

hVIVO plc

HALF-YEAR FINANCIAL REPORT

for the six months ended 30 June 2015

hVIVO plc

Statement from Chief Executive Officer

Introduction

I am pleased to present the hVIVO half-year financial report for the six months ended 30 June 2015. The first half of 2015 saw the Company advance its strategic plans to leverage the hVIVO platform as a drug and diagnostic discovery tool, in response to changing market conditions brought about by our industry's race to address the Ebola crisis in 2014. As companies reprioritised their R&D dollars to find effective Ebola treatments and flu programmes stalled, we took immediate actions to manage our resources and efficiencies to preserve a strong cash position and prioritise our spend for R&D. The resulting capacity in our unit gave hVIVO the opportunity to take major steps towards deepening our understanding of the flu and RSV disease processes, while also broadening the range of disease models that we can offer. As a result, we made significant progress towards achieving our ultimate goal- to create effective treatments and tests in difficult disease areas such as influenza (flu), respiratory syncytial virus (RSV), asthma and chronic obstructive pulmonary disease (COPD).

The first step to realising this aspiration is to map the journey from healthy to sick and back to health, getting a handle on the underlying biological pathways that drive disease activity – arguably for the very first time. This launch pad position makes possible the rational selection of drug targets and biomarkers, and increases the likelihood of successful product development for drugs and diagnostics. In the first of half of 2015, we achieved that critical first map in flu, while also paving the way to do the same in RSV and viral induced asthma exacerbation.

Background

hVIVO is a life sciences company pioneering a technology platform of human disease models to accelerate drug discovery and development in respiratory and infectious diseases.

Through its illumination of the entire disease life cycle from healthy to sick and back to health, the hVIVO platform captures disease in motion. It promotes rational selection of drug targets and biomarkers and provides methodology for testing product safety and efficacy to the highest clinical standards, much earlier than traditional processes. The hVIVO platform enables clients and collaborators to qualify existing assets, extend asset application in new disease areas, and harvest assets for the future – providing a one stop shop in early stage drug development.

With multiple disease models in crucial areas such as flu, RSV and asthma, the hVIVO platform brings together a revolutionary set of capabilities in product validation testing and the mining of biological insights, in order to tackle the long timeline, significant costs and high risks to market facing drug development and diagnostic organisations today.

As market leader, hVIVO has conducted over 40 product validation studies with over 2,000 subjects, for a wide range of industry, government, and academia clients and collaborators.

Overview

A First in Flu

Following the acceleration of our flu sample collection protocol in late 2014, hVIVO set its sights on mining the platform for biological insights into the flu disease process while simultaneously developing the analysis methodology for the Company's wider pathomics discovery approach. By Q3 2015, we established our first pathomics map outlining key biological pathways involved in the host response to flu infection. Based on this, we have begun the exciting task of identifying the biological 'tipping point' when flu becomes severe in order to rationally select drug targets and predictive biomarkers. Work in this area is ongoing in 2015 and is progressing to plan.

RSV: Preparing to Map

In early 2015 we returned to the clinic with the objective of harvesting proprietary samples in RSV infection. RSV is a prevalent upper respiratory tract disease that afflicts children and the

elderly and frequently can cause hospitalisations in children. There is no effective treatment for the disease today and our RSV human disease model has become the gold standard in early phase RSV drug development. Collection of our own samples allows us to construct a map of the healthy host response to RSV, a critical first step in building a meaningful map of disease pathways in children and the elderly. The study was an enormous success and work is ongoing in 2015 to construct the RSV map development plan and the first set of analysis for biomarker identification.

Asthma Model On Line

Another significant milestone was reached in the first half of 2015, with the official release of our human model of viral induced asthma exacerbation. Our initial 'calibration' studies allowed us to develop the model's product specifications (i.e., endpoints, recruitment rates, trial design) and be ready for commercialization. Following confirmation from the independent safety data board that we had successfully and safely induced exacerbations in our asthmatic subjects, we implemented our sales and marketing plans to drive demand and actively pursue client opportunities. We anticipate our first investigational drug product validation study in this model by early 2016.

