IONA KPI

Half yearly progression	1H 2016	2H 2016E	1H 2017E	2H 2017E
IONA sales	£625k	£1,487k	£2,170	£3,394
Active laboratories	4	9	12	17
Sales/client	£156k	£165k	£181k	£200k

Source: Hardman & Co Life Sciences Research

Whilst we would express some caution regarding this KPI, as it is early days, it is important to get an understanding as to how the sales of IONA are developing. Given the number of new labs announced recently, we expect the KPI to progress positively in fiscal 2017.

Concert Party

Sellers from within the Concert Party has now been cleared out

Despite all the good news from Premaitha, the stock has underperformed over the last few months. In our opinion, this has been due to a large stock overhang where members of the Concert Party (largely the venture capital founders) from the time of the IPO have been looking to exit the stock to fund other early stage cash-intensive projects. It was announced that VC sellers no longer have any shares in Premaitha and those that remain in the Concert Party are mostly the Directors of the company. We believe that this large share sale will represent a nadir for the share price.

Investment conclusion

Acquirers have been willing to pay very high prices for novel technologies and assets

Premaitha is trading on an enterprise value of £16.2m, compared to an R&D investment of ca.£5m to get the company where it is today. Premaitha has made considerable progress in the first year of IONA sales, targeting the opportunities for NIPT outside the US. We expect to see even more progress during fiscal 2017 given the host of new countries/distributors coming on stream. Quoted peers are trading on considerably higher ratings and prices that acquirers have been prepared to pay for novel technology and assets also suggest considerable upside potential. Although it is difficult to make a direct comparison to Premaitha, it does provide a guide about value when there is greater evidence regarding IONA sales traction.

Litigation update

Premaita protects its intellectual property (IP) on a global basis wherever possible and, at the same time, is reviewing constantly its Freedom-to-Operate (FTO) by avoiding the infringement of IP owned by third parties.

Freedom to operate

Premaita has commissioned confidential and legally privileged FTO reports over recent years to ensure that the IONA test does not infringe the patents of other companies working in a similar space. Apart from their importance in the normal course of business of the company, these reports formed a significant part of the due diligence process required when Premaita sought its listing on the London Stock Exchange in 2014.

Therefore, it was a surprise when Premaita announced to the market in March 2015 that Illumina Inc and its wholly owned subsidiary, Verinata Health Inc, filed a patent lawsuit in the UK against the company asserting that its assigned patents had been infringed:

- ▶ EP0994963 – Non-invasive prenatal diagnosis (ISIS Innovation Ltd)
- ▶ EP1981995 – Non-invasive digital fetal genetic screening by digital analysis (Stanford University)

In October 2015, Premaita announced that Illumina had extended the infringement claim in the UK to include a third patent:

- ▶ EP2183693 – Diagnosing fetal chromosomal aneuploidy using genomic sequencing (Chinese University of Hong Kong)

Suffice to say, Premaita is vigorously defending these claims.

In January 2016, Illumina extended its IP claims by filing two patent infringement lawsuits in Europe. First, it filed against Premaita's customer in Poland along the same lines that it has used against Premaita in the UK. Secondly, it took a similar action against Roche, its wholly owned subsidiary Ariosa, and its main customer in the UK – The Doctors Laboratory.

Premaita had indicated previously to the market that the date for the first hearing on the first two patent challenges was likely to be October 2016.

Litigation update

Premaita has announced that a Case Management Conference was held in the High Court, London on Monday 18th April. Illumina had sought to change the order of the patent challenges to be heard in October 2016. However, the Court declined this and decided instead that a trial on all three patents should be heard together at a date most likely to be in the middle of 2017.

Moreover, the judge declared that this trial will be in conjunction with the proceedings that Illumina has brought also against TDL Genetics Limited, The Doctors Laboratory Limited, and Ariosa Diagnostics, Inc. Importantly, Premaita will work together with Ariosa (Roche) to defend against the invalidity attacks on the Illumina patents at issue.

In our opinion, this is good news for Premaitha. First, it means that Premaitha will obtain at least another year of IONA sales before the trial commences, during which it is expected to see considerable commercial traction. Secondly, Premaitha will be working together with a large corporate partner (Roche) in its defence which adds considerable credibility and clout.

Anti-trust action

As part of Premaitha's defence, the company had included an application of anti-trust against Illumina. This was presented to the Court as part of the Case Management Conference. The Judge ordered that Illumina, by the 28th May 2016, must present any arguments as to why Premaitha's application to include the anti-trust defence and counter-claim should not proceed.

Conclusion

Although we are not experts and have to rely on publicly available information, it appears that Premaitha has a very strong case in its defence against Illumina's patent infringement claims. Unfortunately, by its very nature, litigation can be a relatively slow process and a distraction that management could do without. However, in our opinion, the outcome of the Case Management Conference could not have been better for the company.

