

# Preliminary results for the year ended 31<sup>st</sup> December, 2015

18<sup>th</sup> May, 2016

## **Highlights**

- Turnover increased 20% to £1.88m (2014:£1.56m)
- Licenses/Sales/Services revenue up 30% to £1.68m (2014:£1.30m)
  - Strong 51% growth in biomarker services
  - TMT® product sales rose 33% in 2015
  - Grant services £0.21m (2014: £0.27m)
- Reduced loss after tax £2.72m (2014:£3.57m)
- Cash at year-end £1.81m (2014:£1.87m)
- Levels of SysQuant<sup>®</sup> /TMTcalibrator<sup>™</sup> production doubled Q4
- Compelling evidence in second in vivo study in Alzheimer's that CK1d compounds reduce tau levels

#### Outlook

- Facilities running at full capacity
- Increasing repeat business and growing demand for SysQuant® and TMTcalibrator™
- Novel clusterin blood assay for brain atrophy in AD later this year
- CE marked stroke test set for 2016 launch by Randox
- Progressing CK1d out-licensing discussions
- 10 protein panel for MCI/AD being developed
- TMT® tags performing strongly
- Expanding sales team
- On track to deliver significant increase in revenue

Commenting on these results, Christopher Pearce, Chairman of Proteome Sciences, said

"The recognition and requirement for Precision Medicine has questioned the historic practice of using genomic approaches almost exclusively in drug development and patient management. As a consequence there has been increasing acceptance of the inclusion of complementary proteomics approaches and these have been driving considerable interest and activity in our biomarker services business.

The current year started well with a strong order book, increasing amounts of repeat business and a growing pipeline in biomarker services. With the level of SysQuant® /TMTcalibrator™ production doubled the increased capacity is being fully utilised at a time when the volume of customer enquiries is rising on a monthly basis and we are looking to further expand the sales team. Current indications point to a strong performance in 2016.

We have been actively engaged with prospective licensing partners in Alzheimer's disease using the compelling results announced in November from a second and different AD model to test our CK1d compounds that mimicked the effects of the previous study, again successfully reducing the level of tau phosphorylation. Following receipt of the analysis from the next cohort of patients with MCI/AD from KCL, we anticipate that the proposed 10 protein panel will be finalised and developed into a panel test later in the year. It is intended that the test will be out-licensed non-exclusively.



The CE marked stroke test is on track for launch by Randox in 2016 at which point further milestone payments will be triggered. Additionally there is the prospect of further non-exclusive licenses to follow. TMT® continues to show good growth and is expected to further increase in market share from new applications in systems biology and again when new generation higher plexing tags are launched in 2017.

The encouraging trends and growth across the business in 2015 have continued in the current year. Proteome Sciences is firmly on track to deliver a significant increase in revenues from biomarker services and TMT® in 2016 and the possibility in addition of further licensing deals from our AD and stroke IP."



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#### **Notes to Editors:**

## About Proteome Sciences plc (<u>www.proteomics.com</u>)

With its HQ in Cobham, UK and laboratory facilities in London and Frankfurt, Proteome Sciences is a global leader in applied proteomics offering high sensitivity, proprietary technologies and workflows in cell signalling pathways (SysQuant<sup>®</sup>, TMTcalibrator<sup>™</sup>) and in protein biomarker discovery, validation and assay development.

PS Biomarker Services® provides proteomics outsourcing services and proprietary biomarker assays from its ISO 9001: 2008 facility in Frankfurt, Germany to pharmaceutical, biotechnology, diagnostics companies and academia.

Proteome Sciences' research has discovered a large number of novel protein biomarkers in key human diseases with a focus mainly in neurological/neurodegenerative conditions and in cancer. It has patented blood biomarkers in Alzheimer's disease, stroke, brain damage and cancers for diagnostic and treatment applications that are available for licenses.



## Preliminary results for the year ended 31st December 2015

We have benefitted from a good performance in all aspects of the business in 2015, in particular biomarker services where there has been strong customer adoption of SysQuant® and TMTcalibrator $^{\text{TM}}$  with the focus on Precision Medicine.

