

Physiomics Plc The Magdalen Centre The Oxford Science Park Robert Robinson Avenue Oxford OX4 4GA UK

12 November 2014

# Physiomics Plc ("Physiomics" or "the Company") Final Results for the year ended 30 June 2014

### Chairman's Statement

# Summary of Results in the year ended 30 June 2014

- The turnover of the Company increased by 12% to £267,903 (2013: £240,000).
- The operating loss reduced by 15% to £465,265 (2013: £548,342).
- On 30 June 2014 the surplus of shareholders' funds was £136,487 (2013: £255,821).

This year, Physiomics has made good progress advancing Virtual Tumour Clinical and has broadened its offering into the personalised medicine market. In summary we have

- Delivered two case studies validating Virtual Tumour Clinical, partially funded by a Technology Strategy Board Biomedical Catalyst grant.
- Won further pre-clinical projects from our existing large pharma customer base.
- Identified potential Virtual Tumour Clinical projects to follow-on from this pre-clinical work.
- Signed a deal with a speciality pharma company to determine the mechanism of action of one of their candidates.
- Gained our first large pharma customer for our cardiotoxicity platform. Launched a web-based portal "EasyAP™" to provide access to literature models of cardiotoxicity.
- Continued discussions with relevant partners around increasing the scope of the business by way of M&A.

- Initiated a new project with a large pharma client to develop an immunomodulatory module for Virtual Tumour. Immunomodulatory agents are being pursued by several large pharmas following the clinical success of agents targeting PD-1 and CTLA-4.
- Signed a heads of terms agreement with Diatech Pharmacogenomics to enter the personalised medicine field, initially in Italy.
- Initiated discussions with a large software provider to determine if part or all of Virtual Tumour could be sold as part of their offering.

Dr Paul Harper, Non-Executive Chairman

### Chairman and Chief Executive Officer's Statement

### Introduction

During the period Physiomics successfully applied Virtual Tumour to clinical predictions for the first time. This was an important step forward for a number of reasons:

Firstly, there was a large degree of direct interest from customers and potential customers for this service. Secondly, the unmet need for better clinical dosing schedules is driven by the need to accelerate development programmes, reduce costs and bring forward potential revenues by designing clinical protocols that are already optimised for patient dosing. The current most commonly used method for determining the clinical regimen is to increase the dosage of the most effective regimen from animal studies to human scale. Animal models often poorly reflect the situation in a human patient due to for example disparities in relative sizes, physiology and pharmacokinetics, parameters that are all fundamental to drug efficacy. The approximations generated through this approach, when used to design a clinical study, can contribute to the failure of a clinical trial. Thirdly the cost of failure in the clinical setting vastly outweighs that in the pre-clinical setting.

Given the high cost and the subsequent consequences arising from a failed clinical trial, if customers can be shown (through pilot projects) that a predictive technology is able to improve the chances of clinical success, then they are likely to progressively adopt the new paradigm. Drug development has for so long relied almost exclusively on extrapolating data from studies in animal models to direct dosing in patients that embracing a new 'black box' based technology approach is a major policy change, despite the fact that adoption of system modelling is being encouraged by FDA and similar agencies.

The predictive power of Virtual Tumour Clinical has been demonstrated in two different indications so far. Initial marketing of the results to large pharmaceutical companies has led to a positive expression of interest. There has also been a desire to see how the technology performs across a number of further indications. Therefore it is the intention of the Company to perform further validation studies in other types of cancer, in addition to initiating collaborations with large pharma companies. Discussions with collaborators to set up such case studies are well advanced.

Relationships with our existing large pharma customer base were strengthened in the period with a number of new pre-clinical projects. These projects have the potential to be extended into the first large pharma Virtual Tumour Clinical projects in due course.