In addition, broadening our platform's therapeutic reach and pipeline potential, our work in asthma revealed previously unrecognised patterns of association that may predict if an asthmatic suffering from a cold will experience an exacerbation of their disease. Such insight offers a compelling opportunity to connect biology and digital data to design powerful disease algorithms, and work is ongoing in 2015 in this area.

Becoming 'Product Ready'

Having moved ahead significantly with our R&D efforts in a short span of time, a priority for the first half of 2015 was to put into place a robust commercial infrastructure for safeguarding our growing list of Intellectual Property (IP) and emerging proprietary know how. From this we evolved our strategy to develop two product types: those that the hVIVO platform "enhances" (drug development tools and drugs that are repurposed, repositioned and rescued (DRPx)) and those "derived" from the platform's insights (*de novo* compounds, digital health solutions and clinical assessment tests).

Platform enhancements, on the whole, are likely to have the quickest route to market, and present an ideal opportunity to realize fully the value that the platform brings to an existing product by decreasing product risk failure, aligning development plans with qualified biology and shortening the time, costs and risks spent in clinical trials.

Strengthening and Evolving: Clients and Collaborators

To support the increasing commercial demands of the Company, the first half of 2015 saw us expand our sales force and base it from the US, enabling a more global reach, while also evolving our marketing capabilities to grow and support partnering opportunities. The goal of these investments is to broaden our customer activities and cultivate platform enhancement opportunities with existing and new pharmaceutical and biotechnology clients. Because the hVIVO platform addresses two of the key pain points in our industry – reliable pre-discovery and fast and efficient clinical trials – we are uniquely positioned to add value in a collaborative fashion, conducting targeted, more informed clinical trials for better decision making, re-energizing existing assets with reprofiling and repositioning, and supporting rational selection of future assets through 'disease in motion' derived targets and biomarkers.

Financial Review

Condensed Consolidated Statement of Comprehensive Income

Revenue for the six months ended 30 June 2015 was £2.9 million (H1'14 - £15.0 million; 2014 - £18.5 million). The lower revenue for H1'15, and comparable to H2'14 of £3.5 million, reflect the effects of Ebola continuing with reduced demand for early phase human challenge studies in influenza in H1'15. Visibility on client engagements for H2'15 and beyond indicate a return of

activity to the sector, with unit bookings for H2'15 trending towards the levels seen in H1'14 and in line with management's expectations for the full year.

Gross profit was £0.9 million and gross margin 29.9% (H1'14 - £4.8 million and 32.1%; 2014 - £5.5 million and 29.6%). Gross margin is consistent with prior periods as we continue to manage the improvement in utilisation and efficiency of our resources.

Research and development expense (excluding provision against virus inventory) was £7.4 million (H1'14 - £3.1 million; 2014 - £10.7 million), as we continue to invest in discovery research and product validation.

Administrative expense was £6.6 million (H1'14 - £7.3 million; 2014 - £17.7m). The reduction is primarily due to managing the efficiency of our resources and implementing cost saving initiatives during the period. The 2014 administrative expense included £3.7 million of leasehold impairments and provisions.

Loss before taxation was £12.0 million (H1'14 - £5.4 million; 2014 - £22.7 million).

Condensed Consolidated Statements of Financial Position and Cash Flows

As at 30 June 2015 net assets amounted to £51.7 million (H1'14 £43.4 million; 2014 £61.2 million), including short term deposits and cash and cash equivalents of £42.5 million (H1'14 - £31.6 million; 2014 - £50.8 million).

Net cash used in operating activities over the six months to 30 June 2015 was £8.2 million (H1'14 - £3.6 million; 2014 - £16.6 million).

Outlook

In the first half of 2015 we launched our new company name, hVIVO plc, to reflect our expanded vision and to recognise the importance of leveraging human biology in motion to resolve pressing unmet medical needs in diseases that are uniquely human. The name change coincided with our first forays into harnessing the platform to obtain biological insights that have alluded us via traditional discovery means, and the platform did not disappoint. We produced the first known human host response map for flu, launched a new asthma model, and gained unprecedented insight into the biology of asthma exacerbations, heralding in a new era for the Company.