Considerable scientific progress has been made over the period, in particular in Alzheimer's disease (AD) across a number of different areas and these have formed the backcloth to the prominent releases and presentations that we have made at major AD meetings in the USA and Europe.

The main themes have centred around our most recent biological data on CK1d inhibitors in tau and blood and CSF biomarkers as neuro-inflammatory markers for measuring AD severity and progression. These discoveries have extended our IP in AD most notably in the tau pathway and provide additional support to licensing discussions, at the same time allowing us to maximise cross-marketing of SysQuant® and TMTcalibrator™ services.

Substantial customer interest for our SysQuant® and TMTcalibrator™ services necessitated a second Fusion mass spectrometer in the summer to satisfy the demand and to significantly increase the scale of the biomarker services division to address the growing capacity requirements for orders from the USA and Europe. This came on stream and was at full capacity in Q4. Provision of the new Fusion more than doubled the existing capacity for customer contracts and made full use of the substantial upgrade already made to the IT infrastructure in Frankfurt and London.

Results were announced over CTAD, Barcelona providing compelling evidence that our two compounds for CK1d in a second and different *in vivo* model of AD mimicked the results of our previous study and successfully lowered the level of tau phosphorylation. This data provides strong additional support to our licensing discussions for our compounds in Alzheimer's disease.

The introduction of TMT® 10-plex added further momentum to TMT®'s dominant position in isobaric mass tagging and raised the profile and usage of TMT® tags for a growing number of applications. Development of a new range of tags with higher plexing rates is in process and that should provide further impetus to future sales.

High levels of interest for our biomarker services from pharmaceutical customers, particularly for SysQuant® and TMTcalibrator™, continued throughout the period and was reflected by the strong increase in services revenue. That trend is ongoing and provides a healthy background for revenue growth and prospects in 2016.

### Revenue

The Group's operations are organised into two geographic regions: the EU (UK and Germany) and US. Internal reporting on performance is allocated accordingly and to its major products and services, as set out below:

## **PS Biomarker Services**

The high levels of customer interest in SysQuant®, TMTcalibrator $^{\text{\tiny M}}$  and TMT® - MS3 biomarker workflows at the beginning of the year converted into a significant increase in contracts in 2015. This resulted in a 51% increase in biomarker services revenues for the full year and has also led to a sizeable uplift in the future pipeline.



With production at full capacity last summer, additional Fusion mass spectrometry capacity came on stream as projected in Q4 that doubled the level of output of SysQuant<sup>®</sup> and TMTcalibrator<sup>™</sup> production. This will go a long way towards addressing the rising customer demand.

Only a small amount of the \$2million contract announced with Genting TauRX Diagnostics (GTD) in Alzheimer's disease (AD) fell into 2015 and the great majority of the work will be undertaken in 2016 and 2017. The pipeline value of contracts under negotiation is improving monthly and is at the strongest position in the company's history. When combined with the improved contract conversion rate, this provides us with confidence that biomarker services revenues will show further strong growth in 2016.

## SysQuant®

Important new results were generated with our collaborators at the Moffitt Center, Florida using two different drug combinations in melanoma in three human skin cell lines where over 9,000 proteins and 17,000 phosphorylation sites were quantified. The data showed which cellular pathways were most affected by each combination and which cell lines responded to treatment. This may have significant implications for the development and management of new skin cancer treatments and further extends the coverage of results presented to date in pancreatic cancer and Alzheimer's disease and provides strong evidence as to how widely SysQuant® can be applied.

Having completed two SysQuant® studies in pancreas cancer that revealed multiple pathways activated and identified unique combinations of targets for existing anti-cancer drugs which could potentially have provided a superior outcome, we were keen to replicate the results in a different area, liver cancer. That process is underway and we wait with great interest results from the samples collected by our collaborators at KCL last year that should be available in the summer. The combination of these results should position SysQuant® centre stage and accelerate its use in clinical applications to improve patient management and outcome using a precision medicine approach in systems-wide biology for any disease condition.