The Company's activities in the cardiotoxicity arena have gathered pace. Early stage drug candidates are now routinely screened for cardiotoxic effects, as required by the regulatory authorities. In particular, all candidate drugs must be screened for activity against the hERG potassium channel. However, such screening is time-consuming and costly. It is also known that a large number of candidates are incorrectly progressed or discarded based on hERG activity alone.

Physiomics' *in silico* platform takes into account activity against hERG and two additional ion channels to deliver better predictions of action potential time courses and duration based on several literature models. *In silico* prediction of cardiotoxic side effects is therefore a more effective way of helping to select which candidates to progress. In addition to Physiomics' cardiotoxicity simulation service, we have now launched our web-based EasyAP™ application. EasyAP™ allows access to the service to a broad range of customers, by allowing customers to run simulations on their own computers on a pay-per-compound or annual subscription basis. Physiomics gained its first large pharma customer for cardiotoxicity prediction in the period and the Directors hope that this new platform will attract further customers.

A heads of terms agreement with Diatech Pharmacogenomics was signed in the period. If translated into a full agreement, this collaboration would provide Physiomics with access to the majority of clinical centres in Italy and also an opportunity to develop personalised medicine models. When combined with Physiomics' Virtual Tumour, which provides information on how much drug to give and when to give it, we believe it will provide an industry-leading platform to support oncology clinical trials worldwide.

The search for an appropriate M&A partner to further build Physiomics and provide the best outcome for shareholders has continued in the period and significant discussions have taken place.

Finally, after the period ended Physiomics gained its first large pharma project to model immunomodulatory agents using Virtual Tumour. Immunomodulatory, or 'immune therapy' agents have been described as an extremely hot topic in the oncology field at present. A number of high profile clinical trials are ongoing and several large pharma companies are entering the field for the first time. The Directors believe that, if the project is successful, this will lead to further interest in Virtual Tumour from other large pharma companies who are active in this area.

# **Technology Development**

# (i) Virtual Tumour product improvements

The immune system can play a significant role in the course of a cancer. While in some cases the immune system does not seem to recognise and attack a tumour, in many other patients the cells of the immune system are recruited to the vicinity of the tumour, but fail to kill enough cancer cells to be really effective. Over the last few years a number of drug candidates have emerged aimed at activating the latent immune response to a tumour or removing a 'brake' on the immune response created by the cancer itself. Several large pharmaceutical companies have targeted this response, with some notable successes in the clinic. Given this burgeoning interest from our primary customer base, Physiomics started to develop an immune system module to work in tandem with Virtual Tumour, to model the effects of these agents. It became clear that one pharma partner in particular was very keen to develop such a model and so our first commercial project in this area was initiated in September 2014. This project should provide all the data required to develop a functional model which could be sold on to other potential customers.

### (ii) Virtual Tumour Clinical

Two critical case studies were completed in the period, allowing us to develop, test and validate Virtual Tumour Clinical for the first time. The first study related to prostate cancer and the data came from the National Institutes of Health (NIH) in the USA. This study allowed us to determine which of the key parameters of the model needed to be modified in order to make accurate clinical predictions. The second project, in collaboration with Oxford University, was a blind validation study in melanoma. Here we

showed that we could make accurate predictions of the outcome of combination therapies in a clinical trial. This was achieved by priming Virtual Tumour with key human data and gaining a deep understanding of the relevant tumour growth rates from the literature. Both case studies were extremely encouraging, demonstrating that the basic architecture of the existing pre-clinical Virtual Tumour could be translated into a clinical setting with the appropriate modifications. The melanoma case study was supported by a Technology Strategy Board Biomedical Catalyst grant award.

# (iii) Cardiac toxicity prediction service

During the period Physiomics gained its first large pharma customer for cardiotoxicity prediction. Feedback obtained during the project and from other potential customers suggested that, in addition to predicting the overall risk of cardiac side effects, customers may also like to predict the outcome of scientific experiments that provide the direct effect of a candidate on a particular ion channel on a particular cell line, which may also provide an useful insight into cardiac toxicity risk. The regulatory agencies are also taking a keen interest in such predictions. For this reason we extended the scope of our cardiotoxicity predictions to include literature models which predict 'action potentials' on cell lines, in our web-based EasyAP<sup>TM</sup> platform, which was launched recently.