Work to build value from these advancements continues in 2015. At the same time, we see demand returning for our clinical services, with a newly emerging asthma model pipeline, pivotal studies in flu and RSV, and a study programme that leverages multiple models against a single drug. At the same time, we are making good strides in the advancement of a more collaborative proposition to offer our clients that enhances the value that together we can achieve from a uniquely positioned drug discovery and development platform. To ensure we maintain momentum in the coming years we continue to diversify our repertoire of disease models, augmenting existing ones to meet the development needs of new product classes and pressing ahead with another respiratory model in COPD for calibration in 2016. As a result, we remain well placed to achieve our 2015 business objectives.

I am delighted with the rapid pace of progress and the ensuing opportunities arising out of 2015 as a result of our broad vision and powerful platform. I would like to thank our hVIVO staff for their innovation, dedication and commitment through such an evolving and fast paced year, while also extending my deep gratitude to our investors for their continuing support. I look forward to bringing you further updates on our progress in the months to come.



Kym Denny
Chief Executive Officer
23 September 2015

hVIVO plc

Condensed Consolidated Statement of Comprehensive Income

For the six months ended 30 June 2015

		6 months ended 30 June 2015 Unaudited £'000	6 months ended 30 June 2014 Unaudited £'000	Year ended 31 December 2014 Audited £'000
	Note			
Revenue		2,888	15,028	18,472
Cost of sales		(2,025)	(10,201)	(12,999)
Gross profit		863	4,827	5,473
Other Income	3	1,002	-	-
Research and development expense (excluding provision against virus inventory)		(7,392)	(3,063)	(10,733)
Research and development expense - provision against virus inventory		(3)	-	(58)
Administrative expense		(6,625)	(7,278)	(17,730)
Loss from operations		(12,155)	(5,514)	(23,048)
Finance income		200	149	358
Finance costs		(9)	(9)	(15)
Loss before taxation		(11,964)	(5,374)	(22,705)
Taxation	3	2,181	1,961	4,269
Loss for the period		(9,783)	(3,413)	(18,436)
Total comprehensive loss for the period attributable to owners of the parent		(9,783)	(3,413)	(18,436)
Loss per share - basic (pence)	4	(14.4p)	(6.3p)	(31.3p)
Loss per share - diluted (pence)	4	(14.4p)	(6.3p)	(31.3p)

All results derive from continuing operations.

The Group has no recognised gains or losses other than the loss for the period

The accompanying notes are an integral part of the Condensed Consolidated Statement of Comprehensive Income.

hVIVO plc
Condensed Consolidated Statement of Financial Position
As at 30 June 2015

	30 June 2015 Unaudited £'000	30 June 2014 Unaudited £'000	31 December 2014 Audited £'000
Note			
Assets			
Non-current assets			
Goodwill	1,722	1,402	1,722
Intangible assets	3,075	3,505	3,333
Property, plant and equipment	2,894	3,665	3,153
	7,691	8,572	8,208
Current assets			
Inventories	3,902	3,570	3,731
Trade and other receivables	3,073	6,576	2,904
Research and development tax credit receivable	2,379	1,818	3,806
Short-term deposits	5 18,020	22,500	28,007
Cash and cash equivalents	5 24,507	9,149	22,826
	51,881	43,613	61,274
Total assets	59,572	52,185	69,482
Equity and liabilities			
Equity			
Share capital	3,447	2,736	3,383
Share premium account	73,591	40,350	72,498
Other reserve	211	922	921
Share-based payment reserve	87	244	249
Merger reserve	4,199	4,199	4,199
Retained deficit	(29,849)	(5,043)	(20,066)
Total equity	51,686	43,408	61,184
Non-current liabilities			
Other payables	513	587	550
Provisions	2,521	110	3,130
	3,034	697	3,680
Current liabilities			
Trade and other payables	4,852	8,080	4,618
	4,852	8,080	4,618
Total liabilities	7,886	8,777	8,298
Total liabilities and equity	59,572	52,185	69,482

The accompanying notes are an integral part of the Condensed Consolidated Statement of Financial Position.

