

Summit Corporation plc
(‘Summit’ or ‘the Company’)

INTERIM RESULTS FOR THE SIX MONTHS ENDED 31 JULY 2014

HIGHLIGHTS

Product Development

Duchenne Muscular Dystrophy

- SMT C1100 met its primary endpoints in a Phase 1b clinical trial in DMD patients with the utrophin modulator shown to be safe and well tolerated at all doses tested
- Potential indicator of SMT C1100 activity in the Phase 1b trial with a statistically significant reduction observed in the levels of three enzymes associated with muscle damage
- Next clinical trial in DMD patients to monitor dietary impact on SMT C1100 uptake expected to start in Q4 2014; it is planned to then enrol these patients into a Phase 2 open-label study

C. difficile Infection

- First patients enrolled and dosed in a Phase 2 clinical trial of the novel antibiotic SMT19969
- SMT19969 designated as a Qualified Infectious Disease Product (‘QIDP’) by the US FDA to provide accelerated development and market exclusivity benefits
- £1.9 million milestone payment received as part of the Wellcome Trust Translational Award

Corporate

- US operations established through opening of Cambridge, Massachusetts office
- Mr Erik Ostrowski appointed Chief Financial Officer, bringing experience in finance, operations and investment banking in the biotechnology and healthcare sector
- Mr Leopoldo Zambelletti appointed as a Non-Executive Director, adding additional experience in healthcare investment banking and product licensing and other strategic transactions

Financial

- Cash position at 31 July 2014: £17.4 million (31 January 2014: £2.0 million)
- £22.0 million (£20.7 million net of costs) financing completed in March 2014
- Increase in operational expenditure in-line with expectation and reflects the increase in product development activities
- Loss for the six months ended 31 July 2014 of £5.9 million (31 July 2013: £2.1 million)

CHAIRMAN'S AND CHIEF EXECUTIVE OFFICER'S STATEMENT

INTRODUCTION

The first half of 2014 has seen strong progress being made across all aspects of the business. Our clinical programmes targeting Duchenne Muscular Dystrophy ('DMD') and C. difficile Infection ('CDI') continue to advance, while our ability to execute on our development plans was enhanced through the raising of equity funding. The clinical and operational team supporting the development of the programmes was also strengthened.

PRODUCT DEVELOPMENT

Utrophin modulator programme for the treatment of DMD

It has been an important period in our DMD programme with the completion of a Phase 1b clinical trial and subsequent planning of our next patient trial, which we expect to initiate by the end of the year. Our programme is developing oral, small molecule utrophin modulators as potential disease modifying drugs for this fatal neuromuscular disease.

DMD is an orphan disease affecting approximately 50,000 boys and young men in the developed world. It is estimated that the value of the DMD market is in excess of \$10 billion per annum based on the current pricing commanded by orphan drugs. DMD is a progressive muscle wasting disorder affecting all muscles in the body including the heart and diaphragm. There is currently no cure for this disease with a patient's average life expectancy being into the late twenties.

The disease is caused by different genetic faults on the gene encoding dystrophin, a protein that is essential in maintaining the healthy function of all muscles. Utrophin is a naturally occurring protein that performs the same functional role as dystrophin in developing and repairing muscles. Our utrophin modulators aim to maintain the production of utrophin in maturing muscle to compensate for the absence of dystrophin and thereby maintain healthy muscle function.

Utrophin modulation is a disease modifying approach that is independent of the various genetic faults in the dystrophin gene causing the disease. This means that our programme may treat all DMD patients while also potentially being complementary to dystrophin-based approaches in development that treat sub-sets of the patient population.

Our lead utrophin modulator is SMT C1100 and during the first half of the year it completed a Phase 1b clinical trial in DMD patients. The trial, the first to evaluate a utrophin modulator drug in DMD patients, achieved its primary endpoint with SMT C1100 shown to be safe and well tolerated at all doses tested. In addition, excellent patient compliance was observed which is important given that this is expected to be a chronic, long-term treatment.