- ▶ Pressure on Illumina to prove that it has not embarked on anti-competitive behaviour by 28th May 2016
- ▶ Delay to the start of the patent trial at least until the middle of 2017, giving Premaitha another year to establish the commercial positioning of IONA
- ▶ The unusual approach for the trial to amalgamate all three patent challenges/counter claims – rarely are more than two heard together
- ▶ The combination of Premaitha and Roche to defend themselves against Illumina adds considerable credibility and fire-power

Financial summary

Lower cash position

Apart from the sales information, the other relevant piece of information in the trading statement was that the cash position at the end of March was £5.4m. This was approximately £2m below our forecast. Given that the sales were exactly in-line, although costs might be marginally higher than our expectations, we do not believe that this cash difference is derived from the P&L account. Therefore, the difference must be attributable to cap-ex, working capital and tax credits.

On reflection, we have increased our cap-ex by £150k to £1.65m, increased working capital (inventories and trade debtors) by £1m and taken the view that the anticipated tax credit of £0.8m did not materialise before the period end.

Profit & Loss account					
Year end March (£m)	2014	2015	2016E	2017E	2018E
IONA kit sales	0.00	0.00	1.86	4.36	7.91
Service income	0.00	0.00	0.25	1.20	2.40
Pass-through sales	0.00	0.00	0.35	0.50	1.00
Other	0.00	0.00	0.05	0.15	0.30
Total sales	0.00	0.00	2.51	6.21	11.61
COGS	0.00	0.00	-1.21	-2.97	-5.31
% sales	nm	nm	56.0%	52.0%	50.0%
SG&A	-1.25	-2.62	-4.40	-4.84	-5.23
% sales	nm	nm	nm	nm	49.3%
R&D	-0.38	-1.85	-1.60	-1.80	-2.00
% sales	nm	nm	74.0%	31.5%	18.8%
EBITDA	-1.44	-4.08	-4.19	-2.64	0.08
Deprec & Amortis	-0.08	-0.26	-0.51	-0.75	-1.00
Other income	0.10	0.13	0.00	0.00	0.00
Underlying EBIT	-1.53	-4.34	-4.70	-3.40	-0.92
EBIT margin	nm	nm	nm	-54.7%	-7.9%
Share based costs	0.00	-0.35	-0.60	-0.60	-0.60
Statutory EBIT	-1.53	-7.54	-6.71	-4.00	-1.52
Net financials	0.00	0.09	0.05	-0.17	-0.27
Pre-tax profit	-1.53	-7.45	-6.66	-4.17	-1.79
Exceptional items	0.00	0.00	0.00	0.00	0.00
Reported pre-tax	-1.53	-7.45	-6.66	-4.17	-1.79
Taxation	-0.04	0.00	0.00	0.00	0.00
Tax rate	nm	nm	nm	nm	nm
Underlying net income	-1.57	-7.43	-6.66	-4.17	-1.79
Statutory net income	-1.57	-7.43	-6.66	-4.17	-1.79
Weighted average shrs (m)	37.95	151.89	217.42	228.16	228.16
Fully diluted shares (m)	37.95	182.38	277.91	288.65	288.65
Underlying Basic EPS (p)	-4.13	-4.89	-3.07	-1.83	-0.79
U/I Fully-diluted EPS (p)	-4.13	-4.07	-2.40	-1.44	-0.62
Statutory Basic EPS (p)	-4.13	-4.89	-3.07	-1.83	-0.79
Stat. Fully-diluted EPS (p)	-4.13	-4.07	-2.40	-1.44	-0.62
DPS (p)	0.00	0.00	0.00	0.00	0.00

Source: Hardman & Co Life Sciences Research

Balance sheet

@ 31st March (£m)	2014	2015	2016E	2017E	2018E
Share capital	8.28	28.17	32.17	32.17	32.17
Reserves	-9.84	-24.28	-26.94	-31.11	-32.90
Minorities	0.00	0.00	0.00	0.00	0.00
Provisions	0.00	0.12	1.67	0.67	0.00
Deferred tax	0.04	0.04	0.00	0.00	0.00
Long-term loans	1.50	0.00	3.00	4.50	5.00
Bank overdrafts	0.54	0.00	0.00	0.00	0.00
less: Cash & securities	0.05	2.71	5.43	1.27	-1.64
less: Marketable securities	0.00	0.00	0.00	0.00	0.00
less: Non-core investments	0.00	0.00	0.00	0.00	0.00
Invested capital	0.47	1.35	4.48	4.97	5.91
Fixed assets	0.44	1.35	2.49	3.39	4.04
Intangible assets	0.00	0.00	0.00	0.00	0.00
Tax asset	0.25	0.80	1.20	1.00	1.00
Capitalised R&D	0.00	0.00	0.00	0.00	0.00
Inventories	0.00	0.45	0.75	0.95	1.14
Debtors less creditors	-0.22	-1.25	0.03	-0.37	-0.27
Invested capital	0.47	1.35	4.48	4.97	5.91
Net cash/(debt)	-1.99	2.71	2.43	-3.23	-6.64

