



Premaitha Health PLC

Interim Financial Report to 30 September 2015

Company number: 3971582



## Premaitha Health PLC

### Results for the half year ended 30 September 2015

#### Financial position

- Revenues of £0.6m (H1 2014: £0.1m) generated from early sales of the IONA® test.
- Loss before one-off and non-cash items of £2.7m (H1 2014: £2.3m) reflecting recruitment of staff, product development and commercialisation activities.
- July 2015, oversubscribed placing raised £8.0m at 20p per share.
- Cash balance at the period end was £6.6m (H1 2014: £5.2m).
- Provision for anticipated litigation costs increased to £1.9m (FY 2015: £0.5m) to enable strong defence against Illumina patent infringement claims.
- £5.0m investment by Thermo Fisher announced today in the form of secured loans and warrants (see separate announcement).

#### Operational highlights

- IONA®, the CE-marked non-invasive prenatal test (NIPT), installed in four laboratories in the UK, Switzerland and Poland, now generating revenues and organically growing with Premaita's support.
- First French customer announced and now in set-up phase.
- NIPT clinical testing service launched from Manchester and Care Quality Commission registration received. Now migrated to dedicated facility with first customers in UK and Chile.
- Two independent clinical performance studies of the IONA® test showed 100% accuracy with 0% false positives.
- European reimbursement policies starting to emerge, firstly in Switzerland, to complement private sector early movers. Other countries expected to follow suit in the near future.
- Management changes – appointment of Barry Hextall as CFO and Dr William Denman as CMO.

#### Dr Stephen Little, CEO of Premaita, said:

*“The first half of our financial year has seen our first four customers go live in three different countries and start to generate revenues with the IONA® test. We also saw the publication of excellent clinical results and are participating in the world's first reflex DNA screening project with the prestigious Wolfson Institute. These achievements demonstrate the high quality and clinical relevance we have built into the IONA® test, the first CE-marked NIPT product which we launched in February 2015.*

*“We continue to enhance the test for laboratory efficiency and include clinically-relevant features such as the recently added fetal sex determination option. We remain on course for our target of 10 contract wins this financial year, despite the unpredictable timing inherent in such a complex sales process and the distraction of a non-CE marked competitor's litigation.*

*“Today's announcement of a partnership with Thermo Fisher also represents a significant opportunity for Premaita.”*

## **Chairman's statement**

I am pleased to present Premaitha Health's interim results for the six months to 30 September 2015. During the period we have made significant progress in introducing the IONA<sup>®</sup> non-invasive prenatal test into various international markets, in demonstrating its excellent clinical performance and in building the capabilities of the Company. We have achieved all this despite the ongoing litigation which we remain confident we will rebuff. During the period we made two appointments to the Board in Barry Hextall, Chief Financial Officer, and Dr William Denman, Chief Medical Officer. The partnership with Thermo Fisher announced separately today also opens up significant opportunities for the Group going forward.

## **Overview**

During the period we installed the IONA<sup>®</sup> NIPT test in four customer laboratories in three countries (UK, Switzerland and Poland) and have started processing patient samples from the UK and Chile in our Care Quality Commission-registered in-house clinical service facility. A fifth laboratory in France was recently announced and we remain on track for our target of 10 contracts this financial year. This represents a significant first step in our ambitious commercialisation plans. We are now seeing revenue pull-through on these contracts and we are supporting these customers as they increase penetration of NIPT testing in their target populations. We have also appointed distributors in Greece and France.

In the period there were also two separate clinical studies published by eminent clinicians, both of which produced results of 100% accuracy and 0% false positives for the IONA<sup>®</sup> test, reflecting the strong clinical foundations on which our test is based.

Switzerland became the first European country to approve reimbursement for NIPT as a secondary screening test and we expect other countries to follow suit in the not too distant future. We believe the testing criteria will be broadened over time until eventually NIPT is made available to all pregnant mothers in the medium term. In the meantime, the private markets are expanding quickly to provide the greater accuracy and peace of mind that NIPT offers.

Product development activities are focused on improving the existing test and the IONA<sup>®</sup> software in terms of laboratory efficiency and also by providing additional requested features that have a sound clinical basis, such as the option for fetal sex determination which we have recently added. We remain focused on making the test more attractive to laboratory customers and to our clinical partners. We are also exploring ways to apply our technology and knowhow to other potential applications in this fast evolving field.

The Illumina litigation remains a distraction to the Company and to customers who are contemplating a significant financial investment in an already-complex purchasing decision. This has inevitably slowed decision-making. However, we are pleased to see that customers are seeing through this opportunistic attempt of a non-CE marked competitor to slow us down and are continuing to sign up to our superior offering. The legal process will be lengthy but customers and investors can rest assured that we will mount the strongest possible defence – reflected in the increased financial provision – and we remain confident of the strength of our position.