## **TMT**calibrator<sup>™</sup>

Proteome Science's three oral presentations at the annual Alzheimer's Association International Conference (AAIC) succinctly demonstrated TMTcalibrator $^{\text{TM}}$ 's ability to identify very low abundance proteins in complex body fluids to find effective new biomarkers for use as highly effective diagnostic and drug biomarkers. The combination of SysQuant® and TMTcalibrator $^{\text{TM}}$  is a unique and powerful protein detection platform to provide unmatched levels of sensitivity that can be used from the earliest stages of diagnostics and drug development to clinical trials. This combined workflow is a key addition to our biomarker services platform that can substantially reduce the costs and timescale in drug development and companion diagnostics.

## **TMT®**

TMT® tags continued to perform well in 2015 with the largest ever order received from Thermo Scientific in the second quarter of the year. Product sales increased 33% in 2015 and TMT® tags are expected to increase market share with TMT® 10plex delivering the highest multiplexing capability available in the global market. Production of a new generation of tags with higher plexing rates is well underway and these are now expected to be launched in 2017. These should further accelerate and extend tandem mass tag use into new areas and applications in the much larger field of systems-wide biology.



## Alzheimer's disease

Major new milestones were attained in our research programmes in Alzheimer's disease (AD) in 2015.

## CK1d

We presented three oral and two poster presentations at AAIC in Washington in July. These highlighted the latest data and developments in our CK1d programme and featured proprietary SysQuant® and TMTcalibrator™ workflows to detect and quantify low abundance disease related proteins to help predict and monitor AD progression and to improve the effectiveness of new drugs and companion diagnostics.

Development of the novel assay presented at AAIC for clusterin in blood to predict the rate of brain atrophy in AD is now being finalised with full commercial availability expected later this year.

Over the 8<sup>th</sup> Cinical Trials on Alzheimer's Disease, Barcelona (CTAD) in November we released results on a study successfully testing our compounds PS110 and PS278-05 that are inhibitors of CK1d in a second *in vivo* model of AD tauopathy. The compounds were given orally for five days and showed that the level of tau phosphorylation in the brain cortex was reduced when compared to the control group. Surprisingly, the effect of acute dosing on phospho tau was nearly as potent as the effect of chronic administration daily over 8 weeks. The results confirmed and were consistent with the previous *in vivo* data in a completely different AD model that similarly reduced tau phosphorylation.

The two studies provided compelling evidence that both acute and chronic dosing with CK1d inhibitors reduced the levels of phosphorylated tau. Strongly positive engagement and feedback has been received from a broad cross section of pharmaceutical companies and has added further substance to our partnering discussions. The wider pharma audience is now becoming increasingly interested in developing tau strategies on a stand-alone basis or in combination with existing amyloid approaches in order to deliver novel and more effective Alzheimer's drugs. Additional interest in tau is likely to be stimulated when Phase III results of the first drug specifically targeting tau are announced this summer and if these are promising, there may be considerable activity in the space.

## MCI/AD

Results from the large 1148 patient study published in Alzheimer's and Dementia Journal highlighted the candidate AD biomarkers that we identified in blood and their utility to predict patients with early memory problems who would subsequently be diagnosed with Alzheimer's. We continue to await the data from our collaborators for a further cohort of patient samples that should add new intellectual property and accelerate the development of the clinical diagnostic for MCI. The proposed 10 protein MCI/AD panel will open up new horizons in patient stratification and the opportunity to develop and out-license a simple blood test and with that additional data available, we anticipate seeing that panel being developed in 2016.

In addition to the MCI/AD panel, we have applied TMTcalibrator™ to identify key brain proteins linked to different aspects of the disease in cerebrospinal fluid (CSF). Not only have we identified more than 100 regulated proteins in CSF from Alzheimer's disease patients reflecting amyloid, tau, inflammatory and metabolic processes, but we have also seen virtually all of the proteins encoded by established Alzheimer's disease associated genes. We believe that many of these CSF proteins may prove to be detectable very early in the disease process. We now aim to apply this same approach in blood where a parallel study in Motor Neurone Disease has delivered excellent proof of concept.