# **Business Development Strategy**

Further pre-clinical Virtual Tumour projects were forthcoming in the period. The Directors believe that the interest in Virtual Tumour Clinical will translate into further projects which are likely to start in the pre-clinical phase and extend through to the clinical setting, as it will be clear from the outset that Physiomics can provide predictions of optimised clinical regimens. Several new leads have been generated in the period which provides confidence that the customer base will be extended in the near future. In addition, our increased scope of services means that we can sell multiple services into the same large pharma customer and this strategy has already borne fruit. The US will remain an important target territory for such services and an ongoing focus for our lead generation efforts.

The initial response to our EasyAP<sup>TM</sup> web-based cardiotoxicity portal is being closely monitored. To the knowledge of the directors, there is no commercially available website that provides users with models that they can run using their own data and with no input required from the provider. There may be further opportunities to provide web-based versions of industry models which will be studied if EasyAP<sup>TM</sup> is successful.

Finally we have also started to investigate whether Virtual Tumour or elements of it could be provided as software or a web-based platform. This will make the technology easier and more cost effective to access for customers than the current service offering. At least one large software provider has shown interest in adding Virtual Tumour to its software and initial discussions have taken place. Over the next period Physiomics will evaluate whether and how Virtual Tumour could be integrated into this company's system. The advantage of this approach is that such large software vendors are already selling products to nearly all of the major pharmaceutical companies worldwide, so a subsequent deal with such a company would provide a ready and extensive sales channel.

### Outlook

The landscape of the pharmaceutical sector remains mixed, with a number of notable companies downsizing and closing key sites. The failed Pfizer bid for Astra Zeneca and the Abbvie bid for Shire, interfered with the decision making processes in each of the companies, shelving or at least delaying any significant plans. Events that have an impact on decision making have occurred throughout the Industry, slowing the pace of development and deferring the need for third party services. Fortunately oncology remains an important indication in those companies that have programmes. Certain key pharma clients have made significant pipeline and resource decisions, most notably focusing efforts on immunomodulatory agents for the treatment of cancers. Physiomics has aligned itself with this trend and

the Directors are confident that this will allow us to engage with new customers. We believe the interest displayed in Virtual Tumour Clinical has vindicated our strategy to develop further the technology into the clinical arena and large pharma collaborations are also expected in this regard. The pipeline of potential opportunities is the strongest that we have seen in recent years.

In addition the Company has the opportunity to extend the scope of its predictive technology for oncology through its collaboration with Diatech Pharmacogenomics. Initially focusing on the delivery of already marketed drugs to patients, the work could be extended in future to help support decisions on appropriate patient populations for clinical trials.

Finally interest from large software providers in the Virtual Tumour platform, the launch of our first webbased models and the continued search for the right M&A deal suggest that the next period will be an exciting one in the development of Physiomics.

Dr Paul Harper, Non-Executive Chairman Dr Mark Chadwick, Chief Executive Officer

# Income Statement for the year ended 30 June 2014

	Year ended 30-Jun-14		Year ended 30-Jun-13	
Revenue	£ 267,903		£ <b>240,000</b>	
Net operating expenses Share-based compensation	(733,168) -		(776,520) (11,822)	
Operating loss	(465,265)	. <u>-</u>	(548,342)	
Finance income Finance costs	1,013		4,551 -	
Loss before taxation	(464,252)		(543,791)	
UK corporation tax	38,631		43,220	
Loss for the year attributable to equity shareholders  Loss per share (pence)	(425,621)		(500,571)	
Basic and diluted	(0.026)	p	(0.033)	р