## Financial position

The Group's results for the six months to 30 September 2015 are presented in the financial statements and show first trading revenues of £624,988 (H1 2014: £83,506) and a gross profit of £259,029 (H1 2014: £83,506).

General administrative expenses before one-offs and non-cash items increased to £2,913,191 (H1 2014: £2,350,888) as we build our commercial capabilities. The litigation provision increased by £1,413,248 (H1 2014: £0) reflecting initial legal costs paid out and an increase in the estimate of future costs to mount a strong defence.

The total comprehensive loss was £4,422,357 (H1 2014: £4,371,334) and the loss per share was £0.02 (2014: £0.04).

The Group concluded an oversubscribed share issue in July 2015, raising £8,000,000 before fees and commissions at an issue price of 20 pence per share. Cash and cash equivalents at the end of the period were £6,605,374 (H1 2014: £5,238,614).

After the period end, the Company has announced today the completion of an investment by Thermo Fisher which will provide secured loan finance of £5,000,000 and the issuance of £5,000,000 in warrants exercisable at 24.6 pence per share.

## Outlook

The overall outlook for the uptake of NIPT at a macro level is increasingly positive with recent moves in certain European territories indicating that non-invasive screening will become the norm, the question is not if but when. We believe expectant mothers should be offered the choice now irrespective of their economic status.

At a Company-specific level, the outlook continues to be dominated by the impact of the outstanding litigation. As announced today the investment from Thermo Fisher significantly strengthens our position as a Company overall and hopefully this will instil the same level of confidence in you as a Shareholder as it has done for me as Chairman.

We have much work to do to build the business we know Premaitha can become and I am encouraged with the positive start we have made since launching the IONA<sup>®</sup> test in February this year. The foundations for a successful business are being laid and I would like to thank our whole team for their commendable efforts to date.

We have a good pipeline of prospects and we are confident that we will continue to build our revenues throughout the forthcoming period. The direction of travel remains very positive even if the absolute timing of contract wins is difficult to predict particularly when we are bidding in a tender process. Until we reach a critical mass of revenues it is inevitable that we will all have to live with the uncertainty of revenue timing. However, we remain very confident overall for the prospects for the Company and we have created something that is strategically valuable.

Premaitha Health PLC

Consolidated income statement for the six months ended 30 September 2015

	Unaudited 6 months to 30 September 2015	Unaudited 7 months to 30 September 2014 <i>(restated – note 7)</i>	Audited 13 months to 31 March 2015 <i>(restated – note 7)</i>
Notes	£	£	£
<b>Continuing Operations</b>			
Revenue	624,988	83,506	132,267
Cost of sales	(365,959)	-	-
<b>Gross profit</b>	<b>259,029</b>	83,506	132,267
General administrative expenses	(2,913,191)	(2,350,888)	(4,468,129)
Fundraising expenses	(35,422)	(436,819)	(738,604)
Deemed cost of reverse acquisition	-	(1,615,282)	(1,615,282)
Increase in litigation provision	(1,413,248)	-	(500,000)
Share-based payments charge	(317,130)	(124,431)	(345,769)
Total administrative expenses	(4,678,991)	(4,527,420)	(7,667,784)
<b>Operating loss</b>	<b>(4,419,962)</b>	(4,443,914)	(7,535,517)
Finance income	81	76,864	88,005
<b>Loss on ordinary activities before taxation</b>	<b>(4,419,881)</b>	(4,367,050)	(7,447,512)
Tax on loss on ordinary activities	-	-	-
<b>Loss from continuing operations</b>	<b>(4,419,881)</b>	(4,367,050)	(7,447,512)
<b>Other comprehensive income</b>			
Exchange translation differences	(2,476)	(4,284)	19,558
<b>Total comprehensive loss</b>	<b>(4,422,357)</b>	(4,371,334)	(7,427,954)
<b>Attributable to :</b>			
Owner of the parent	(4,422,357)	(4,371,334)	(7,427,954)
	<b>(4,422,357)</b>	(4,371,334)	(7,427,954)
<b>Loss per share:</b>			
Basic and diluted (£)	3	0.02	0.05