The non-placebo controlled trial also reported encouraging results about the disease-modifying potential of SMT C1100. After the 10 days of dosing a reduction was observed in the enzymes creatine kinase ('CK'), aspartate aminotransferase ('AST') and alanine aminotransferase ('ALT'). The levels of these enzymes are typically low in healthy people but, in DMD patients, the muscle cells are weakened by the disease leading to the accumulation of these enzymes in the blood. When dosed with SMT C1100, there was a reduction in CK (10/11 patients), AST (11/12 patients) and ALT (12/12 patients). These reductions were statistically significant compared to the pre-dose levels. After dosing, the enzyme levels increased towards pre-dose levels. The lower levels of these enzymes may indicate a reduction in muscle damage, which is consistent with the proposed mechanism of action of our utrophin modulator.

These data on SMT C1100 are encouraging and yet were achieved with levels of drug uptake in the majority of patients that we believe can be improved on. In a previous healthy volunteer clinical trial we observed that significantly higher plasma concentrations of drug were achieved when SMT C1100 was

taken with food. In our recent Phase 1b trial, there was variability between patients with the majority of them having levels of drug uptake that were similar to those of a fasted healthy adult. Initial evidence suggests that this may be due to differences in diet and other disease related-factors.

The next stage of clinical development for SMT C1100 will comprise two parts. The first part will be a DMD patient trial that will include a placebo control as well as a modification to the diet of the patients. The aim of this study will be to establish the optimal diet for improving the uptake of SMT C1100 in DMD patients. If successful, we plan to enact the second part that will enrol these patients into a Phase 2 open-label study to generate long-term efficacy and safety data.

Our commitment to utrophin modulation as a treatment approach is highlighted by the parallel development of next generation compounds. These activities include research being undertaken as part of our strategic alliance with the University of Oxford as we develop a deeper, long-term pipeline of utrophin-related drugs.

C. difficile Infection programme

SMT19969 is a novel antibiotic being developed for the treatment of infections caused by the bacteria *Clostridium difficile* and it has continued to make excellent progress during the first half of the year following the initiation of a Phase 2 clinical trial in North America.

C. difficile infection is a major healthcare threat. It accounts for approximately 60% of gastrointestinal infections in hospitals and is estimated to be responsible for 14,000 deaths per year in the US alone. Consequently CDI has a high economic burden with direct acute care costs in the US estimated at \$4.8 billion per annum.

The infection typically occurs following prior use of antibiotics that cause disruption to the natural balance of gut flora leading to overgrowth of *C. difficile*. Antibiotics that are currently used to treat CDI can cause further disruption to the gut flora and pre-dispose patients to recurrent episodes of the disease. Recurrence represents the key clinical issue in CDI with up to 30% of patients having at least one recurrent infection. The rate of recurrence rises to 65% following a third episode of the disease with each recurrence of the infection normally being more severe and having an increased risk of mortality.

Previously reported clinical and preclinical studies have shown that SMT19969 has an ideal profile to become an effective treatment for CDI with the potential to significantly reduce the current high-rates of recurrent disease. In these studies, SMT 19969 demonstrated high potency for *C. difficile* combined with a minimal antibiotic effect against the bacteria that make up a healthy gut flora. This high selectivity means SMT19969 has the potential to treat the CDI and allow restoration of the gut flora to provide protection against repeat infection.

In March this year we were pleased to report that our Investigational New Drug ('IND') application received clearance from the US Food and Drug Administration ('FDA') to enable commencement of a Phase 2 proof of concept study. This Phase 2 trial, named CoDIFY, is a double blind, randomised, active control trial evaluating the efficacy of SMT19969 against the current standard of care, the antibiotic vancomycin. The trial is being conducted in the US and Canada and enrolment and dosing of the first patients into this study was announced in July. The trial remains on-track to report top-line data during the first half of 2015.

Also in July, we were delighted to be informed by the FDA that SMT19969 had been designated as a Qualified Infectious Disease Product ('QIDP'). This status recognises the serious threat posed by specific life threatening pathogens including *C. difficile* and will confer a number of advantages that are intended to accelerate the development of new antibiotics. These include eligibility for Priority Review and Fast Track status and, if SMT19969 receives marketing approval from the FDA, a five-year extension of market exclusivity. The QIDP incentives are provided under the Generating Antibiotics Incentives Now Act (GAIN Act) that was signed into law by the US Government in 2012.

A £4.0 million Translational Award from the Wellcome Trust has continued to provide substantial funding towards the development of SMT19969 through to completion of the on-going Phase 2 trial.

