

Interim results for the six months ended 30 June 2018

11 September 2018

Silence Therapeutics plc, AIM:SLN (“Silence” or “the Company”) a leader in the discovery, delivery, and development of novel RNA therapeutics for the treatment of serious diseases, announces its unaudited interim results for the half year to 30 June 2018.

Highlights

- New leadership in place with the recruitment in July of Dr David Horn Solomon as Chief Executive Officer, an experienced public company biotech CEO, board member and biotech investor.
- The field is advancing: Gene-silencing as a therapeutic modality was granted its first drug approval by the FDA on 10 August for patisiran, validating RNAi as a class of drugs that now have a clear path to market.
- Positive regulatory feedback and promising data in clinically validated animal disease models representative of iron overload disorders, increases confidence in Silence’s lead candidate SLN124, with the first patient entered into a Phase Ib study anticipated in H2 2019.
- Out-licenced programme, QPI-1002 for Prevention of Acute Kidney Injury progressed to Phase III clinical trial by partner Quark Pharmaceuticals, Inc.
- patisiran remains accused of infringement of Silence’s Intellectual Property in the United Kingdom and Portugal.

Financial Highlights

- Loss after tax of £8.7 million (2017 H1: £5.5 million), reflecting increasing costs associated with the progression of lead programmes SLN124 and SLN226 towards the clinic.
- Cash and cash equivalents and term deposits of £34.3 million (FY 2017 £42.7 million).
- Net cash outflow from operating activities £8.8 million (H1 2017: £4.4 million).

Post Half-Year Events

- Departure of Dr Annalisa Jenkins as Chair on 19 August 2018, having upgraded Silence’s R&D operations and successfully reshaped the Company’s strategy, with appointment of Dr Andy Richards, CBE, as Interim Chair.
- Completion of new management review of clinical timelines results in first patient dosing for SLN124 now expected in H2 2019.

Dr David Horn Solomon, Chief Executive Officer of Silence Therapeutics, commented:

“The RNAi space is maturing with the first marketing approval of patisiran from Alnylam. I am excited for the opportunity to build Silence into a leading drug development company in this cutting-edge field of technology. Since joining Silence, I have been impressed by the calibre of our scientists and developers, our growing pipeline, our innovative technology platform and the commercial opportunities that these present.”



“In the coming months, we will apply for Orphan Drug designation for our clinically validated lead medicine candidate, SLN124, for the treatment of Beta-Thalassemia, in order to expedite progress towards a Phase Ib trial planned to begin in H2 2019. Whilst also advancing the development of our other pipeline of product candidates, we are targeting validating Business Development deals and continue to explore a range of financing options.”

Dr Andy Richards, CBE, Interim Chair of Silence Therapeutics, commented:

“This has been a transformational period for Silence, with the recent recruitment of Dr David Horn Solomon as CEO, who brings extensive biotech industry leadership experience with an international track record of successful pipeline delivery, financing and deal making. At the Board level, we have also been delighted to welcome Dave Lemus who brings further expertise in commercialisation and strategic partnerships, as well as financing and transactions, especially in the US. I will serve as Interim Chair to ensure a smooth transition period to a new Chair, following the successful completion of the changes that have provided Silence with such a clear and well-directed strategy.”

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About Silence Therapeutics plc

Silence Therapeutics is developing a new generation of medicines by harnessing the body’s natural mechanism of RNA interference, or RNAi, within its cells. Its proprietary technology can selectively inhibit any gene in the genome, specifically silencing the production of disease-causing proteins. Using its enabling delivery systems, it has achieved an additional level of specificity by delivering its therapeutic RNA molecules exclusively to target cells. Silence’s proprietary RNA chemistries and delivery systems are designed to improve the stability of our molecules and enhance effective delivery to target cells, providing a powerful modular technology well suited to tackle life-threatening diseases. For more information, please visit: <https://www.silence-therapeutics.com/>

Chief Executive's Report

Overview

The FDA approval of patisiran demonstrates that, after 20 years of development, the RNAi class of medicines is now a therapeutic reality. Silence has a renewed vision with new leadership, new management and a focussed strategy to pursue our development opportunities. With a broad and growing pipeline of candidate medicines in a number of therapeutic areas and a robust financial position, the company is well-positioned to grow and to maximise the potential of its GalNAc-based siRNA platform.

