



Premaitha Health plc

(Formerly Vialogy plc)

Half Year Results for the period
ended 30 September 2014



Premaitha Health plc (Formerly Vialogy plc)

Introduction

In January 2014, the new Board members of Premaitha Health plc (Formerly Vialogy plc) ("the Company") Adam Reynolds and Mark Collingbourne recognised the need for a complete change of strategy and direction for the Company, which had technically become a cash shell. The intention was to find a suitable acquisition target via a reverse takeover that would transform the Company, have growth opportunities and enhance shareholder value over the long term.

In March 2014 negotiations were initiated with Premaitha Health Limited (Premaitha), which culminated in the announcement on 13 June 2014 of the acquisition of the entire issued share capital of Premaitha for £10.5 million in equity and a fund raising of £7.2 million.

At the General Meeting on 3 July 2014 all resolutions were passed and David Evans, Stephen Little, Peter Collins and Charles Roberts were appointed to the Board of the enlarged group, Premaitha Health plc.

Overview

The acquisition was a fundamental change in direction for the business. Premaitha is an innovative molecular diagnostics company employing the latest advances in DNA analysis technology to develop tests for non-invasive prenatal screening (NIPT) and other applications. Premaitha's flagship product, the IONA® test, will be the first non-invasive *in vitro* diagnostic product for prenatal screening enabling clinical laboratories to offer CE-marked NIPT in-house for the first time. The award of the CE mark is expected to take place in January 2015.

The immediate focus since IPO has been the development and regulatory approval of the IONA® prenatal screening product prior to its launch, which is anticipated in early 2015 following the CE mark award. The next six months will involve several major milestones for the Company about which we look forward to updating shareholders on in due course.

Financial review

In July 2014, Premaitha was acquired by the Company and the enlarged group was admitted to the AIM Market. The issued share capital of the Company on admission to AIM comprised 188,163,709 ordinary shares of 10 pence each. The Company raised £7.2 million (before expenses) by way of a placing and open offer at 11p. A significant amount of the funds raised were from institutional investors.

The company reported a loss for the period of £3.7m which includes a non-cash loss of £1.2m for the adjustments required under IFRS3, reverse acquisition accounting, share based payments and depreciation.

The IONA® test

Premaitha has made significant progress towards the goal of being the first company to offer laboratory customers a CE marked *in vitro* diagnostic product to allow them to offer non-invasive prenatal screening tests in their own institutions.

Market strategy

The possibility of a reliable and safe non-invasive prenatal screening test for Down's syndrome and other serious genetic diseases was first suggested in 1997 with the discovery that fetal DNA could be found in the maternal circulation. However, it has only been in the last few years with the development of next generation DNA sequencing technology that this has become a practical proposition.

In the US and Europe there are 11.5 million births per annum, therefore, there is a significant potential market opportunity for a reliable, more accurate and safe prenatal screening test, estimated in the range of c. US\$5-10 billion. The new generation of NIPT tests have impressive clinical performance but, unless they are readily available to pregnant women across the world, these benefits are of little value.

The IONA® test is designed to allow clinical laboratories, even without a background in DNA analysis technology, to offer the new NIPT tests thereby ensuring broad uptake and access to pregnant women. The product will initially be available in the EU.

Product development

The priority for the Company has been in preparing the IONA® test for its commercial launch which is expected to take place as planned in Q1 2015. To meet the needs of Premaitha's potential customers, there are a number of key features that the Management team have been focused on since admission in anticipation of launch.

- **Ease of Use and Throughput**

A typical prenatal screening laboratory will analyse thousands of blood samples from pregnant women in a single year therefore the laboratory process must be as robust and simple as possible.

As set out in the Company's Admission Document published on 13 June 2014 the priority for the last 6 months has been to "develop IONA® testing and interpretation system to meet user needs" and "Design Verification (Analytical Validation) of the IONA® test and software". The first of these activities is complete as is the second, with the exception of the final verification of the analysis software which will now take place in January 2015. This, latter step is not expected to affect the launch of the IONA® test scheduled for Q1 2015.

Premaitha scientists have finalised the first version of the IONA® test so that as much as possible of the workflow is automated, thereby minimising the hands-on time of the laboratory technicians who will operate the test.

- **Data analysis**

The IONA® test generates a significant amount of DNA sequence data which must be analysed to generate a report on the health of the fetus. In July 2014, Premaitha partnered with Sagentia Group plc, a leading global science, technology and product development company. The aim has been to develop the custom clinical bioinformatics analysis application that performs the test analysis, computes test results and generates test reports. This project has progressed well and the final version of the IONA® software is now available.