## Stroke

We have been informed by Randox that the CE marked blood test for stroke that incorporates Proteome Sciences biomarkers is on track to be launched in 2016. This will trigger further milestone payments under the terms of the license and raise the profile and value of our biomarker IP. In addition, there is the prospect of further similar non-exclusive licenses being taken up by other leading diagnostics companies on the back of the CE test coming on the market.

## IP portfolio

Our IP portfolio of key biomarkers across a broad range of diseases, applications and technologies that supports our extensive asset base has been further extended. Another 17 patents were granted in 2015 with a further 23 applications filed over the period. Our IP estate underpins the value that has been created through our research and is reflected by licence fees, milestones and royalties.

## Financial review

Financial performance

Revenue for the twelve month period ended 31st December, 2015 increased 20% to £1.88m (2014: £1.56m). In the breakdown of revenue, Licences/Sales/Services revenue rose 30% to £1.68m (2014: £1.30m) of which TMT® product sales increased 33%. Grant services were £0.21m (2014: £0.27m). The loss before tax was £3.33m (2014: £4.23m).

## Costs and available cash

Administrative expenses in 2015 were £4.17m (2014:£4.95m) and are likely to remain relatively constant in 2016. After the tax credit of £0.61m (2014:£0.66m), the loss after taxation for the period was £2.72m (2014: £3.57m). The net cash outflow from operating activities was £2.36m (2014: £3.27m). A placing of 13.8m ordinary shares was completed in July 2015 which raised £2.50m pre-expenses.

Cash at the year-end was £1.81m (2014:£1.87m).

## Outlook

The current year started well with a strong order book, increasing amounts of repeat business and a growing pipeline in biomarker services. With the level of SysQuant® /TMTcalibrator™ production doubled following the installation of the additional Fusion mass spectrometer, the increased capacity is being fully utilised at a time when the volume of customer enquiries is rising on a monthly basis and we are looking to expand the sales team. Current indications point to a strong performance in 2016.

We have been actively engaged with prospective licensing partners in Alzheimer's disease using the compelling results announced in November from a second and different AD model to test our CK1d compounds that mimicked the effects of the previous study, again successfully reducing the level of tau phosphorylation. Following receipt of the analysis from the next cohort of patients with MCI/AD from KCL, we anticipate that the proposed 10 protein panel will be finalised and developed into a panel test later in the year. It is intended that the test will be out-licensed non-exclusively.



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The encouraging trends and growth across the business in 2015 have continued in the current year. Proteome Sciences is firmly on track to deliver a significant increase in revenues from biomarker services and TMT® in 2016 and the possibility in addition of further licensing deals from our AD and stroke- IP.



## **Consolidated income statement**

For the year ended  $31^{\text{st}}$  December 2015

	Year ended 31 <sup>st</sup> December 2015 £'000	Year ended 31st December 2014 £'000
Revenue		
Licenses, sales and services	1,675	1,295
Grant services	207	<u>266</u>
Revenue- total	1,882	1,561
Cost of sales	(791)	(605)
Gross profit	1,091	956
Administrative expenses	(4,172)	(4,949)
Operating loss	(3,081)	(3,993)
Finance income	5	8
Finance costs	(250)	(242)
Loss before taxation	(3,326)	(4,227)
Tax	608	661
Loss for the period attributable to shareholders of the company	(2,718)	(3,566)
Loss per share		
Basic and diluted	(1.23p)	(1.69p)



# **Consolidated statement of comprehensive income**For the year ended 31st December 2015

	Year ended 31 <sup>st</sup> December 2015 £'000	Year ended 31st December 2014 £'000
Loss for the year	(2,718)	(3,566)
Other comprehensive income for the year Exchange differences on translation of foreign operations	18	(88)
Total comprehensive expense for the year	(2,700)	(3,654)