Management and Board alignment

Important appointments have been made recently, strengthening and aligning the senior management and Board of Silence. In June, Ali Mortazavi stepped down as CEO having served the company for six years. Newly appointed CEO, Dr David Horn Solomon, formerly served as CEO of Zealand Pharma A/S from 2008 to 2015. Under David's leadership the company went public on NASDAQ and its lead product, Adlyxin[®], a GLP-1 receptor agonist for the treatment of type II diabetes, was approved in the US and globally and is now marketed by Sanofi as a monotherapy and in combination with Lantus[®] as Soliqua[®]. Having held senior management roles in both the US and Europe, David brings extensive international leadership experience in the biotech industry with a track record of successful pipeline delivery, financing and deal making.

Dave Lemus joined the Board of Directors in June as Non-Executive Director, bringing a track record and proven leadership in building and managing high performance management teams. In August, Dr Annalisa Jenkins left her role as Chair, with Dr Andy Richards assuming the role of non-executive Chair in an interim capacity to ensure a smooth transition. In June, the appointment of Richard Jenkins as Head of Clinical Development was also announced. Richard has over 28 years' experience in clinical development and drug discovery and will be heading the clinical development function as Silence advances its lead asset through the clinic.

Pipeline

RNAi is now an approved class of medicines, and Silence's two lead programmes, SLN124 and SLN226, both have robust animal model data supporting progression to clinical trials in H2 2019 and 2020, respectively. Management remains fully committed to progressing these candidates to the clinic. Following the submission of the SLN124 Briefing Document to the UK Medicines and Healthcare products Regulatory Agency, positive feedback was received at the June Scientific Advice Meeting. The first in-human study for SLN124, for the treatment of patients with Beta-Thalassemia and Myelodysplastic Syndrome, will be a Phase Ib trial. Silence will examine a variety of end points suggested by animal models as markers of efficacy to inform the clinical trial approach, and in order to seek the best possible results for patients and their caregivers.

Silence is pursuing additional therapeutic opportunities selected in a risk-diversified manner, focusing on indications with high unmet need where the Company's therapies can make a dramatic difference to patients. To this end, four new indications were added to the pipeline in H1 2018, including for the treatment of rare renal and rare metabolic conditions. Silence will continue to develop treatments



both for rare and non-rare conditions, periodically assessing options and seeking strategic partnerships for the larger markets.

External partnerships

Silence's foundational IP has already been validated through out-licensing to Quark Pharmaceuticals, Inc ("Quark"), and future licensing agreements are anticipated. In July 2018, Quark announced the first patient dosed in the phase III clinical trial of QPI-1002 for prevention of Acute Kidney Injury (AKI) following cardiac surgery. The product is exclusively partnered with Novartis, who have an option for worldwide development and commercialisation in AKI. Novartis also has an option on QPI-1002 in Delayed Graft Function for which a Phase III study is ongoing, with Quark stating that first interpretative results are expected in Q4 2018.

Strong Intellectual Property

Technology innovation is key to remaining at the forefront of disruptive new treatment modalities such as RNAi, and this is underpinned by intellectual property (IP). In recent years GalNAc conjugates have become the main accepted and clinically validated technology for optimised stability, delivery, targeting, specificity and efficacy of RNAi.