- **Clinical Performance**

It is essential that the IONA® test can correctly identify pregnancies which are either affected or unaffected with Down's syndrome and other genetic diseases. In initial tuning and testing studies of 351 samples, the test was 100% accurate and correctly identified all affected samples with sufficient fetal DNA (99.7%) Further clinical studies are now ongoing to confirm the test performance prior to launch and these will be completed prior to launch of the product with publication of the results to follow.

- **Regulatory Status**

To allow the sale of the IONA® test as an *in vitro* diagnostic (IVD) product it must meet the requirements laid down in the European IVD directive. This is ongoing with the first sections of the technical file already submitted to the notified body. This process is expected to be completed in Q1 2015.

- **Manufacture and Distribution**

The manufacturing process for the IONA® test reagents has been established with Premaitha's suppliers and an order has been placed for the first commercial batch which will be delivered before 31 December 2014.

Technical Support

An important feature of Premaitha's proposition to laboratory customers is the ability to offer training and technical support to laboratories who may not be familiar with the technology used in the IONA® test. To support this activity, Premaitha recently opened a new training suite in close proximity to its original development site and recruited heads of Technical Support and Clinical Testing. Premaitha has a long term commitment to supporting the IONA® test in its customer's laboratories and this function will expand further in 2015.

Sales and Marketing

The first step in establishing the Sales and Marketing operation was the appointment of Chief Commercial Officer, Peter Collins. He joined Premaitha at the time of the admission to AIM from GlaxoSmithKline where he was Vice President, Head of Diagnostics.

He is actively recruiting a sales and marketing team and, last month, the Company announced the appointment of Yves Derveaux who will support in leading business development for the IONA® test in Southern Europe. Further appointments are planned to strengthen the sales outreach in central Europe and to expand the technical product specialist team in Manchester.

The Company has also begun to promote the forthcoming availability of the IONA® test through its website and by attending and exhibiting at national and international conferences in the field of prenatal screening. There has been a good level of interest in the product, with over 200 expressions of interest from potential customers and distributors.

Outlook

Premaitha has made substantial advances over the past six months and will have the only non-invasive in vitro diagnostic product for prenatal screening enabling clinical laboratories to offer a CE-marked NIPT in-house for the first time. In the short term, the main focus for the Management team is finalising preparations – both regulatory and commercial – for the launch of the product as planned in Q1 2015 and then winning the first commercial contracts. As set out in the Admission Document, the focus of the R&D team will move to extending applications and platforms to provide customers with additional features and greater ease of use.

The Board is delighted with the progress of the Company since its admission to AIM in July 2014. The corporate landscape has changed dramatically, which is believed to be to the Company's advantage, witnessed last week by the acquisition of Ariosa Diagnostics by Roche. Premaitha is positioned within a market place that has exponential growth opportunities and the Board is confident of delivering enhanced shareholder value

David Evans
Chairman

Stephen Little
Chief Executive Officer

Date: 9 December 2014

Consolidated statement of profit or loss and other comprehensive income

For the seven months ended 30 September 2014

	Unaudited 1 March 2014 30 September 2014 Notes	Unaudited Period to 30 September 2013 £	Audited Period to 28 February 2014 £
Continuing operations			
Revenue	83,506	42,500	102,500
General and administrative expenses	(2,651,689)	(870,690)	(1,882,883)
AIM IPO costs	(436,819)	–	–
Deemed cost of reverse acquisition	(964,967)	–	–
Share based payments	(124,431)	–	–
Group operating loss	(4,094,400)	(828,190)	(1,780,383)
Interest received	76,864	–	–
Loss on ordinary activities before taxation	(4,017,536)	(828,190)	(1,780,383)
Tax on loss on ordinary activities	300,801	198,970	214,714
Loss for the period from continuing operations	(3,716,735)	(629,220)	(1,565,669)
Exchange translation differences	(4,284)	–	–
Total comprehensive loss for the period	(3,721,019)	(629,220)	(1,565,669)
Attributable to:			
Owners of the parent	(3,721,019)	(629,220)	(1,565,669)
	(3,721,019)	(629,220)	(1,565,669)
Loss per share:			
Loss per share – basic and diluted, attributable to ordinary equity holders of the parent (pence)	3 (3.55)	(0.06)	(0.64)

