

# Concepta PLC

Annual Results RNS Number : 8860Y Concepta PLC 14 May 2019

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# Concepta Plc ("Concepta" or the "Company") Annual Results

Concepta Plc (AIM: CPT), the innovative UK personalised healthcare company and developer of the proprietary self-test platform ("myLotus®") and suite of emerging test products targeting the mobile health market with a primary focus on women's fertility and hormone health, announces today its final results for the twelve months to 31 December 2018. Concepta Plc is also announcing today in a separate release its first myLotus® pregnancies.

### **Operational Highlights**

- Appointment of Matthew Walls as Chairman in July 2018 and subsequently Executive Chairman from September 2018
- Appointment of David Darrock as Chief Operating Officer in February 2018 with main Board appointment in September 2018
- Appointment of Peter Dines as Non Executive Director in July 2018, replacing Mark Wyatt, to represent the largest shareholder, Mercia Technologies PLC
- Successful completion of UK user trials and CE Mark submission in September 2018
- CE Mark certification received in October 2018
- Launched myLotus® product at the Fertility Show, London in November 2018
- Completed validation and ISO 13485 manufacturing approval
- Launched the <u>www.myLotus.com</u> eCommerce website and listing on Amazon

#### **Financial Overview**

• Revenue of £0.00m (2017 : £0.10m)

EBITDA loss £2.65m (2017 : £2.3m loss)

- Cash at year end £0.74m (2017: £1.5m)
- Completion of £2.0m (net of expenses) share placing at 4p per share in August 2018

#### **Post Financial Year End**

• In April 2019 Concepta completed a £2.2m (net of expenses) share placing at 3p per share to accelerate business development and to support working capital requirements

#### **Chairman's Statement**

Healthcare and personalised health is in an era of transformational change. Recent advances in technological innovation and online access to published medical reports and healthcare communities is enabling patients to gain greater insight and understanding of their health, empowering them to take control of their wellbeing whilst easing the burden on state funded healthcare. Concepta and the myLotus<sup>®</sup>, personalised diagnostic device is at the forefront of this healthcare innovation and change.

Following my appointment as Chairman in July 2018, I am pleased to present my first Annual Report for the year ended 31 December 2018. The past twelve months have been definitive for the Company. The 2018 financial year saw the successful delivery of our CE Mark certification for the myLotus product, its subsequent launch and initial sales in the fertility monitoring and pregnancy market. In addition, the recent announcement of the UK supply agreement with Boots UK (part of Walgreens Boots Alliance) and the completion of the April 2019 placing will help accelerate our business development activities and deliver a turnaround of the Company's prospects.

We are also announcing today the hugely important news of our first pregnancies which are beginning to emerge from the early adopters of myLotus. Whilst brand awareness of the myLotus product is low, sales are gathering momentum and the increasingly positive news will continue to build demand. The myLotus women's fertility monitor is unrivalled in helping women to personally monitor their hormone cycles and ovulation profile ('signatures') to find their most fertile days to conceive naturally.

### **Business Overview**

The historic performance of the Company necessitated a change in the strategy over the past year with a strengthening of the Board, Executive and Management team. In July 2018 I joined the Board of Concepta Plc as Chairman and Adam Reynolds who had led the transition of Concepta onto the AIM market in 2016 moved to a Non-Executive role. Peter Dines joined the Board as Non-Executive Director representing our main investor (Mercia Technologies PLC). In September 2018 David Darrock, who had been instrumental to the delivery of the myLotus® product, was appointed to the Board as Chief Operating Officer.

Whilst the historic strategy had focused on the China market, our limited investment and arm's length management from the UK was increasingly complex and costly. Our China launch was deferred and resources realigned to focus on finishing the development of the myLotus product, resolving the delays in technical and app development, completing clinical validation and gaining CE Mark certification and regulatory approval.

Our focus and attention in the second half of 2018 was to ensure a successful UK launch of myLotus. UK sales and marketing channels were developed across business-to-business (B2B) and business-to-consumer (B2C) channels including Boots UK and smaller fertility test providers, and key opinion leader support was put in place. We developed a new myLotus product website (<a href="https://www.myLotus.com">www.myLotus.com</a>) and established our proprietary eCommerce platform capable of supporting our UK business growth and future EU and longer term international roll out. We have also adopted a digital marketing strategy to target and engage users via social media content, email, Amazon online shop and search engine marketing.