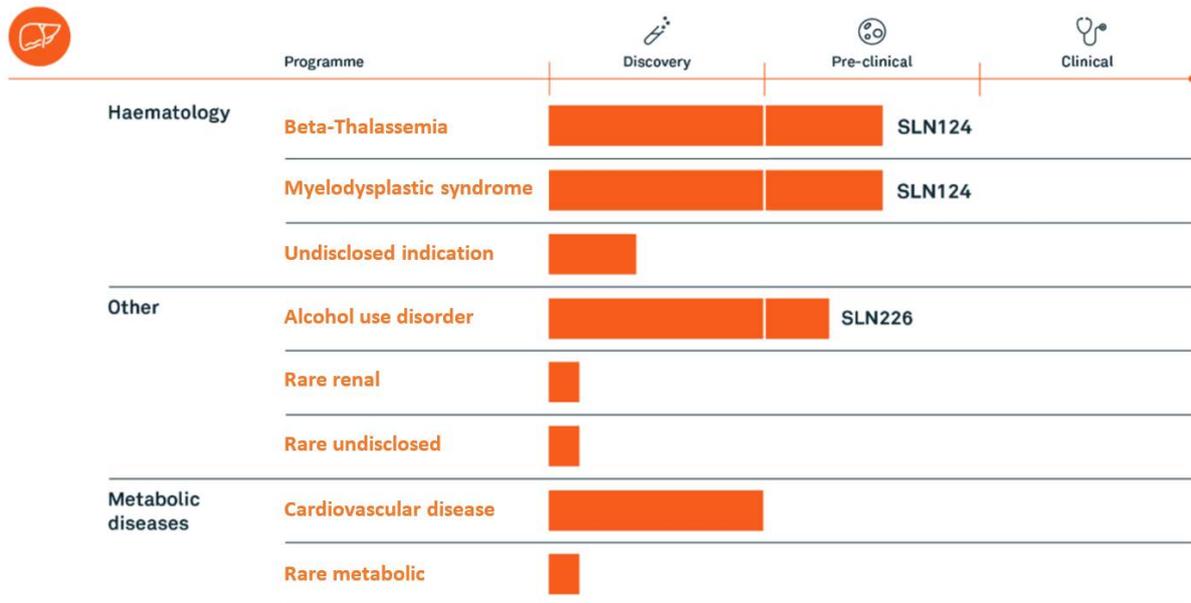
In 2018, Silence continued to strengthen its overall patent estate, and protection of its GalNAc siRNA IP in particular, by filing additional patent applications for several lead sequences, several linker chemistries, multiple RNAi constructs and rules for chemical modification. Silence believes that several granted patent claims protecting its proprietary chemical modification technology are relevant to third-party RNAi medicines and that, more generally, its foundational IP underpins the RNAi field. As part of Silence's determination to enforce its patent estate against potential infringers, litigation in the UK and Portugal is ongoing against Alnylam Pharmaceuticals Inc. (NASDAQ:ALNY) ("Alnylam"). The UK litigation is proceeding towards a trial in the High Court in London beginning on, or around, 10 December 2018. While Silence continues to develop further innovation and to protect its rights and inventions, the Company remains focused on executing its core business of drug discovery and development to continue to build its therapeutic pipeline.

Outlook

With the management team led by Dr David Horn Solomon, complemented by a supportive and highly experienced Board, Silence has a closely aligned leadership team well-equipped to grow the Company. Silence has a strong cash position to drive the value of its platform technology and therapeutic portfolio and continues to explore a range of financing options.

Our programmes

A core focus is the development of our proprietary clinical-stage RNA therapeutics, having developed a broad pipeline of product candidates in a number of therapeutic areas.



SLN124

- SLN124 represents a highly promising therapeutic candidate medicine for patients with iron overload disorders, such as Beta-Thalassemia and Myelodysplastic syndrome (MDS)
- Positive feedback received from June Scientific Advice meeting with the UK MHRA, following the submission of the SLN124 Briefing Document
- Orphan designation application to be filed for Beta-Thalassemia in H2 2018
- Clinical development is progressing SLN124 towards a CTA filing for a First in Human study for both Beta-Thalassemia and MDS indications, with the first patient entered into the Phase Ib study anticipated in H2 2019

SLN226

- SLN226 has the potential to aid abstinence in alcohol dependent patients. With its unique mode of action, it provides a significantly improved therapeutic option due to its high target specificity and long duration of action
- Currently in preclinical development with plans to enter clinical development in 2020

Other indications

- Four new target indications added to the pipeline in H1 2018
- Pre-clinical models of cardiovascular disease efficacy scheduled for H2 2018

Out-licensed programmes

We have out-licensed our siRNA stabilisation chemistry technology (AtuRNAi™) to Quark Pharmaceuticals, who are progressing two drug candidates using this technology in late-stage clinical trials.



Delayed Graft Function

- The Quark drug received Orphan Drug Designation from the US Food and Drug Administration (FDA) and European Medicines Agency (EMA) and Fast Track designation by the FDA for the DGF indication
- Quark completed dosing of 594 patients in a Phase III study for delayed graft function (DGF) following kidney transplantation in January 2018, with first interpretative results anticipated in Q4 2018

Acute Kidney Injury

- On 9th July, Quark Pharmaceuticals, Inc announced its first patient dosed in the Phase III clinical trial of QPI-1002 for prevention of Acute Kidney Injury (AKI) following cardiac surgery
- The Phase III study will enrol approximately 1,038 subjects at high risk for AKI following cardiac surgery at 115 sites globally

Silence is eligible to receive 1.5%-4% royalties from Quark plus milestones, or 15% royalties on the clinical, regulatory and commercial milestone payments and royalties received by Quark from its partner Novartis.