## **Consolidated balance sheet**

As at 31st December 2015

	2015 £'000	2014 £'000
Non-current assets		
Goodwill	4,218	4,218
Property, plant and equipment	857	314
Equipment on loan	237	474
	5,312	5,006
Current assets		
Inventories	291	344
Trade and other receivables	1,318	1,073
Cash and cash equivalents	1,808	1,869
	3,417	3,286
Total assets	8,729	8,292
Current liabilities		
Trade and other payables	(778)	(317)
Current tax liabilities	(1)	(34)
Short-term borrowings	(8,443)	(8,193)
Short-term provisions		(313)
	(9,222)	(8,857)
Net current liabilities	(5,805)	(5,571)
Non-current liabilities		
Hire purchase payables	(386)	-
Long-term provisions	<u>(276)</u>	(313)
	(662)	(313)
Total liabilities	(9,884)	(9,170)
Net liabilities	<u>(1,155)</u>	(878)
Equity		
Share capital	2,280	2,141
Share premium account	48,986	46,737
Share-based payment reserve	3,402	3,367
Other reserve	10,755	10,755
Translation reserve	(188)	(206)
Retained loss	(66,390)	(63,672)
Total equity (deficit)	(1,155)	(878)



# **Consolidated statement of changes in equity** For the year ended 31st December 2015

	Share capital	Share premium account	Share- based payment reserve	Translation reserve	Other reserve	Retained loss	Total equity/ (deficit)
	£'000	£'000	£'000	£'000	£'000	£'000	£'000
At 1st January 2014 Loss for the year Exchange differences on translation of	1,962 -	42,122	3,186 -	(118)	10,755 -	(60,106) (3,566)	(2,199) (3,566)
foreign operations	-	-	-	(88)	-	-	(88)
Total comprehensive expense for the year	-	-	-	(88)	-	(3,566)	(3,654)
Issue of share capital Share issue	179	4,821	-	-	-	-	5,000
expenses Credit to equity for share-based	-	(206)	-	-	-	-	(206)
payment	-		181		-	-	181
At 31st December 2014	2,141	46,737	3,367	(206)	10,755	(63,672)	(878)
At 1st January 2015	2,141	46,737	3,367	(206)	10,755	(63,672)	(878)
Loss for the year Exchange differences on translation of	-	-	-	-	-	(2,718)	(2,718)
foreign operations				18			18
Total comprehensive expense for the year	_	_	_	18	_	(2,718)	(2,700)
Issue of share capital	139	2,258	-	-	-	-	2,397
Share issue expenses Credit to equity for	-	(9)	-	-	-	-	(9)
share-based payment	-	-	35	-	-	-	35
At 31st December 2015 Page <b>12</b> of <b>16</b>	2,280	48,986	3,402	(188)	10,755	(66,390)	(1,155)

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## **Consolidated cash flow statement**

For the year ended 31st December 2015

	Group Year ended 31st December 2015 £'000	Group Year ended 31st December 2014 £'000
Cash flows from operating activities		
Cash used in operations Tax refunded	(2,921) 563	(3,958) 688
Net cash outflow from operating activities	(2,358)	(3,270)
Cash flows from investing activities Purchases of property, plant and equipment	(52)	(155)
Interest received	5	8
Net cash (outflow) from investing activities	(47)	(147)
Financing activities Proceeds on issue of shares	2,388	4,794
Repayment of HP creditors	(55)	-
Net cash inflow from financing activities	2,333	4,794
Net (decrease)/increase in cash and cash equivalents	(72)	1,377
Cash and cash equivalents at beginning of year	1,869	600
Foreign exchange differences	11	(108)
Cash and cash equivalents at end of year	1,808	1,869



## Notes to the Consolidated cash flow statement

	Group 2015 £'000	Group 2014 £'000
Operating loss	(3,326)	(4,227)
Adjustments for:		
Net finance costs	245	234
Depreciation of property, plant and equipment	395	406
Share-based payment expense	35	181
Operating cash flows before movements in working capital	(2,651)	(3,406)
Decrease/(increase) in inventories	54	58
(Increase)/Decrease in receivables	(233)	(280)
(Decrease)/Increase in payables	258	(459)
(Increase)/Decrease in provisions	(349)	129
Cash used in operations	(2,921)	(3,958)



## Notes to the financial information

## 1. Basis of Preparation

The financial information for the year ended 31 December 2015 and the year ended 31 December 2014 contained in these preliminary results does not constitute the company's statutory accounts for those years.