Consolidated statement of financial position

As at 30 September 2014

	Notes	Unaudited As at 1 March 2014 to 30 September 2014 £	Unaudited As at 8 March 2013 to 30 September 2013 £	Audited As at 8 March 2013 to 28 February 2014 £
Assets				
Non-current assets				
Intangible assets	4	–	–	–
Property, plant and equipment		1,003,997	312,745	436,380
R & D tax credits		555,060	198,970	254,259
Total non-current assets		1,559,057	511,715	690,639
Current assets				
Trade and other receivables		314,719	199,267	196,536
Cash and cash equivalents		5,238,614	27,904	49,850
Total current assets		5,553,333	227,171	246,386
Total assets		7,112,390	738,866	937,025
Equity and liabilities				
Equity				
Share capital	5	28,173,133	1,000	8,281
Share premium	5	23,310,939	–	–
Merger relief reserve		954,545	–	–
Reverse acquisition reserve		(40,597,348)	–	–
Share based payment reserve		124,431	–	–
Retained earnings		(5,286,688)	(629,220)	(1,565,669)
Equity attributable to owners of the parent		6,679,012	(628,220)	(1,557,388)
Non-controlling interests		–	–	–
Total equity		6,679,012	(628,220)	(1,557,388)
Current liabilities				
Trade and other payables		393,833	223,973	312,457
Borrowings		–	–	538,133
Total current liabilities		393,833	223,973	850,590
Non-current liabilities				
Trade and other payables		–	–	104,278
Borrowings		–	1,143,133	1,500,000
Deferred tax liability		39,545	–	39,545
Total non-current liabilities		39,545	1,143,133	1,643,823
Total equity and liabilities		7,112,390	738,886	937,025

Consolidated cash flow statement

For the seven months ended 30 September 2014

	Unaudited 1 March 2014 to 30 September 2014	Unaudited 8 March 2013 to 30 September 2013	Audited 8 March 2013 to 28 February 2014
Notes	£	£	£
Cash flows from operating activities			
Group operating loss	(4,017,536)	(828,190)	(1,780,383)
Finance income	(76,864)	–	–
Deemed cost of reverse acquisition	964,967	–	–
Depreciation	94,236	39,620	84,920
Share option expense	124,431	–	–
Foreign exchange movements	(4,284)	–	–
Net cash flow from operating activities before changes in working capital	(2,915,050)	(788,570)	(1,695,463)
(Increase)/Decrease in trade and other receivables	(28,183)	(198,267)	(191,730)
Increase/(Decrease) in trade and other payables	(102,902)	223,973	416,735
Net cash flow from operating activities	(3,046,135)	(762,864)	(1,470,458)
Cash flow from investing activities			
Purchase of property, plant and equipment	(557,853)	(352,365)	(521,300)
Acquisition, net of cash acquired	1,229,127	–	–
Interest received	76,864	–	–
Net cash flow from investing activities	(748,138)	(352,365)	(521,300)
Cash flow from financing activities			
Proceeds from issue of equity instruments	6,986,761	–	3,475
Proceeds from borrowing	500,000	1,143,133	2,038,133
Net cash flow from financing activities	7,486,761	1,143,133	2,041,608
Net change in cash and cash equivalents	5,188,764	27,904	49,850
Cash and cash equivalents at beginning of period	49,850	–	–
Cash and cash equivalents at end of period	4 5,238,614	27,904	49,850

Consolidated statement of changes in equity

For the seven months ended 30 September 2014

	Share capital	Deferred shares	Share premium account	Merger relief reserve	Reverse acquisition reserve	Share based payment reserve	Retained earnings	Total
	£	£	£	£	£	£	£	£
Premaitha Health Limited								
Balance at 1 March 2014	8,281	–	–	–	–	–	(1,565,669)	(1,557,388)
Issue of share capital:	4,798	–	–	–	–	–	–	4,798
Loss for the period	–	–	–	–	–	–	(3,721,019)	(3,721,019)
Premaitha Health plc								
Balance at 1 March 2014	2,689,460	–	–	–	–	–	–	2,689,460
Issue of share capital	16,113,832	9,356,762	23,310,939	954,545	–	–	–	50,333,868
Charge for the period on the reverse acquisition of Premaitha Health Limited	–	–	–	–	(40,597,348)	124,431	–	(41,070,707)
Balance at 30 September 2014	18,816,371	9,356,762	23,310,939	954,545	(40,597,348)	124,431	(5,286,688)	6,679,012

Notes

1 General information

Premaitha Health plc is a company incorporated and domiciled in England and Wales. Details of the registered office, the officers and advisers to the Company are presented on the Company information page at the end of this report. The Company's offices are in Manchester. The Company is quoted on the AIM market of the London Stock Exchange (ticker: NIPT.L). The Company is a molecular diagnostics company employing next generation DNA analysis technology to develop, manufacture and sell molecular diagnostic products intended to have a major beneficial impact on human health.

2 Basis of preparation

The financial information for the seven months ended 30 September 2014 and period from incorporation to 30 September 2013 is unaudited.

Basis of consolidation

In July 2014 Premaittha Health plc acquired via s share for share exchange the entire share capital of Premaittha Limited. Under IFRS 3 'Business combinations' the Premaittha Limited share exchange has been accounted for as a reverse acquisition.

Although the consolidated financial information has been issued in the name of the legal parent Premaittha Health plc, it represents in substance continuation of the financial information of the legal subsidiary Premaittha limited.