Financial review

Operating expenses

Research & Development Expenses

Research and development expenses increased by £1.4 million to £5.2 million for H1 2018 (H1 2017: £3.8 million). Contract Research Organisation and R&D consulting costs increased by £2.1 million to £2.9 million for H1 2018 (H1 2017: £0.8 million), reflecting increasing costs associated with the progression of lead programmes SLN124 and SLN226 towards CTA filings. This increase was offset by payroll related costs, which decreased by £0.6 million to £1.0 million in H1 2018 (H1 2017: £1.6 million), driven mainly by headcount reduction in H1 2017. Material costs remained steady at £0.4 million in H1 2018 (H1 2017: £0.4 million).

General and Administration Expenses

General and administration expenses increased by £1.7 million to £4.7 million for H1 2018 (H1 2017: £3.0 million). Payroll related costs increased by £0.2 million to £2.1 million in H1 2018 (H1 2017: £1.9 million) following investment in key permanent hires. Legal fees increased by £1.2 million to £1.5 million (H1 2017: £0.3 million), reflecting our commitment to defending our IP and securing the appropriate value from this IP.

Disposal of available-for-sale financial assets

In January 2018, the Company announced the disposal of the final tranche of Arrowhead Pharmaceuticals shares with cumulative proceeds of \$24.7 million. The gain realised on disposal of these available-for-sale financial assets in H1 2018 is £0.2 million (H1 2017: nil; Full Year 2017 £9.1 million).

Cash flows

The Group continues to maintain a strong cash position, with cash and cash equivalents and term deposits at 30 June 2018 of £34.3 million (30 June 2017: £29.8 million; 31 December 2017: £42.7 million). The net decrease in cash and cash equivalents, including the effect of exchange rate fluctuations on cash held, was £13.4 million for H1 2018. Of this, £5.0 million was invested in a term deposit with an original maturity date of 6 months.

Taxation

During H1 2018 we recognised a £1.1 million current tax asset in respect of R&D tax credits (H1 2017: £1.1 million). Additionally, an estimated £1.8 million is receivable relating to 2017 R&D expenditure.

Principal risks and uncertainties

The principal risks and uncertainties facing the Group are set out in the 2017 Annual Report which is available on our website, www.silence-therapeutics.com. The Board does not believe that the risks and uncertainties set out in that Annual Report have changed.

Consolidated income statement - unaudited

	6 months ended		Year ended
	30 June 2018	30 June 2017	31 December 2017
	£000s	£000s	£000s
Revenue	-	16	16
Research and development costs	(5,212)	(3,817)	(7,943)
General & administration expenses	(4,681)	(3,021)	(6,464)
Operating loss	(9,893)	(6,822)	(14,391)
Realised gain on disposals of available-for-sale financial assets	163	-	9,066
Reclassification of foreign exchange gains on liquidation of overseas subsidiary	-	-	1,344
Finance and other (expenses) / income	(57)	166	206
Loss for the period before taxation	(9,787)	(6,656)	(3,775)
Taxation	1,100	1,140	2,157
Loss for the period after taxation	(8,687)	(5,516)	(1,618)
Loss per ordinary share (basic and diluted)	(12.4p)	(7.9p)	(2.3p)

Consolidated statement of comprehensive income – unaudited

	6 months ended		Year ended
	30 June 2018	30 June 2017	31 December 2017
	£000s	£000s	£000s
Loss for the period after taxation	(8,687)	(5,516)	(1,618)
Other comprehensive expense, net of tax - Items that may subsequently be reclassified to profit & loss:			
Foreign exchange differences arising on consolidation of foreign operations	(25)	320	404
Reclassification of foreign exchange gains on liquidation of overseas subsidiary	-	-	(1,344)
Fair value movements on available-for-sale financial assets	-	(783)	9,104
Reclassification of fair value movements on disposal of available-for-sale financial assets	(156)	-	(9,066)
Total other comprehensive (expense)/income for the period	(181)	(463)	(902)
Total comprehensive expense for the period	(8,868)	(5,979)	(2,520)