Statutory accounts for the year ended 31 December 2014 have been delivered to the Registrar of Companies. The statutory accounts for the year ended 31 December 2015 will be delivered to the Registrar of Companies in due course and once delivered, will be available at the Company's registered office: Coveham House, Downside Bridge Road, Cobham, Surrey KT11 3EP.

The auditors' reports on the accounts for 31 December 2015 and the year ended 31 December 2014 were unqualified, and did not contain a statement under 498(2) or 498(3) of the Companies Act 2006. However, while the year ended 31 December 2014 did not draw attention to any matters by way of emphasis, the audit report for the ended 31st December 2015 contained a statement in respect of uncertainly over going concern, further details are included in note 2.

The financial information contained in these preliminary results has been prepared using the recognition and measurement requirements of International Financial Reporting Standards (IFRSs) as adopted by the EU. The accounting policies adopted in these preliminary results have been consistently applied to all the years presented and are consistent with the policies used in the preparation of the financial statements for the year ended 31 December 2014. New standards, amendments and interpretations to existing standards, which have been adopted by the Group for the year ended 31 December 2015, have not been listed since they have no material impact on the financial information.

## 2. Liquidity and going concern

These financial statements have been prepared on the going concern basis. The Directors have reviewed Proteome Sciences ('the Group's') going concern position taking account of its current business activities, budgeted performance and the factors likely to affect its future development, are set out in the Annual report, and include the Group's objectives, policies and processes for managing its capital, its financial risk management objectives and its exposure to credit and liquidity risks.

The directors have prepared cashflow forecasts covering a period of at least 12 months from the date of approval of the financial statements. If the forecast is achieved, the Group will be able to operate within its existing facilities, however the timeline required to close sales contracts and the order value of individual sales continues to vary considerably, which constrain the ability to accurately predict revenue performance. Furthermore, the Group's products are still in the research and development phase and as such the directors consider that costs could exceed income in the short term. The directors therefore consider the Group may need to raise financing within the next 12 months, but the directors are confident they will be able to raise sufficient financing, should it be required though a placement of shares or other funding. The directors have a history of successfully raising financing.

The directors have concluded that the circumstances set forth above represent a material uncertainty, which may cast significant doubt about the Group's ability to continue as going concerns. However they believe that taken as a whole, the factors described above enable the Group to continue as a going concern for the foreseeable future. The financial statements do not include the adjustments that would be required if the Group was unable to continue as going concern.



## 3. Loss per share from continuing operations

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

	2015 £'000	2014 £'000
Loss for the financial year	(2,718)	(3,566)
	2015 Number of shares	2014 Number of shares
Weighted average number of ordinary shares for the purposes of calculating basic earnings per share:	221,036,176	211,129,430

In 2015 and 2014 the loss attributed to ordinary shareholders and weighted average number of ordinary shares for the purpose of calculating the diluted earnings per ordinary share are identical to those used for basic earnings per ordinary share. This is because the exercise of share options that are out of the money would have the effect of reducing the loss per ordinary share and is therefore not dilutive under the terms of the International Financial Reporting Standard 33.

## 4. Cautionary statement on forward-looking statements

Proteome Sciences ('the group') has made forward-looking statements in this preliminary announcement. The Group considers any statements that are not historical facts as "forward-looking statements". They relate to events and trends that are subject to risk and uncertainty that may cause actual results and the financial performance of the Group to differ materially from those contained in any forward-looking statement. These statements are made in good faith based on information available to them and such statements should be treated with caution due to the inherent uncertainties, including both economic and business risk factors, underlying any such forward-looking information.