CE Mark certification was confirmed in October 2018 and the myLotus product was launched in November 2018 at the Fertility Show, Olympia London. With low brand recognition and awareness of myLotus we started the task of raising the brand profile through user testimonials, fertility events and news coverage. Following today's announcement we will be lifting the myLotus profile and user case studies around our first pregnancies. The marketing message is clear - myLotus increases a woman's chance of a natural pregnancy by monitoring her ovulation profile, finding her most fertile days and optimal time to conceive. A key requirement for the myLotus pregnancy journey was the delivery of our first app developed in iOS/Android formats enabling women to track their hormone levels over their menstrual cycle. The development of our free app was completed in October 2018 and launched together with the myLotus monitor.

Supply chain operations and logistics continued to strengthen throughout the year. The Doncaster manufacturing and assembly facility received ISO 13485 approval in September 2018 and the scale up and efficiency of production of our myLotus monitor continues to improve with a second monitor manufacturer now identified. We will maintain our focus on a continuous improvement and cost reduction in the manufacturing processes to improve our margins. Working capital requirements also continued to build over the year and this trend is expected to continue through 2019.

Over the past few months strategic and distributor discussions have commenced with larger diagnostic and retail pharmacy groups. The discussions are expected to deliver further collaborative opportunities in 2019.

We are also exploring applications for myLotus in hospitals and IVF (In Vitro Fertilisation) fertility clinics. The opportunity for myLotus to carve out a new strategic position in the 'pathway to

pregnancy' is compelling. According to the US BabyCentre Medical Advisory Board, clinical evidence indicates that 93-95% of women aged below 35 years who have regular unprotected sex will naturally fall pregnant over a 4 year period (48 cycles). myLotus will help women identify their fertile days and optimal time to conceive thereby helping to accelerate the natural pregnancy process. myLotus is especially relevant with the reduction in state funded fertility support enabling couples a lower cost alternative prior to considering more costly IVF treatment.

#### Product development

Development of the myLotus product includes the core areas of the myLotus monitor and immunodiagnostic tests, iOS/Android app and data monitoring. Each of these areas have ongoing developments and we will continue to build our internal expertise to accelerate these programmes. The myLotus monitor will be improved to include Bluetooth capability and enhanced display. We will be developing the myLotus test menu to widen our test coverage of the menstrual cycle by including new hormone tests for Follicle Stimulating Hormone (FSH) and progesterone. These tests will both improve our fertility monitoring and extend the window on the menstrual cycle to include coverage of menopause. We will also continue to grow our user database to provide improved diagnosis of women's hormone health, wellbeing and diagnostic predictive analysis.

### **Financial Overview**

Further details of the results for the period are covered in the Financial Report, but financially the year to 31 December 2018 saw the Company deliver income of £0.0m (2017: £0.1m). Following high levels of investment made in the development of myLotus<sup>®</sup>, the Company reported a loss after tax of £2.8m (2017: £2.3m loss after tax) and a loss per share of £0.02 (2017: £0.02).

In August 2018 the Company completed a £2.0m placing to finish the development of myLotus<sup>®</sup>. Cash reserves at 31 December 2018 were £0.7m (2017: £1.5m.)

In April 2019 Concepta completed a £2.2m placing net of expenses to accelerate business development and to support working capital requirements.

#### Outlook

The market opportunity for myLotus<sup>®</sup> in fertility, pregnancy and women's health is substantial and with limited direct competition, the Board believes Concepta has strong prospects for growth. We are at the early stages of our product launch and program build and we will

continue to educate users on the value of myLotus<sup>®</sup>, raise brand awareness and bolster our sales and marketing expertise over the coming year.

Our priority for 2019 is to develop our UK sales channels in B2C and B2B and engage a sustainable growth model which we can extend across the EU. We will also develop our strategic relationships with large diagnostic groups capable of internationally exploiting our diagnostic platform across personalised health and wellbeing.

We will accelerate the development of our additional test menu for myLotus<sup>®</sup> to target a broader women's hormone health product and to achieve the following key objectives:

- Development of a sustainable revenue growth model
- EU roll-out to take advantage of our CE Mark approval and eCommerce platform capability
- Development of our collaboration with Boots UK and the Walgreens Boots Alliance
- Piloting of myLotus<sup>®</sup> for use in IVF
- Piloting of myLotus fertility and pregnancy support journey
- Bluetooth capability and improved display
- Development of new hormone tests
- App version 2.0 development
- Development of data mining tools and diagnostic predictive analytics capability

Based on our increasing pregnancies and user testimonials, we expect to raise the profile of myLotus<sup>®</sup> over the coming year and take advantage of our new technology innovation and industry know-how to drive our growth strategy.

