Interim results for the six months ended 30 June 2019

12 September 2019

LONDON, Silence Therapeutics, PLC (LON: SLN) ("Silence" or "the Company"), a leader in the discovery, development and delivery of novel RNA therapeutics for the treatment of serious diseases, today announces its unaudited interim results for the half year to 30 June 2019.

Operational Highlights

- SLN124 Clinical Trial Application, for the treatment of β-thalassemia and myelodysplastic syndrome (MDS), filed in Q1 2019 with first patient dosed expected before year end
- SLN124 granted Orphan Drug Designation by the European Medicines Agency for the treatment of β-thalassemia
- SLN360, an Lp(a)-targeting siRNA for the treatment of cardiovascular disease, entered IND-Enabling studies in February 2019 and is on track for an IND and/or CTA in H2 2020
- SLN500 progressed to non-clinical development (see Post Period Events below)
- Management team strengthened with the addition of Dr. Rob Quinn as Chief Financial Officer and Dr. Giles Campion as Head of R&D and Chief Medical Officer
- Board augmented with the appointment of Iain Ross as Chairman and James Ede-Golightly as Non-Executive Director
- Collaboration with Genomics England to identify novel target genes associated with human disease

Financial Highlights

- Loss after tax of £8.2 million (H1 2018: £8.7 million), with operating costs in H1 2019 driven by increasing R&D spend on SLN124 in preparation to enter the clinic
- Cash and cash equivalents and term deposits of £16.5 million (FY 2018 £26.5 million)
- Net cash outflow from operating activities £10.3 million (H1 2018: £8.8 million)

Post Period Events

- In July 2019, announced a collaboration with Mallinckrodt Pharmaceuticals to develop and commercialise RNAi therapeutics for complement-mediated diseases
    - Agreement provides Mallinckrodt with an exclusive worldwide license for one preclinical asset that targets a specific protein in the complement pathway, C3 (SLN500), and an option for up to two additional assets with different complement protein targets
    - Silence has received a $20 million upfront payment, with potential for near- and long-term development and commercial milestones and royalties on net sales
- Mallinckrodt equity investment of $5 million in exchange for 5,062,167 new ordinary shares
- Cash and cash equivalents and term deposit balance of £36.0 million at 31 August 2019
- Dr. Steven Romano appointed to the Board as Non-Executive Director as part of the equity subscription agreement with Mallinckrodt, and Jørgen Wittendorff appointed to the management team as Head of Manufacturing

Dr. David Horn Solomon, Chief Executive Officer of Silence Therapeutics, commented: *"The first half of 2019 has been transformational for Silence with the game-changing RNAi collaboration with Mallinckrodt reached in July, following months of business development work in H1 – a deal which provided us with a significant cash injection through the upfront and equity investment and provides for significant development and commercial milestones. We have made excellent progress in returning to the clinic with SLN124 and expect to dose our first patient in H2 2019 and we are excited about the potential of this asset to treat patients with serious diseases such as β-thalassemia. We are well capitalised to deliver on our strategic objectives as we continue to drive value for shareholders and offer hope to patients with rare and serious conditions."*

Iain Ross, Chairman of Silence Therapeutics, commented: "*We have made significant progress in our three key R&D programmes, secured a major validating partnership with Mallinckrodt, and significantly strengthened our Balance Sheet. The senior management team under the dedicated leadership of David Horn Solomon has been strengthened considerably through key hires and the Board has been revitalised with the appointment of three experienced Directors.*

As the new Chairman of Silence, I have been impressed by the dedication of the management team and the innovation shown by the Company's scientists. I would like to thank the entire Silence team for their ongoing hard work and the shareholders for their continued support. I believe we are now well placed for the future and will continue to execute on our strategic goals in order to drive value for all our stakeholders."

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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. Silence Therapeutics remains focused and is determined to be responsive to creating shareholder value as well as the appropriate growth and development of its business. Silence Therapeutics continues to assess a number of options in addition to its organic plan which it believes would be additive to the Company's future growth prospects and shareholder value, which may include equity fundraisings as well as other strategic licensing and collaboration opportunities.

For more information, please visit: https://www.silence-therapeutics.com/

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Chief Executive's Report

Overview

The first half of 2019 has been a tremendously productive period for Silence during which we have achieved a great number of milestones. Not only have we made progress advancing our whole pipeline but business development efforts in H1 culminated in July when we signed a transformational deal with Mallinckrodt, validating Silence's underlying technology and platform.