Consolidated balance sheet - unaudited

	30 June 2018 £000s	30 June 2017 £000s	31 December 2017 £000s
Non-current assets			
Property, plant and equipment	982	1,346	1,170
Goodwill	8,009	7,944	8,029
Other intangible assets	18	37	28
Available-for-sale financial assets	-	8,555	-
Other receivables	233	233	233
	9,242	18,115	9,460
Current assets			
Trade and other receivables	1,136	601	733
R&D tax credit receivable	2,850	2,740	1,750
Investments held for sale	-	3	-
Available-for-sale financial assets	-	-	319
Six-month term deposit	5,000	-	-
Cash and cash equivalents	29,336	29,849	42,745
	38,322	33,193	45,547
Current liabilities			
Trade and other payables	(3,603)	(2,768)	(2,657)
Total assets less current liabilities	43,961	48,540	52,350
Net assets	43,961	48,540	52,350
Capital and reserves attributable to the owners of the parent			
Share capital	3,504	3,499	3,500
Capital reserves	163,517	163,751	163,215
Translation reserve	2,038	3,323	2,063
Retained loss	(125,098)	(122,033)	(116,428)
Total equity	43,961	48,540	52,350

Consolidated statement of changes in equity - unaudited

six months ended 30 June 2018

	Share Capital £000s	Capital Reserves £000s	Translation Reserve £000s	Accumulated Losses £000s	Total £000s
At 1 January 2018	3,500	163,215	2,063	(116,428)	52,350
Recognition of share-based payments	-	388	-	-	388
Lapse of vested options in period	-	(128)	-	128	-
Options exercised in the period	-	(45)	-	45	-
Proceeds from shares issued	4	87	-	-	91
Transactions with owners recognised directly in equity	4	302	-	173	479
Loss for six months	-	-	-	(8,687)	(8,687)
Other comprehensive income					
Exchange differences arising on consolidation of foreign operations	-	-	(25)	-	(25)
Reclassification of fair value movements on disposal of available-for-sale financial assets	-	-	-	(156)	(156)
Total comprehensive expense for the period	-	-	(25)	(8,843)	(8,868)
At 30 June 2018	3,504	163,517	2,038	(125,098)	43,961

year ended 31 December 2017

	Share Capital £000s	Capital Reserves £000s	Translation Reserve £000s	Accumulated Losses £000s	Total £000s
At 1 January 2017	3,490	163,641	3,003	(115,950)	54,184
Recognition of share-based payments	-	638	-	-	638
Lapse of vested options in period	-	(1,015)	-	1,015	-
Options exercised in the period	-	(87)	-	87	-
Proceeds from shares issues	10	38	-	-	48
Transactions with owners recognised directly in equity	10	(426)	-	1,102	686
Loss for year	-	-	-	(1,618)	(1,618)
Other comprehensive income					
Exchange differences arising on consolidation of foreign operations	-	-	404	-	404
Reclassification of foreign exchange gains on liquidation of overseas subsidiary	-	-	(1,344)	-	(1,344)
Fair value movements on available-for-sale financial assets	-	-	-	9,104	9,104
Reclassification of fair value movements on disposal of available-for-sale financial assets	-	-	-	(9,066)	(9,066)
Total comprehensive expense for the year	-	-	(940)	(1,580)	(2,520)
At 31 December 2017	3,500	163,215	2,063	(116,428)	52,350

Consolidated cash flow statement - unaudited

	6 months ended		Year ended
	30 June 2018	30 June 2017	31 December 2017
	£000s	£000s	£000s
Cash flow from operating activities			
Loss before tax	(9,787)	(6,656)	(3,775)
Depreciation charges	185	189	414
Amortisation charges	8	9	19
Charge for the period in respect of share-based payments	388	288	638
Realised gain on disposal of available-for-sale financial assets	(163)	-	(9,066)
Reclassification of foreign exchange gains on liquidation of overseas subsidiary	-	-	(1,344)
Finance and other expense/(income)	57	(166)	(206)
Impairment of investment	-	-	3
(Increase)/Decrease in trade and other receivables	(403)	796	664
Increase in trade and other payables	946	1,158	1,047
Cash spent on operations	(8,769)	(4,382)	(11,606)
Corporation tax credits received	-	-	2,007
Net cash outflow from operating activities	(8,769)	(4,382)	(9,599)
Cash flow from investing activities			
Acquisition of financial assets available for sale	-	(4,921)	(4,921)
Disposal of financial assets available for sale	320	-	18,123
Purchase of six-month term deposit	(5,000)		
Interest received/(paid)	4	4	(15)
Purchase of property, plant and equipment	-	(118)	(173)
Net cash (outflow)/inflow from investing activities	(4,676)	(5,035)	13,014
Cash flow from financing activities			
Proceeds from issue of share capital	91	48	48
Net cash inflow/(outflow) from financing activities	91	48	48
(Decrease)/increase in cash and cash equivalents	(13,354)	(9,369)	3,463
Cash and cash equivalent at start of period	42,745	39,012	39,012
Net decrease in the period	(13,354)	(9,369)	3,463
Effect of exchange rate fluctuations on cash held	(55)	206	270
Cash and cash equivalent at end of period	29,336	29,849	42,745