I would like to thank the Board, management team and employees for their effort and commitment in driving Concepta's progress over the past year, as well as our investors whose support has provided a stable platform for our continued growth plans.

# Matthew Walls Chairman

### CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

		Year ended	Year ended
		31 December 2018	31 December 2017
	Notes	£	£
Revenue	4	4,838	108,115
Cost of sales		(540,721)	(519,522)
Gross loss		(535,883)	(411,407)
Other administrative expenses		(2,213,695)	(1,925,482)
Share-based payments		(92,291)	(109,523)

Administrative expenses		(2,305,986)	(2,035,005)
Operating loss	5	(2,841,869)	(2,446,412)
Finance expenses	7	(23,915)	(3,355)
Loss before income tax		(2,865,784)	(2,449,767)
Tax credit	8	52,277	104,818
Loss for the period		(2,813,507)	(2,344,949)
Attributable to owners of the parent:		(2,813,507)	(2,344,949)
Loss per ordinary share - basic and diluted			
(£)	9	(0.02)	(0.02)

# **CONSOLIDATED STATEMENT OF FINANCIAL POSITION**

		31 December 2018	31 December 2017
	Notes	£	£
Non-current assets			
Property, plant and equipment	10	789,189	473,247
Intangible assets	11	509,195	390,743
Total non-current assets		1,298,384	863,990
Current assets			
Inventories	12	399,182	296,548
Trade and other receivables	13	164,933	678,236
Corporation tax receivable		52,277	104,818
Cash and cash equivalents	14	740,227	1,537,759
Total current assets		1,356,619	2,617,361
Total assets		2,655,003	3,481,351
Current liabilities			
Trade and other payables	15	259,681	462,895
Loans and borrowings	16	64,228	16,211
Total current liabilities		323,909	479,106
Non-current liabilities			
Loans and borrowings	16	227,243	62,310
Total non-current liabilities		227,243	62,310
Total liabilities		551,152	541,416
Net assets		2,103,851	2,939,935
Share capital	17	4,704,917	3,454,917
Share premium account	17	10,448,263	9,813,131

Share-based payment reserve	19	743,178	650,887
Capital redemption reserve		1,814,674	1,814,674
Reverse acquisition reserve		(6,044,192)	(6,044,192)
Retained earnings		(9,562,989)	(6,749,482)
Total equity		2,103,851	2,939,935

These financial statements were approved and authorised for issue by the board of directors on 13 May 2019

# **CONSOLIDATED STATEMENT OF CHANGES IN EQUITY**

	Share	Share	Capital redemption	Retained	Reverse acquisition	Share- based payment	
	capital	Premium	reserve	earnings	reserve	reserve	Total
	£	£	£	£	£	£	£
Equity as at 31 December 2016	2,740,631	8,663,326	1,814,674	(4,404,533)	(6,044,192)	541,364	3,311,270
	2,740,031	8,003,320	1,814,074		(0,044,132)	341,304	
Loss for the period				(2,344,949)			(2,344,949)
Total comprehensive							
loss	-	-	-	(2,344,949)	-	-	(2,344,949)
Issue of shares net							
of expenses	714,286	1,149,805	-	-	-	-	1,864,091
Share-based payments	_	_	_	_	_	109,523	109,523
Equity as at						103,323	103,323
31 December							
2017	3,454,917	9,813,131	1,814,674	(6,749,482)	(6,044,192)	650,887	2,939,935
Loss for the period	-	-	-	(2,813,507)	-	-	(2,813,507)
Total							
comprehensive							
loss	-	-	-	(2,813,507)	-	-	(2,813,507)
Issue of shares net	1 250 000	625 422					1 005 122
of expenses Share-based	1,250,000	635,132	-	-	-	-	1,885,132
payments			-		-	92,291	92,291
Equity as at							
31 December 2018	4,704,917	10,448,263	1,814,674	(9,562,989)	(6,044,192)	743,178	2,103,851