Additions to Management Team and Board

During the period, and post-period, Silence has made several additions to the senior leadership team and the Board. These additions include the appointments of Dr. Rob Quinn as Chief Financial Officer, Dr. Giles Campion as Head of R&D and Chief Medical Officer and Jørgen Wittendorff as Head of Manufacturing. In April, Iain Ross, a highly experienced board director with a career in the international life sciences and technology sectors that spans 40 years, was appointed as Chairman of the Board and James Ede-Golightly was appointed as a Non-Executive Director. In July, Dr. Steven Romano, Chief Scientific Officer at Mallinckrodt, was appointed as a Non-Executive Director. These new additions have significantly strengthened the Company, ensuring that Silence has the right experience and expertise within the Group as it moves into the next stage of its development. The Board would like to thank former interim-Chair Dr. Andy Richards, CBE and Stephen Parker, who stepped down from their positions as non-executive directors of the Company during the period.

Pipeline

RNAi therapeutics are a highly innovative, specific, new class of medicines with life-saving potential for patients with serious and rare diseases. During the first half of 2019 we have continued to make significant progress across our pipeline, particularly with our lead candidate, SLN124, which is being developed for patients with iron overload disorders, such as β-thalassemia and MDS. We have made excellent progress in advancing SLN124 towards the clinic and expect to dose the first patient in a Phase Ib First-in-Human study in β-thalassemia and MDS in H2 2019. SLN124 has already been granted Orphan Drug Designation by the European Medicines Agency (EMA), highlighting the potential that this product has to transform the lives of patients.

We are also continuing to advance SLN360, an Lp(a) targeting siRNA for the treatment of cardiovascular disease, through pre-clinical studies. IND-Enabling studies commenced in February 2019 and we remain on track to submit an IND and/or CTA in H2 2020.

Collaborations

Post-period, we announced a collaboration with Mallinckrodt to develop and commercialize RNAi Therapeutics for complement-mediated diseases. Under the terms of the agreement, Mallinckrodt has obtained an exclusive worldwide license to SLN500, an siRNA targeting C3, with options to license up to two additional complement-targeted assets from our preclinical development program. Silence is responsible for preclinical activities, and for executing the development program of each asset until the end of Phase I, after which Mallinckrodt will assume clinical development and responsibility for global commercialization.

Mallinckrodt agreed to provide Silence with an upfront payment of $20 million (since received). Silence is also eligible to receive up to $10 million in research milestones for SLN500 and for each optioned asset, in addition to funding for Phase I clinical development including GMP manufacturing. Silence will fund all other preclinical activities. The collaboration provides for potential added clinical and regulatory milestone payments of up to $100 million for SLN500, as well as commercial milestone payments of up to

$563 million for SLN500. Should Mallinckrodt opt to license one or two additional assets, Silence could receive up to $703 million in similar clinical, regulatory, and commercial milestone payments per asset. Silence would also receive tiered, low double-digit to high-teen royalties on net sales for SLN500 and each optioned asset. Furthermore, Mallinckrodt made a $5 million investment in Silence equity at a subscription price equating to a 10% premium to the 20-day volume weighted average price, prior to announcing the deal.

Additionally, in May 2019, Silence entered into a collaboration with Genomics England Limited ("Genomics England") for the investigation of novel targets involved in human disease. Under the terms of the agreement, Silence has been approved for access to a subset of Genomics England's dataset as the Company plans to focus its research on rare disease and cardiometabolic cohorts. Silence will now proceed to mine data with the objective of identifying novel disease-modifying target genes best suited to its proprietary platform technology, as well as optimising patient stratification and UK recruitment in the development of its RNAi product candidates.

Outlook

As a leader in RNAi technology, and at the cutting edge of an extremely promising new class of therapeutics, we are committed to continue leveraging Silence's expertise in this field to advance our pipeline of new medicines through the clinic to show safety, tolerability and efficacy for patients and their caregivers.

We remain committed to improving the lives of patients by helping to treat and cure disease through the development of new and better medicines and are focused and determined to create value for shareholders. I look forward to updating the market with our continued progress in due course.