Notes to the financial statements

six months ended 30 June 2018

1. Basis of Preparation and Accounting Policies

These condensed consolidated interim financial statements for the six months ended 30 June 2018 have been prepared in accordance with IAS 34 – ‘Interim Financial Reporting’ as adopted by the European Union. The accounting policies adopted are consistent with those of the financial statements for the year ended 31 December 2017.

This condensed consolidated interim financial information has been neither reviewed nor audited. The interim financial statements do not comprise statutory accounts within the meaning of Section 434 of the Companies Act 2006. The comparative figures for the six months ended 30 June 2017 are not the Company's statutory accounts for that financial period. The 2017 full year accounts have been reported on by the Company's auditors and delivered to the Registrar of companies. The report of the auditors was unqualified and did not contain a statement under section 498(2) or (3) of the Companies Act 2006.

IFRS 15 was implemented by the Group on 1 January 2018. This has not had a material impact for the Group.

IFRS 9 was implemented by the Group on 1 January 2018. This has not had a material impact on the accounting for financial instruments held by the Group.

2. Going concern

The financial statements have been prepared on a going concern basis that assumes that the Company will continue in operational existence for the foreseeable future.

During the period, the Company met its day-to-day working capital requirements through existing cash resources. The Company had a net decrease in the cash and cash equivalent in the period ended 30 June 2018 of £13.4 million and at 30 June 2018 had cash balances of £29.3 million plus a six-month term deposit of £5.0 million. The Directors have reviewed the working capital requirements of the Company for the next 12 months from the date of the approval of these interim financial statements and are confident that these can be met.

3. Segment reporting

In the six months ended 30 June 2018, the Group operated in the specific technology field of RNA therapeutics.

Business segments

The Group has identified the Chief Executive Officer as the Chief Operating Decision Maker (“CODM”). The CODM determined the Group had one business segment, the development of RNAi based medicines. This is in line with reporting to the Executive Committee and senior management. The information used internally by the CODM is the same as that disclosed in the Financial Statements.

Non-current assets	UK £000s	Germany £000s	Total £000s
As at 30 June 2018	550	8,692	9,242
As at 30 June 2017	9,200	8,915	18,115
As at 31 December 2017	611	8,849	9,460

Revenue Analysis	6 months ended		Year ended
	30 June 2018	30 June 2017	31 December 2017
	£000s	£000s	£000s
Research collaboration	-	16	16

The country of registration of the single fee-paying party is the USA. The revenue was billed and received in US Dollars.

4. Loss per share

The loss per share is based on the loss for the period after taxation attributable to equity holders of £8.69 million (year ended 31 December 2017 – loss £1.62 million; six months ended 30 June 2017 – loss £5.52 million) and on the weighted average of 70,033,448 ordinary shares in issue during the period (year ended 31 December 2017 – 69,924,558; six months ended 30 June 2017 – 69,876,568).

The options outstanding at 30 June 2018, 31 December 2017 and 30 June 2017 are considered to be non-dilutive in that their conversion into ordinary shares would decrease the net loss per share. Consequently, there is no diluted loss per share to report for the periods reported.

5. Taxation

A £1.10 million current tax asset was recognised in respect of research and development tax credits in the six months ended 30 June 2018 (six months ended 30 June 2017: £1.14 million).

6. Related party transactions

Transactions between the Company and its subsidiaries, which are related parties, have been eliminated on consolidation and are not disclosed in this note. There are no other related party transactions which would require disclosure.