	Year ended 30-Jun-14 £	Year ended 30-Jun-13 £
Non-current assets		
Intangible assets	11,669	16,336
Property, plant and equipment	3,589	4,250
Investments	1_	1
	15,259	20,587
Current assets		
Trade and other receivables	96,576	180,717
Cash and cash equivalents	132,358	179,162
	228,934	359,879
Total assets	244,193	380,466
Current liabilities		
Trade and other payables	(107,706)	(124,645)
Total liabilities	(107,706)	(124,645)
Net assets	136,487	255,821
Capital and reserves		
Share capital	687,663	602,620
Capital reserves	4,017,602	3,796,358
Retained earnings	(4,568,778)	(4,143,157)
Equity shareholders' funds	136,487	255,821

# Statement of changes in equity for the year ended 30 June 2014

	Share capital £	Share premium account	Share-based compensation reserve	Retained Earnings £	Total shareholders' funds £
At 1 July 2012	599,420	3,697,169	80,567	(3,642,586)	734,570
Share issue (net of costs) Loss for the year Share-based	3,200 -	6,800 -	11,822	- (500,571)	10,000 (500,571) 11,822
compensation	-	-	11,022	-	11,022
At 30 June 2013	602,620	3,703,969	92,389	(4,143,157)	255,821
Share issue (net		221,244			
of costs)	85,043	-	-	-	306,287
Loss for the year	-		-	(425,621)	(425,621)
Share-based compensation	-	-	-	-	-
At 30 June 2014	687,663	3,925,213	92,389	(4,568,778)	136,487

# Cash Flow Statement for the year ended 30 June 2013

	Year ended 30-Jun-14 £	Year ended 30-Jun-13 £
Cash flows from operating activities:		
Operating loss Amortisation and depreciation Share-based compensation (Decrease) increase in receivables Decrease in payables	(465,265) 7,925 - 85,833 (16,939)	(548,342) 8,540 11,822 (47,994) 19,114
Cash generated from operations	(388,446)	(556,860)
UK corporation tax received Interest paid	36,939 -	32,373 -
Net cash generated from operating activities	(351,507)	(524,487)
Cash flows from investing activities:		
Interest received Purchase of non-current assets, net of grants received	1,013 (2,597)	4,551 (1,852)
Net cash received by investing activities	(1,584)	2,699
Cash outflow before financing	(353,091)	(521,788)
Cash flows from financing activities: Issue of ordinary share capital (net of expenses)	306,287	10,000
Net cash from financing activities	306,287	10,000
Net decrease cash and cash equivalents	(46,804)	(511,788)
Cash and cash equivalents at beginning of year	179,162	690,950
Cash and cash equivalents at end of year	132,358	179,162

# Earnings per share

The calculations of loss per share are based on the following losses and numbers of shares.

	2014 £	2013 £
Loss on ordinary activities after tax	(425,621)	(500,571)
Weighted average no of shares:	No.	No.
For basic and diluted loss per share	1,666,241,670	1,502,013,088
Basic and diluted loss per share	(0.026p)	(0.033p)

### **Notes**

## 1. Extract from Annual Report and Accounts

The financial information set out above does not constitute statutory accounts within the meaning of the Companies Act 2006.

### 2. Basis of preparation

Physiomics Plc has adopted International Financial Reporting Standards ("IFRS"), IFRIC interpretations and the Companies Act 2006 as applicable to companies reporting under IFRS.

## 3. Report Distribution

Copies of the annual report will be sent to shareholders on 18<sup>th</sup> November 2014 and will be available for a period of one month to the public at the offices of Physiomics Plc, The Magdalen Centre, Robert Robinson Avenue, Oxford Science Park, Oxford, OX4 4GA, and at the Company's website www.physiomics-plc.co.uk.

# 4. Annual General Meeting

The Annual General Meeting of the Company will be held at the offices of Taylor Vinters LLP, Tower 42, 33rd Floor, 25 Old Broad Street, London, EC2N 1HQ at 11.00 am on 15 December 2014.

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