The Interim Condensed Consolidated Financial Statements of hVIVO plc (registered company number 08008725) were approved by the Board of Directors and authorised for issue on 23 September 2015 and signed on its behalf by:



Graham E Yeatman
Chief Financial and Business Officer

hVIVO plc
Condensed Consolidated Statement of Changes in Equity
As at 30 June 2015

	Share capital £'000	Share premium account £'000	Share- based payment reserve £'000	Merger reserve £'000	Other reserve £'000	Retained deficit £'000	Total equity £'000
As at 1 January 2014	2,686	37,363	239	4,199	-	(1,630)	42,857
Proceeds from shares issued:							
Acquisition of subsidiary	50	2,987	-	-	921	-	3,958
Issue of new shares	-	15	-	-	-	-	15
Placing net of related expense	647	32,133	-	-	-	-	32,780
Total transactions with owners in their capacity as owners	697	35,135	-	-	921	-	36,753
Loss for the period	-	-	-	-	-	(18,436)	(18,436)
Share-based payment expense	-	-	10	-	-	-	10
As at 31 December 2014	3,383	72,498	249	4,199	921	(20,066)	61,184
Acquisition of subsidiary – deferred consideration	11	699	-	-	(710)	-	-
Exercise of warrant and share options	52	360	(184)	-	-	-	228
Loss for the period	-	-	-	-	-	(9,783)	(9,783)
Issue of new shares	1	34	-	-	-	-	35
Share-based payment expense	-	-	22	-	-	-	22
As at 30 June 2015	3,447	73,591	87	4,199	211	(29,849)	51,686

As at 1 January 2014	2,686	37,363	239	4,199	-	(1,630)	42,857
Issued to acquire subsidiary company	50	2,987	-	-	-	-	3,037
Acquisition of subsidiary company - deferred consideration	-	-	-	-	922	-	922
Loss for the period	-	-	-	-	-	(3,413)	(3,413)
Share-based payment expense	-	-	5	-	-	-	5
As at 30 June 2014	2,736	40,350	244	4,199	922	(5,043)	43,408

The accompanying notes are an integral part of the Condensed Consolidated Statement of Changes in Equity.

hVIVO plc
Condensed Consolidated Statement of Cash Flows
For the six months ended 30 June 2015

	6 months ended 30 June 2015 Unaudited £'000	6 months ended 30 June 2014 Unaudited £'000	Year ended 31 December 2014 Audited £'000
Cash flow from operating activities			
Loss before taxation	(11,964)	(5,374)	(22,705)
Adjustments for:			
Depreciation of property, plant and equipment	658	580	1,221
Impairment of property, plant and equipment	-	-	672
Amortisation of intangible assets	273	174	435
Share-based payment expense	22	5	10
Payment of Non-Executive Director fees by issue of shares	35	-	15
Finance costs	9	9	15
Finance income	(200)	(149)	(358)
Loss on foreign exchange	-	27	8
(Decrease)/increase in provisions	(609)	-	3,020
Changes in working capital:			
Increase in inventories	(171)	(454)	(615)
(Increase)/decrease in trade and other receivables	(281)	(709)	2,965
Increase/(decrease) in trade and other payables	235	(276)	(3,835)
Cash used in operations	(11,993)	(6,167)	(19,152)
Finance costs	(9)	(9)	(15)
Income tax refund	3,775	2,568	2,568
Net cash used in operating activities	(8,227)	(3,608)	(16,599)
Cash flows from investing activities			
Acquisition of intangible assets	(15)	(59)	(148)
Acquisition of property, plant and equipment	(400)	(578)	(1,355)
Decrease/(increase) in balances on short-term deposit	9,987	-	(5,507)
Acquisition of subsidiary	-	-	67
Finance income	146	149	361
Net cash generated from/(used in) investing activities	9,718	(488)	(6,582)
Cash flows from financing activities			
Net proceeds from issue of shares	228	-	32,780
Other payables repaid	(38)	(38)	(75)
Net cash generated from/(used in) financing activities	190	(38)	32,705
Net increase/(decrease) in cash and cash equivalents	1,681	(4,134)	9,524
Exchange loss on cash and cash equivalents	-	(27)	(8)
Cash and cash equivalents at the start of financial period	22,826	13,310	13,310
Cash and cash equivalents at the end of financial period	24,507	9,149	22,826

The accompanying notes are an integral part of the Condensed Consolidated Statement of Cash Flows.

hVIVO plc

Notes to the Condensed Consolidated Interim Financial Statements

1. Accounting policies

Basis of preparation and approval of the Interim Financial Statements

The accounting policies adopted in the preparation of the Interim Financial Statements are consistent with those set out in the Group's Annual Report and Financial Statements 2014, which were prepared in accordance with International Financial Reporting Standards ("IFRS") as adopted by the European Union and as issued by the International Accounting Standards Board ("IASB"), and are expected to be consistent with the accounting policies that will be applied in the Group's Annual Report and Financial Statements 2015.