**Premaitha Health PLC**  
**Consolidated statement of financial position as at 30 September 2015**

	Notes	Unaudited 30 September 2015 £	Unaudited 30 September 2014 (restated – note 7) £	Audited 31 March 2015 (restated – note 7) £
<b>Assets</b>				
<b>Non-current assets</b>				
Property, plant and equipment		2,027,522	1,003,997	1,347,280
<b>Total non-current assets</b>		<b>2,027,522</b>	1,003,997	1,347,280
<b>Current assets</b>				
Inventories		480,155	-	450,038
Trade and other receivables		827,620	314,719	339,354
Cash and cash equivalents		6,605,374	5,238,614	2,709,355
Tax receivable		914,514	555,060	800,454
<b>Total current assets</b>		<b>8,827,663</b>	6,108,393	4,299,201
<b>Total assets</b>		<b>10,855,185</b>	7,112,390	5,646,481
<b>Equity and liabilities attributable to equity holders of the parent company</b>				
Share capital	4	32,173,133	28,173,133	28,173,133
Share premium		27,023,661	23,310,939	23,307,021
Merger relief reserve		954,545	954,545	954,545
Reverse acquisition reserve		(39,947,033)	(39,947,033)	(39,947,033)
Foreign exchange translation reserve		17,082	-	19,558
Retained losses		(12,666,367)	(5,812,572)	(8,611,027)
<b>Total equity</b>		<b>7,555,021</b>	6,679,012	3,896,197
<b>Liabilities</b>				
<b>Current liabilities</b>				
Trade and other payables		1,185,688	393,833	1,085,818
Litigation provision		1,913,248	-	500,000
<b>Total current liabilities</b>		<b>3,098,936</b>	393,833	1,585,818
<b>Non-current liabilities</b>				
Deferred tax liability		39,545	39,545	39,545
Dilapidations provision		161,683	-	124,921
<b>Total non-current liabilities</b>		<b>201,228</b>	39,545	164,466
<b>Total equity and liabilities</b>		<b>10,855,185</b>	7,112,390	5,646,481

**Premaitha Health PLC**

**Consolidated statement of changes in equity for the six months ended 30 September 2015**

	Share capital	Share premium	Merger relief reserve	Reverse acquisition reserve (restated)	Currency translation reserve	Retained losses (restated – note 7)	Total equity (restated – note 7)
	£	£	£	£	£	£	£
<b>Seven months ended 30 September 2014 – unaudited and restated</b>							
<b>Balance at 1 March 2014</b>	12,046,223	22,813,765	-	-	-	(1,565,669)	33,294,319
Profit for the period	-	-	-	-	-	(4,371,334)	(4,371,334)
Total comprehensive expense for the period	-	-	-	-	-	(4,371,334)	(4,371,334)
<b>Transactions with owners</b>							
Issue of share capital	16,126,910	658,147	954,545	-	-	-	17,739,602
Share issue expenses	-	(160,973)	-	-	-	-	(160,973)
Share-based payment charge	-	-	-	-	-	124,431	124,431
Reverse acquisition reserve	-	-	-	(39,947,033)	-	-	(39,947,033)
Total transactions with owners	16,126,910	497,174	954,545	(39,947,033)	-	124,431	(22,243,973)
<b>Balance at 30 September 2014</b>	28,173,133	23,310,939	954,545	(39,947,033)	-	(5,812,572)	6,679,012
<b>13 months ended 31 March 2015 – audited and restated</b>							
<b>Balance at 1 March 2014</b>	12,046,223	22,813,765	-	-	-	(1,565,669)	33,294,319
Profit for the period	-	-	-	-	-	(7,447,512)	(7,447,512)
Other comprehensive expense	-	-	-	-	19,558	-	19,558
Total comprehensive income/(expense) for the period	-	-	-	-	19,558	(7,447,512)	(7,427,954)
<b>Transactions with owners</b>							
Issue of share capital	16,126,910	658,147	954,545	-	-	-	17,739,602
Share issue expenses	-	(164,891)	-	-	-	-	(164,891)
Share-based payment charge	-	-	-	-	-	402,154	402,154
Reverse acquisition reserve	-	-	-	(39,947,033)	-	-	(39,947,033)
Total transactions with owners	16,126,910	493,256	954,545	(39,947,033)	-	402,154	(21,970,168)
<b>Balance at 31 March 2015</b>	28,173,133	23,307,021	954,545	(39,947,033)	19,558	(8,611,027)	3,896,197

Premaitha Health PLC

Consolidated statement of changes in equity for the six months ended 30 September 2015

(continued)