Our programmes

Our core focus is the development of our proprietary clinical-stage RNAi 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 β-thalassemia and myelodysplastic syndrome (MDS)
- SLN124 Clinical Trial Application filed in Q1 2019 with first patient dosed expected in H2 2019
- SLN124 granted Orphan Drug Designation by EMA for the treatment of β-thalassemia in January

SLN360

- SLN360 announced in December 2018 as an additional asset to the pre-clinical pipeline for the potential treatment of cardiovascular disease
- SLN360 silences apolipoprotein (a), a component of lipoprotein(a) ("Lp(a)"), which is a highly validated target based on extensive human genetic data. Elevated Lp(a) levels have been associated with increased risk of cardiovascular disease, independent of additional risk factors
- IND/CTA for SLN360 anticipated to be filed in H2 2020

SLN500

- SLN500, being developed for the treatment of complemented-mediated diseases (targeting C3), is in pre-clinical development
- Signed an exclusive worldwide license agreement and collaboration with Mallinckrodt for development of the asset

Out-licensed programmes

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

- Quark completed dosing of 594 patients in a Phase III study for delayed graft function (DGF) following kidney transplantation in January 2018. We await further updates on this programme
- In July 2018, Quark announced its first patient dosed in a Phase III clinical trial of QPI-1002 for prevention of Acute Kidney Injury (AKI) following cardiac surgery

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.

Additionally, following the December 2018 Settlement and License Agreement with Alnylam Pharmaceuticals, Alnylam will license patents from Silence and will pay Silence a tiered royalty on net sales of ONPATTRO™, in the EU, ranging from 0.33% to 1.0% through 2023.

Financial Review

Research & Development Expenses
Research and development expenses decreased by £0.1 million to £5.1 million for H1 2019 (H1 2018: £5.2 million). People costs decreased by £0.3 million to £1.7 million for H1 2019 (H1 2018: £2.0 million) driven by new in-house clinical development team, reducing the need for more expensive external consultants. Additionally, patent costs decreased by £0.3 million to £0.2 million for H1 2019 (H1 2018: £0.5 million) following the completion of certain projects in 2019. These decreases were offset by Contract Research Organisation (CRO) costs, which increased by £0.5 million to £2.5 million for H1 2019 (H1 2018: £2.0 million), reflecting the costs associated with the set-up for a First in Human study for SLN124 in H2 2019, as well as increasing spend on SLN360 with IND-Enabling activities well under way.

General and Administration Expenses
General and administration expenses remained steady at £4.7 million (H1 2018: £4.7 million).

Taxation
During H1 2019, a £1.2 million current tax asset for R&D tax credits was recognised in respect of eligible R&D expenditure in the period (H1 2018: £1.1 million). Additionally, £2.3 million is estimated as receivable relating to 2018 R&D expenditure.

Liquidity, cash and cash equivalents
The Group's cash and cash equivalents and term deposit at 30 June 2019 totalled £16.5 million (30 June 2018: £34.3 million; 31 December 2018: £26.5 million). The cash spent on operations was £10.3 million (H1 2018: £8.8 million) against an operating loss of £9.7 million (H1 2018: £9.9 million).

Other balance sheet items
Current trade and other payables decreased by £0.9 million to £2.9 million at 30 June 2019 from £3.8 million at 31 December 2018, following the settlement of legal proceedings. With the prospective adoption of IFRS 9 Financial Instruments, the balance sheet classification of certain items changed from 30 June 2018 to 30 June 2019; however, the underlying balances have not changed significantly.

Post half-year events
On 18 July 2019, a collaboration with Mallinckrodt was announced, to develop and commercialise RNAi Therapeutics for complement-mediated diseases. Silence received a $20 million upfront payment post period end, with potential near- and long-term development and commercial milestones, and royalties on net sales.

Further to the collaboration, Mallinckrodt made an equity investment of $5 million in exchange for 5,062,167 Silence new ordinary shares, which was also received post period end.

Cash and cash equivalents and term deposits at 31 August 2019 of £36.0 million was considered in supporting the assumption that the Company will continue in operational existence for the foreseeable future. As at 30 June 2019, a £2.3 million R&D tax credit relating to eligible R&D expenditure for the year-ended 31 December 2018 was reflected as receivable on the balance sheet, and this remained receivable at 31 August 2019. The Directors have reviewed the working capital requirements of the Group and Company for the twelve months from signing these financial statements and are confident that these can be met, as further explained in Note 2 Going concern on page 12.