Source: Hardman & Co Life Sciences Research

Cashflow

Year end March (£m)	2014	2015	2016E	2017E	2018E
Trading profit	-1.53	-4.34	-4.70	-3.40	-0.92
Depreciation	0.08	0.26	0.51	0.75	1.00
Amortisation	0.00	0.00	0.00	0.00	0.00
Inventories	0.00	-0.45	-0.30	-0.20	-0.19
Working capital	0.23	0.64	-1.20	-1.10	-1.32
Exceptionals/provisions	0.00	0.00	-0.70	-1.10	-0.50
Disposals	0.00	0.10	0.00	0.00	0.00
Other	0.00	0.14	0.00	0.00	0.00
Company op cashflow	-1.22	-3.65	-6.39	-5.04	-1.93
Net interest	0.00	0.09	0.05	-0.17	-0.27
Tax	0.00	0.25	0.00	1.20	0.45
Operational cashflow	-1.22	-3.30	-6.35	-4.01	-1.75
Capital Expenditure	-0.52	-1.17	-1.65	-1.65	-1.65
Sale of fixed assets	0.00	0.00	0.00	0.00	0.00
Free cashflow	-1.74	-4.47	-8.00	-5.66	-3.40
Dividends	0.00	0.00	0.00	0.00	0.00
Acquisitions	0.00	0.00	0.00	0.00	0.00
Disposals	0.00	1.23	0.00	0.00	0.00
Other investments	-0.28	0.00	0.00	0.00	0.00
Cashflow after investments	-2.01	-3.24	-8.00	-5.66	-3.40
Share repurchases	0.00	0.00	0.00	0.00	0.00
Share issues	0.00	7.48	7.72	0.00	0.00
Currency effect	0.00	0.00	0.00	0.00	0.00
Borrowings acquired	0.00	0.46	3.00	1.50	0.50
Change in net cash/(debt)	-2.01	4.70	2.72	-4.16	-2.90
Hardman FCF/S (p)	-3.20	-2.18	-2.92	-1.76	-0.77

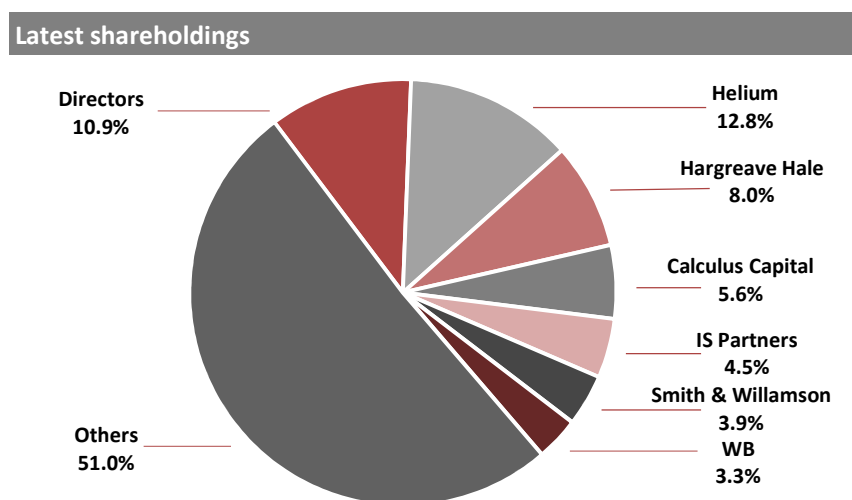
Source: Hardman & Co Life Sciences Research

Latest shareholder analysis

The shares have been under pressure for some months. Initially, this was thought to be due to the uncertainty surrounding the patent litigation and fears that potential distribution partners would not commit while this uncertainty was in place. However, we believe that a more significant reason has been the overhang of a very large amount of stock as members of the Concert Party – mostly the venture capital founders looking to exit to fund other early stage cash-intensive projects – sought to sell just over 40 million shares (ca.18%).

Removal of stock overhang

All of this stock has now been placed with existing and new shareholders. The following chart provides an updated share register following this change of share ownership.



Source: Company reports; RNS announcements

Conclusion

In our opinion, the removal of this share overhang, the positive performance of IONA in its first year of commercialisation, and the positive assessment of the litigation update is expected to result in a significant revaluation of the shares.

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(Disclaimer Version 2 – Effective from August 2015)

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