	Share capital	Share premium	Merger relief reserve	Reverse acquisition reserve  (restated)	Currency translation reserve	Retained losses (restated – note 7)	Total equity (restated – note 7)
	£	£	£	£	£	£	£
<b>Six months ended 30 September 2015 - unaudited</b>							
<b>Balance at 1 April 2015</b>	28,173,133	23,307,021	954,545	(39,947,033)	19,558	(8,611,027)	3,896,197
Profit for the period	-	-	-	-	-	(4,419,881)	(4,419,881)
Other comprehensive expense	-	-	-	-	(2,476)	-	(2,476)
Total comprehensive expense for the period	-	-	-	-	(2,476)	(4,419,881)	(4,422,357)
<b>Transactions with owners</b>							
Issue of share capital	4,000,000	4,000,000	-	-	-	-	8,000,000
Share issue expenses	-	(283,360)	-	-	-	-	(283,360)
Share-based payment charge	-	-	-	-	-	364,541	364,541
Total transactions with owners	4,000,000	3,716,640	-	-	-	364,541	8,081,181
<b>Balance at 30 September 2015</b>	32,173,133	27,023,661	954,545	(39,947,033)	17,082	(12,666,367)	7,555,021

Premaitha Health PLC

Consolidated statement of cash flows for the six months ended 30 September 2015

	Unaudited 6 months to 30 September 2015	Unaudited 7 months to 30 September 2014 <i>(restated – note 7)</i>	Audited 13 months to 31 March 2015 <i>(restated – note 7)</i>
Notes	£	£	£
<b>Cash flow from operating activities</b>			
Loss before tax	(4,419,881)	(4,367,050)	(7,447,512)
Adjustments for :			
Finance income	(81)	(76,864)	(88,005)
Deemed cost of reverse acquisition	-	1,615,282	1,615,282
Depreciation	237,448	94,236	258,413
Loss on disposal of property, plant and equipment	-	-	98,707
Increase in litigation provision	1,413,248	-	500,000
Share-based payment and warrant expense	364,541	124,431	402,154
Foreign exchange movements	(2,476)	(4,284)	(11,806)
R&D tax credit	(114,060)	-	(800,454)
	(2,521,261)	(2,614,249)	(5,473,221)
Changes in working capital:			
Increase in inventories	(30,117)	-	(450,038)
Increase in trade and other receivables	(488,266)	(28,183)	(52,818)
Increase/(Decrease) in trade and other payables	99,870	(102,902)	695,722
<b>Cash generated from operating activities</b>	<b>(2,939,774)</b>	<b>(2,745,334)</b>	<b>(5,280,355)</b>
R & D tax credit received	-	-	254,259
<b>Net cash used in operating activities</b>	<b>(2,939,774)</b>	<b>(2,745,334)</b>	<b>(5,026,096)</b>
<b>Cash flow from investing activities</b>			
Acquisition of parent, net of cash acquired	-	1,229,127	1,229,128
Purchase of property, plant and equipment	(880,928)	(557,853)	(1,168,110)
Interest received	81	76,864	88,005
<b>Net cash (used in)/generated from investing activities</b>	<b>(880,847)</b>	<b>748,138</b>	<b>149,023</b>
<b>Cash flow from financing activities</b>			
Net proceeds from issue of equity instruments	7,716,640	6,986,761	7,074,711
Proceeds from borrowing	-	500,000	461,867
<b>Net cash (used in)/generated from financing activities</b>	<b>7,716,640</b>	<b>7,486,761</b>	<b>7,536,578</b>
<b>Net change in cash and cash equivalents</b>	<b>3,896,019</b>	<b>5,188,764</b>	<b>2,659,505</b>
Cash and cash equivalents at beginning of period	2,709,355	49,850	49,850
<b>Cash and cash equivalents at end of period</b>	<b>6,605,374</b>	<b>5,238,614</b>	<b>2,709,355</b>

**1 General information**

The principal activity of Premaita Health PLC (the "Company") and its subsidiaries (together, the "Group") is that of that of a molecular diagnostics business for research into, and the development and commercialisation of gene analysis techniques for pre-natal screening and other clinical applications in the early detection, monitoring and treatment of disease. The Company is incorporated and domiciled in the United Kingdom. The address of its registered office is St James' House, St James' Square, Cheltenham, Gloucestershire, GL50 3PR. The registered number is 03971582.

As permitted, this Interim Report has been prepared in accordance with the AIM rules and not in accordance with IAS 34 "Interim Financial Reporting".

The consolidated financial statements are prepared under the historical cost convention.

This Consolidated Interim Report and the financial information for the six months ended 30 September 2015 does not constitute full statutory accounts within the meaning of section 434 of the Companies Act 2006 and are unaudited. This unaudited Interim Report was approved by the Board of Directors on 11 December 2015.