Principal risks and uncertainties
The principal risks and uncertainties facing the Group are set out in the 2018 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

	6 months ended		Year ended
	30 June 2019 £000s (unaudited)	30 June 2018 £000s (unaudited)	31 December 2018 £000s (audited)
Revenue	-	-	-
Research and development costs	(5,054)	(5,212)	(9,743)
Administrative expenses	(4,654)	(4,681)	(10,828)
Operating loss	**(9,708)**	**(9,893)**	**(20,571)**
Reclassification of fair value movements on disposal of available-for-sale financial assets	-	163	-
Finance and other income	110	(57)	45
Loss for the period before taxation	**(9,598)**	**(9,787)**	**(20,526)**
Taxation	1,388	1,100	2,115
Loss for the period after taxation	**(8,210)**	**(8,687)**	**(18,411)**
Loss per ordinary share (basic and diluted)	(11.5p)	(12.4p)	(26.2p)

Consolidated statement of comprehensive income

	6 months ended		Year ended
	30 June 2019 £000s (unaudited)	30 June 2018 £000s (unaudited)	31 December 2018 £000s (audited)
Loss for the period after taxation	(8,210)	(8,687)	(18,411)
Other comprehensive expense, net of tax - Items that may subsequently be reclassified to profit & loss:			
Foreign exchange differences arising on consolidation of foreign operations	(23)	(25)	94
Reclassification of fair value movements on disposal of available-for-sale financial assets	-	(156)	–
Total comprehensive expense for the period	**(8,233)**	**(8,868)**	**(18,317)**

Consolidated balance sheet

	30 June 2019 £000s (unaudited)	30 June 2018 £000s (unaudited)	31 December 2018 £000s (audited)
Non-current assets			
Property, plant and equipment	840	982	921
Goodwill	8,104	8,009	8,127
Other intangible assets	47	18	64
Financial assets at amortised cost	275	-	275
Other receivables	-	233	-
	9,266	9,242	9,387
Current assets			
Cash and cash equivalents	11,511	29,336	21,494
Financial assets at amortised cost – term deposit	5,000	5,000	5,000
Financial asset at amortised cost – other	-	-	43
R&D tax credit receivable	3,468	2,850	2,080
Other current assets	774	-	881
Trade and other receivables	-	1,136	-
	20,753	38,322	29,498
Current liabilities			
Trade and other payables	(2,859)	(3,603)	(3,830)
Net assets	27,160	43,961	35,055
Capital and reserves attributable to the owners of the parent			
Share capital	3,608	3,504	3,554
Capital reserves	162,726	163,517	163,121
Translation reserve	2,134	2,038	2,157
Accumulated losses	(141,308)	(125,098)	(133,777)
Total equity	27,160	43,961	35,055

Consolidated statement of changes in equity

six months ended 30 June 2019 (unaudited)

	Share Capital £000s	Capital Reserves £000s	Translation Reserve £000s	Accumulated Losses £000s	Total £000s
At 31 December 2018	3,554	163,121	2,157	(133,777)	35,055
Change in accounting policy (Note 1)	-	-	-	(10)	(10)
Restated At 1 January 2019	3,554	163,121	2,157	(133,787)	35,045
Recognition of share-based payments	-	148	-	-	148
Options exercised in the period	-	(689)	-	689	-
Proceeds from shares issued	54	146	-	-	200
Transactions with owners recognised directly in equity	54	(395)	-	689	348
Loss for six months	-	-	-	(8,210)	(8,210)
Other comprehensive income					
Foreign exchange differences arising on consolidation of foreign operations	-	-	(23)	-	(23)
Total comprehensive expense for the period	-	-	(23)	(8,210)	(8,233)
At 30 June 2019	3,608	162,726	2,134	(141,308)	27,160

year ended 31 December 2018 (audited)

	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	-	681	-	-	681
Lapse of vested options in period	-	(297)	-	297	-
Options exercised in the period	-	(765)	-	765	-
Proceeds from shares issues	54	287	-	-	341
Transactions with owners recognised directly in equity	54	(94)	-	1,062	1,022
Loss for year	-	-		(18,411)	(18,411)
Other comprehensive income					
Foreign exchange differences arising on consolidation of foreign operations	-	-	94	-	94
Total comprehensive expense for the year	-	-	94	(18,411)	(18,317)
At 31 December 2018	3,554	163,121	2,157	(133,777)	35,055