The Interim Report has been prepared using the same accounting policies as were applied in the Premaittha Limited's audited financial statements to 28 February 2014, which have been prepared in accordance with International Financial Reporting Standards ("IFRS"). The Directors consider that the financial information presented in this Interim Report represents fairly the financial position, operations and cash flows for the period, in conformity with IFRS. The Interim Report for the six months ended 30 September 2014 was approved by the Directors on 9 December 2014.

The assets and liabilities of the legal subsidiary, Premaittha Health Limited are recognised and measured in the Group financial statements at the pre-combination carrying amounts, without restatement of fair value. The retained earnings and other equity balances recognised in the Group financial statements reflect the retained earnings and other equity balances of Premaittha Health plc immediately before the business combination and the results of the period from 1 March 2014 to the date of the business combination are those of Premaittha Health Limited. However, the equity structure appearing in the Group financial statements reflects the equity structure of the legal parent, Premaittha Health plc, including the equity instruments issued in order to effect the business combination; and comparatives numbers presented in the financial statements are the consolidated numbers of Premaittha Health Limited for the periods ended 30 September 2013 and 28 February 2014.

The aggregate deemed fair value of the consideration paid, assets and liabilities acquired and resulting charge to the income statement in respect of the above acquisition is £965k.

Merger relief reserve

The reserve represents a premium on the issue of the ordinary shares for the acquisition of subsidiary undertakings. The relief is only available to the issuing company securing at least a 90% equity holding in the acquired undertaking in pursuance of an arrangement providing for the allotment of equity shares in the issuing company on terms that the consideration for the shares allotted is to be provided by the issue of equity shares in the other company.

The financial information presented for the period 28 February 2014 is an extraction from Premaittha's audited accounts on which the auditors issued an unqualified report, the information presented does not constitute full accounts for that period.

3 Loss per share

Basic loss per share is calculated by dividing the loss attributable to equity shareholders by the weighted average number of ordinary shares in issue during the period:

	Unaudited 30 September 2014 £	Unaudited 30 September 2013 £	Audited 28 February 2014 £
Loss after tax attributable to equity holders of the parent	3,721,019	629,220	1,565,669
Weighted average number of ordinary shares in issue ('000)	104,870,874	1,039,523,650	2,014,231,609
Basic and diluted loss per share (pence)	(3.55)	(0.06)	(0.08)

Basic and diluted earnings per share are the same, since where a loss is incurred the effect of outstanding share options and warrants is considered anti-dilutive and is ignored for the purpose of the loss per share calculation. The share options outstanding as at 30 September 2014 totalled 30,488,332 (30 September 2013: 33,890,242, 31 March 2014: 261,916,546) and are potentially dilutive.

The weighted average number of ordinary shares for the period ended 30 September 2014 has been restated to reflect the total number of shares arising from the share for share exchange on acquisition and is considered to be in place from the earliest period.

4 Cash and cash equivalents

	Unaudited 30 September 2014 £	Unaudited 30 September 2013 £	Audited 28 February 2014 £
Cash at bank	5,238,614	27,904	49,850
Cash and cash equivalents	5,238,614	27,904	49,850

5 Share capital

Allotted, called up and fully paid

	Ordinary shares of £0.10 each		Deferred shares of £0.009 each		Share Premium account £	Total consideration £
	Number	Nominal value £	Number	Nominal value £		
Premaitha Health Limited						
Balance at 1 March 2014	828,100	8,281	–	–	–	8,281
Shares issued	479,800	4,798	–	–	–	4,798
Premaitha Health plc						
Balance at						
1 March 2014	2,689,460,366	2,689,460	–	–	–	2,689,460
Shares consolidation	(2,662,565,762)	–	–	–	–	–
Shares issued	159,961,205	16,113,832	1,039,640,244	9,356,762	23,310,939	48,781,533
Balance at 30 September 2014	188,163,709	18,816,371	1,039,640,244	9,356,762	23,310,939	51,484,072

The comparative figures for share capital in the financial statements are for Premaitha Health Limited for the period ended 30 September 2013 and for the period ended 28 February 2014.

On 4 July 2014 through an ordinary resolution the Company's share capital was reorganised as follows:

- Every 100 Ordinary shares held by a shareholder was consolidated into 1 Ordinary share of £0.10

The Company issued 95,545,545 new Ordinary shares of £0.10 each at £0.11, 59,090,909 Ordinary shares of £0.10 each at £0.11 by way of a placing and 6,723,651 Ordinary shares of £0.10 each at £0.11 by way of an open offer to acquire the share capital of Premaitha Health Limited.

6 Subsequent events

There are no subsequent events to report.

7 Copy of the Interim Report

Copies of the Interim Report are available to download from the Company's website at www.premaitha.com



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