The Group's financial statements for the period ended 31 March 2015 have been filed with the Registrar of Companies. The Group's auditor's report on these financial statements was unqualified and did not contain a statement under section 498 (2) or (3) of the Companies Act 2006.

*Electronic communications*

The Company is not proposing to bulk print and distribute hard copies of this Interim Report for the six months ended 30 September 2015 unless specifically requested by individual shareholders.

The Board believes that by utilising electronic communication it delivers savings to the Company in terms of administration, printing and postage, and environmental benefits through reduced consumption of paper and inks, as well as speeding up the provision of information to shareholders.

News updates, Regulatory News and Financial statements can be viewed and downloaded from the Group's website, [www.premaitha.com](http://www.premaitha.com). Copies can also be requested from; The Company Secretary, Premaita Health PLC, Rutherford House, Manchester Science Park, Manchester M15 6SZ or by email: [investors@premaitha.com](mailto:investors@premaitha.com).

## 2 Accounting policies

### *Basis of preparation*

This financial information has been prepared in accordance with International Financial Reporting Standards (IFRS), including IFRIC interpretations issued by the International Accounting Standards Board (IASB) as adopted by the European Union and in accordance with the accounting policies which will be adopted in presenting the Group's Annual Report and Financial Statements for the year ended 31 March 2016. These are consistent with the accounting policies used in the Financial Statements for the year ended 31 March 2015.

### *Going concern*

The Group meets its day-to-day working capital requirements through its cash and cash equivalents, through management of its working capital cycle and its bank facilities. The Directors have carefully considered the adequacy of these arrangements in light of the current and future cash flow forecasts and they believe that the Group is appropriately positioned to ensure the conditions of its funding will continue to be met and therefore enable the Group to continue in operational existence for the foreseeable future by meeting its liabilities as they fall due for payment.

### *Taxation*

Taxes on income in the interim periods are accrued using the rate of tax that would be applicable to expected total annual earnings.

## 3 Loss per share

### *Basic*

Basic loss per share is calculated by dividing the loss after tax attributable to the equity holders of the parent company for the period of £4,422,357 by the weighted average number of ordinary shares in issue during the period of 208,054,419.

### *Diluted*

Due to losses in the period there is no calculation of a diluted earnings (loss) per share.

## 4 Litigation provision

A claim for patent infringement was made against the Group on 13 March 2015, and a provision of £500,000 was recognised in the 2015 accounts. The provision was management's best estimate at the time based on the estimate of fees and probability of recovery. The legal process has developed further since the year end and the likely procedure is now more clearly defined. In addition, a second claim from the same litigant was received on 1 October which the Group has now had the opportunity to assess with its advisers. After review of both claims the Group has decided to pursue a more aggressive defence based on its assessment of the legal merits of its defence. As a result management has reviewed its estimates and decided to increase the provision by £1,500,000. The resulting provision after charging expenditure of £86,752 incurred between April and September 2015 is now £1,913,248.

## **5 Share capital**

On 2 July 2015 the Company issued 40,000,000 new Ordinary shares of £0.10 each at £0.20 raising £8 million before expenses.

On 14 July 2015 the Company granted options over 5,500,000 ordinary shares in the Company to certain directors and employees. The options have an exercise price of £0.20 per share and expire after 10 years. The vesting conditions are: (i) options only vest if there is a positive movement in earnings per share; and (ii) options become exercisable in respect of one third of the ordinary shares over which they are granted on the second, third and fourth anniversaries of the date of grant.

## **6 Events after the reporting period**

On 14 December 2015 the Group announced an investment from Thermo Fisher in the form of a £5,000,000 loan secured against selected intellectual property. In addition to the loan, the Group has issued warrants to Thermo Fisher to the value of £5,000,000, exercisable at 24.6 pence per share.

On 1 October 2015 the company received a second claim of patent infringement as described in note 4 in this statement.

## **7 Prior period adjustments**

The comparatives for the year-ended 31 March 2015 and for the seven months to 30 September 2014 have both been restated in this Interim Financial report to reflect an error in the accounting for the reverse acquisition of Premaita Health Plc and its subsidiaries.

The deemed fair value of the consideration for this reverse acquisition was previously stated at £2,308,094. Subsequent to the prior period adjustment this has been amended to £2,958,409. The resulting charge to the income statement in respect of the reverse acquisition has, consequently, increased from £964,967 to £1,615,282.

This increase in the charge also causes a decrease in the reverse acquisition reserve from £40,597,348 to £39,947,033.

This adjustment, and the consequential increase in the loss after tax attributable to the parent company for the year to 31 March 2015, results in an increase in the basic loss per share to £0.05 compared to the previously reported loss of £0.04 per share.