The Interim Financial Statements for the six months to 30 June 2015 do not include all of the information required for full Annual Financial Statements and should be read in conjunction with the Consolidated Financial Statements for the year ended 31 December 2014. The financial information for the six months ended 30 June 2015 and for the six months ended 30 June 2014 is unaudited.

The Interim Financial Statements do not comprise statutory accounts within the meaning of Section 434 of the Companies Act 2006. Statutory accounts for the year ended 31 December 2014 were approved by the Board on 15 April 2015 and delivered to the Registrar of Companies. The report of the auditors on those accounts was unqualified, did not contain an emphasis of matter paragraph and did not contain any statement under Section 498(2) or Section 498(3) of the Companies Act 2006.

The Interim Financial Statements have been prepared on a going concern basis which the Directors believe is appropriate for the following reason:

The Directors have prepared cash flow forecasts which show the Group expects to meet its liabilities as they fall due for a period in excess of twelve months from the date of the Interim Financial Statements. Management prepares detailed working capital forecasts which are reviewed by the Board on a regular basis. The forecasts include assumptions regarding the status of client engagements and sales pipeline, future revenues and costs together with various scenarios which reflect growth plans, opportunities, risks and mitigating actions. The forecasts also include assumptions regarding the timing and quantum of investment in the Group's research and development programme. Whilst there are inherent uncertainties regarding the cash flows associated with the development of the hVIVO platform, together with the timing of signature and delivery of client engagements, the Directors are satisfied that there is sufficient discretion and control as to the timing and quantum of cash outflows to ensure that the Group is able to meet its liabilities as they fall due for the foreseeable future. At 30 June 2015, the Group had cash and short-term deposits of £42.5m.

The Company is a limited liability company incorporated and domiciled in England & Wales and whose shares are quoted on AIM, a market operated by The London Stock Exchange. The Group Financial Statements are presented in pounds Sterling (£), which is the Group's presentational currency, and all values are rounded to the nearest thousand (£'000) except where indicated otherwise.

The Interim Financial Statements were approved by the Board of Directors on 23 September 2015.

hVIVO plc

Notes to the Condensed Consolidated Interim Financial Statements

2. Segmental information

The Group's Chief Operating Decision Maker, the Chief Executive Officer, is responsible for resource allocation and the assessment of performance. In the performance of this role, the Chief Executive Officer reviews the Group's activities in aggregate. The Group has therefore determined that it has only one reportable segment under IFRS 8 Operating Segments, which is "medical and scientific research services".

The Group carries out its main activities from the United Kingdom. The Group conducts sales activity in the US and in Europe which is carried out through hVIVO Inc and hVIVO Services Limited respectively. All revenue is derived from activities undertaken in the UK.

3. Taxation

	6 Months ended 30 Jun 2015 Unaudited £'000	6 Months ended 30 Jun 2014 Unaudited £'000	Year ended 31 Dec 2014 Audited £'000
Tax Benefit:			
R&D tax credit	(2,212)	(1,818)	(3,806)
Adjustments in respect of prior periods	31	(143)	(143)
Origination and reversal of temporary timing differences	-	-	(320)
	<u>(2,181)</u>	<u>(1,961)</u>	<u>(4,269)</u>

The Group continues to account for its recurring annual SME R&D tax credit as an income tax benefit due to the requirement to surrender tax losses in exchange for recoverable R&D credits. Additionally, the Group's loss from operations before taxation includes Other Income of £1.0m, of which £0.8m relates to amounts receivable following submission to HM Revenue & Customs of an R&D Expenditure Credit (RDEC) claim for 2014 and £0.2m accrued for the first half of 2015. The Group classifies such RDEC claims as a government grant. No such claims for RDEC have been submitted in prior periods.