# **CONSOLIDATED STATEMENT OF CASH FLOWS**

	Year ended	Year ended	
	31 December 2018	31 December 2017	
	£	£	
Cash flows from operating activities			
Loss before taxation	(2,865,784)	(2,449,767)	
Adjustments for:			
Depreciation and amortization	192,260	209,228	
Finance expenses	23,915	3,355	
Share-based payments	92,291	109,523	
Operating loss before working capital changes	(2,557,318)	(2,127,661)	

Changes in working capital		
Increase in inventory	(102,634)	(226,047)
Decrease/(increase) in trade and other receivables	513,302	(463,134)
(Increase)/Decrease in trade and other payables	(203,213)	280,937
Cash used in operations	(2,349,863)	(2,535,905)
Tax received	104,818	96,221
Interest paid on sale & leaseback	(21,415)	(1,142)
Other interests	(2,500)	(784)
Net cash outflow from operating activities	(2,268,960)	(2,441,610)
Investing activities		
Purchase of property, plant and equipment	(457,836)	(430,033)
Purchase of intangible assets	(169,560)	(240,259)
Sale of asset	742	-
Net cash flows used in investing activities	(626,654)	(670,292)
Financing activities		
Issue of ordinary shares (net of issue expenses)	1,885,132	1,864,091
Proceeds from sale and leaseback	381,215	118,000
Repayment of sale and leaseback	(168,265)	(40,907)
Net cash flows from financing activities	2,098,082	1,941,184
Net change in cash and cash equivalents	(797,532)	(1,170,718)
Cash and cash equivalents at the beginning of the		
period	1,537,759	2,708,477
Cash and cash equivalents at the end of the period	740,227	1,537,759

### Notes to the preliminary financial results

- 1. The figures for the years ended 31 December 2018 and 2017 do not constitute statutory accounts within the meaning of Section 434 of the Companies Act 2006. The figures for the year ended 31 December 2018 have been extracted from the statutory accounts for that year on which the auditor has issued an unqualified audit report which has yet to be delivered to the Registrar of Companies. The figures for the year ended 31 December 2017 have been extracted from the statutory accounts for that year which have been delivered to the Registrar of Companies and on which the auditor has issued an unqualified audit report. No statement has been made by the auditor under Section 498(2) or (3) of the Companies Act 2006 in respect of either of these sets of accounts. This announcement was approved by the board of directors on 13 May 2019 and authorised for issue on 14 May 2019.
- 2. The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards adopted by the International Accounting Standards Board ('IASB') and interpretations issued by the International Financial Reporting Interpretations Committee of the IASB (together 'IFRS') as endorsed by the European Union. The information in this preliminary statement has been extracted from the audited financial statements for the year ended 31 December 2018 and as such, does not contain all the information required to be disclosed in the financial statements prepared in accordance with the International Financial Reporting Standards ('IFRS').

3. Earnings per share is based on the loss for the year after tax of £2,813,507 (2017: £2,344,949), and the weighted average number of ordinary shares in issue during the year of 158,321,675 (2017: 112,564,863). Due to the loss in the periods the effect of the share options was considered anti-dilutive and hence no diluted loss per share information has been provided.

The 2018 Annual Report and Accounts will be available to download from the investor relations section on the Company's website <a href="https://www.conceptaplc.com">www.conceptaplc.com</a>

### \*\*ENDS\*\*

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### About Concepta Plc:

Concepta Plc is an AIM-quoted pioneering UK healthcare company that has developed a proprietary product, myLotus®, targeted at the personalised mobile health market with a primary focus on hormone testing and increasing a woman's chances of naturally getting pregnant and to provide insight to unexplained infertility.

myLotus® is currently the only consumer product which allows both quantitative and qualitative home (self-test) test measurement of a woman's personal luteinizing hormone (LH) during ovulation and human chorionic gonadotropin (hCG) hormone level during pregnancy, facilitating higher conception rates and early diagnosis of fertility issues. The proposition of myLotus® is to empower women to better understand their hormone levels and menstrual cycle and help women conceive naturally by identifying their window of fertility and optimal time for conception.

The Company has received CE Mark certification for myLotus® and has launched its first product in the UK. The Company is preparing plans to roll-out across the core EU countries in 2019.

myLotus® is expected to be beneficial to users who have been unable to conceive after 6 months of trying. This highly motivated target group of women won't typically be offered medical intervention until after 12 months of unsuccessfully trying to conceive, with IVF not usually offered until after two years of trying to conceive. Research indicates couples start to take positive action ahead of this time typically with little medical support to help them do so.

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