Consolidated cash flow statement

	6 months ended		Year ended
	30 June 2019	30 June 2018	31 December 2018
	£000s (unaudited)	£000s (unaudited)	£000s (audited)
Cash flow from operating activities			
Loss before tax	(9,598)	(9,787)	(20,526)
Depreciation charges	240	185	379
Amortisation charges	17	8	20
Charge for the period in respect of share-based payments	148	388	681
Reclassification of fair value movements on disposal of available-for-sale financial assets	-	(163)	-
Finance and other income	(110)	57	(45)
Loss on disposal of property, plant and equipment	1	-	6
Decrease/(increase) in trade and other receivables	-	(403)	691
Decrease / (increase) in other current assets	107	-	(881)
Decrease / (increase) in current financial assets at amortised cost – other	43	-	(43)
(Decrease) / increase in trade and other payables	(1,100)	946	1,146
Cash spent on operations	(10,252)	(8,769)	(18,572)
Corporation tax credits received	-	-	1,812
Net cash outflow from operating activities	(10,252)	(8,769)	(16,760)
Cash flow from investing activities			
Disposal of financial assets available for sale	-	320	319
Purchase of financial asset at amortised cost – term deposit	-	(5,000)	(5,000)
Interest received/(paid)	7	4	39
Purchase of property, plant and equipment	(5)	-	(130)
Purchase of intangible assets	-	-	(58)
Net cash (outflow)/inflow from investing activities	2	(4,676)	4,830
Cash flow from financing activities			
Proceeds from issue of share capital	200	91	341
Net cash inflow/(outflow) from financing activities	200	91	341
(Decrease)/increase in cash and cash equivalents	(10,050)	(13,354)	21,249
Cash and cash equivalent at start of period	21,494	42,745	42,745
Net decrease in the period	(10,050)	(13,354)	(21,249)
Effect of exchange rate fluctuations on cash and cash equivalents held	67	(55)	(2)
Cash and cash equivalents at end of period	11,511	29,336	21,494

1. Basis of Preparation and Accounting Policies

These condensed consolidated interim financial statements for the six months ended 30 June 2019 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 2018, except for the adoption of IFRS 16 from 1 January 2019 as described below.

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 2018 are not the Company's statutory accounts for that financial period. The 2018 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, however it did contain a material uncertainty relating to going concern, consistent with the Directors' assessment at the time that additional funding needed to be raised. See Note 2 below for the current Directors' assessment of going concern.

IFRS 16 Leases was issued in January 2016 and was implemented by the Group from 1 January 2019. The Standard replaces IAS 17 and requires lease liabilities and 'right of use' assets to be recognised on the balance sheet for almost all leases. The adoption methodology of IFRS 16 is the cumulative catch-up method, and the impact is not material with an adjustment to opening retained earnings of £0.01m. Further disclosure will be provided as part of the notes to the year-end financial statements.

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 equivalents in the period ended 30 June 2019 of £10.1 million and at 30 June 2019 had cash balances of £11.5 million plus a six-month term deposit of £5.0 million. As set out under Post half-year events on page 7, $5 million was received on 24 July 2019 and $20 million on 16 August 2019. Cash and cash equivalents and term deposits at 31 August 2019 of £36.0 million was considered in supporting the assumption that the Company will continue in operational existence for the foreseeable future.

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 2019, 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 2019	685	8,581	9,266
As at 30 June 2018	550	8,692	9,242
As at 31 December 2018	651	8,736	9,387

4. Loss per share

The loss per share is based on the loss for the period after taxation attributable to equity holders of £8.21 million (year ended 31 December 2018 – loss £18.41 million; six months ended 30 June 2018 – loss £8.69 million) and on the weighted average of 71,229,864 ordinary shares in issue during the period (year ended 31 December 2018 – 70,312,880; six months ended 30 June 2018 – 70,033,448).

The options outstanding at 30 June 2019, 31 December 2018 and 30 June 2018 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 £1.16 million current tax asset was recognised in respect of research and development tax credits in the six months ended 30 June 2019 (six months ended 30 June 2018: £1.10 million). Additionally, the current tax asset in respect of research and development tax credits for the year ended 31 December 2018 was increased during the period by £0.23 million to £2.31 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.