The Group has not recognised deferred tax assets relating to carried forward losses and other temporary differences. These deferred tax assets have not been recognised as the Group's management considers that there is insufficient taxable income, taxable temporary differences and feasible tax planning strategies to utilise all of the cumulative losses and it is probable that the deferred tax assets will not be realised in full.

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Notes to the Condensed Consolidated Interim Financial Statements

4. Loss per share (LPS)

The calculation of the basic and diluted LPS is based on the following data:

	6 Months ended 30 Jun 2015 Unaudited £'000	6 Months ended 30 Jun 2014 Unaudited £'000	Year ended 31 Dec 2014 Audited £'000
Loss:			
Loss for the period	(9,783)	(3,413)	(18,436)
Number of shares:			
Weighted average number of ordinary shares for the purpose of basic LPS	68,106,047	54,384,217	58,839,405
Effect of dilutive potential ordinary shares:			
- share options	-	-	-
- warrants	-	-	-
Weighted average number of ordinary shares for the purpose of diluted LPS	68,106,047	54,384,217	58,839,405

In the six months ended 30 June 2015 and in the comparative periods presented, the potential ordinary shares were not treated as dilutive as the Group is loss making, therefore the weighted average number of ordinary shares for the purposes of the basic and diluted loss per share were the same.

5. Financial assets and liabilities

Carrying value of financial assets:

	30 June 2015 Unaudited £'000	30 June 2014 Unaudited £'000	31 December 2014 Audited £'000
Cash and cash equivalents	24,507	9,149	22,826
Short-term deposits	18,020	22,500	28,007
Trade receivables	948	3,484	446
Other receivables	663	486	667
Accrued income	233	824	162
Total financial assets	44,371	36,443	52,108

Carrying value of financial liabilities:

	30 June 2015 Unaudited £'000	30 June 2014 Unaudited £'000	31 December 2014 Audited £'000
Trade payables	1,941	2,881	2,754
Accruals	1,223	2,256	903
Repayable lease incentive from related parties	588	663	625
Other payables	80	163	177
Total financial liabilities	3,832	5,963	4,459

Independent review report to hVIVO plc

We have been engaged by the Company to review the condensed set of Financial Statements in the interim financial report for the six months ended 30 June 2015 which comprise the Condensed Consolidated Statement of Comprehensive Income, the Condensed Consolidated Statement of Financial Position, the Condensed Consolidated Statement of Changes in Equity, the Condensed Consolidated Statement of Cash Flows and related notes 1 to 5. We have read the other information contained in the interim financial report and considered whether it contains any apparent misstatements or material inconsistencies with the information in the condensed set of interim Financial Statements.

This report is made solely to the Company in accordance with International Standard on Review Engagements (UK and Ireland) 2410 "Review of Interim Financial Information Performed by the Independent Auditor of the Entity" issued by the Auditing Practices Board. Our work has been undertaken so that we might state to the Company those matters we are required to state to it in an independent review report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the Company, for our review work, for this report, or for the conclusions we have formed.

Directors' responsibilities

The interim financial report is the responsibility of, and has been approved by, the directors. The directors are responsible for preparing the interim financial report in accordance with the AIM Rules of the London Stock Exchange. As disclosed in note 1, the annual Financial Statements of the Group are prepared in accordance with IFRSs as adopted by the European Union. The condensed set of Financial Statements included in this half-yearly financial report has been prepared in accordance with International Accounting Standard 34, "Interim Financial Reporting," as adopted by the European Union.

Our responsibility

Our responsibility is to express to the Company a conclusion on the condensed set of Financial Statements in the interim financial report based on our review.

Scope of review

We conducted our review in accordance with International Standard on Review Engagements (UK and Ireland) 2410 "Review of Interim Financial Information Performed by the Independent Auditor of the Entity" issued by the Auditing Practices Board for use in the United Kingdom. A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing (UK and Ireland) and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the condensed set of Financial Statements in the interim financial report for the six months ended 30 June 2015 is not prepared, in all material respects, in accordance with International Accounting Standard 34 as adopted by the European Union and the AIM Rules of the London Stock Exchange.



Deloitte LLP

Chartered Accountants and Statutory Auditor
Reading, United Kingdom
23 September 2015