CORPORATE UPDATE

A number of important corporate developments occurred during the period that are intended to support the implementation of our strategy of advancing the two clinical stage programmes through to key development milestones.

In June, Summit established US operations in Cambridge, Massachusetts. This expansion into the US is important for our two clinical programmes, as each will have a significant proportion of their development undertaken in North America. In addition it will support our strategy of strengthening communications with our investor base and provide greater access to academic and industry key opinion leaders in the region.

The operational and clinical development team has also been strengthened following a number of key hires. Most notably, Mr Erik Ostrowski was appointed as the Company's Chief Financial Officer in June. Prior to joining Summit, Erik held a senior management position at Organogenesis, a US commercial-stage biotechnology company, and he also has had a successful career in healthcare investment banking, most recently with Leerink Partners. With this diverse background, he brings a unique blend of attributes and expertise in strategic, financial and operational matters. Erik is based at the new US office, along with members of the clinical development team who are supporting the development of the DMD and CDI programmes.

The Board has also been strengthened through the appointment of Mr Leopoldo Zambelletti as a Non-Executive Director. We are delighted that Leopoldo has joined the Board as he is a highly respected and experienced investment banker having led the European healthcare teams at JP Morgan and Credit Suisse and he currently acts as a strategic advisor to the life sciences industry. He therefore brings expertise in a range of areas including mergers and acquisitions, equity financing and product out-licensing.

FINANCIAL REVIEW

Cash at 31 July 2014 was £17.4 million (31 January 2014: £2.0 million). The enhanced cash position is predominantly due to the completion in March of a financing that raised £22.0 million (£20.7 million net of costs) through the issue of new ordinary shares. These funds, raised primarily from existing shareholders and specialist healthcare investors in the US and Europe, will support the execution of our clinical development plans towards establishing proof of concept in the DMD and CDI programmes. In addition a £1.9 million milestone payment was received as part of the £4.0 million Wellcome Trust Translation Award supporting the CDI programme. A total of £3.9 million of this award has now been received.

Combined Revenue and Other operating income for the period totalled £1.1 million (31 July 2013: £0.6 million). All revenues received related to the Wellcome Trust Translational Award with the outstanding revenue from this award expected to be recognised on completion of the on-going Phase 2 clinical trial. The vast majority of Other operating income related to the Biomedical Catalyst award that is supporting the development of SMT C1100.

Investment in research and development was £4.9 million (31 July 2013: £2.1 million) and reflected the increased costs associated with conducting patient clinical trials in both programmes. General and administration expenses increased to £2.1 million (31 July 2013: £0.7 million). This increase includes a provision of £0.7 million for milestone payments due under funding agreements with two US not-for-profit DMD organisations, a non-cash charge of £0.2 million in respect of losses on foreign currency translation as well increased infrastructure costs to support the programme activities and the new US operations.

The net loss for the period was £5.9 million (31 July 2013: £2.1 million).

OUTLOOK

It is an exciting time for Summit and the development of our two clinical programmes. Patient trials are either on-going or expected to start in the near future and will generate further data that we hope will provide a fuller understanding about the potential of these life-changing treatments for two serious diseases.

We thank all staff, shareholders and the patients and their families who are supporting our clinical programmes. We look forward to reporting on our progress.

Frank Armstrong, FRCPE, FFPM
Non-Executive Chairman

Glyn Edwards
Chief Executive Officer

3 September 2014

FINANCIAL STATEMENTS
CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME (unaudited)

For the six months ended 31 July 2014

	Note	Six months ended 31 July 2014 £000s	Six months ended 31 July 2013 £000s	Year ended 31 January 2014 £000s
Revenue		574	504	1,375
Cost of sales		-	-	-
Gross profit		574	504	1,375
Other operating income		570	50	469
Administrative expenses				
Research and development		(4,931)	(2,084)	(6,564)
General and administration		(2,149)	(708)	(1,737)
Depreciation and amortisation		(15)	(11)	(26)
Share-based payment		(446)	(138)	(226)
Total administrative expenses		(7,541)	(2,941)	(8,553)
Operating loss		(6,397)	(2,387)	(6,709)
Finance income		25	6	9
Loss before income tax		(6,372)	(2,381)	(6,700)
Income tax		466	242	607
Loss for the period		(5,906)	(2,139)	(6,093)
Loss for the period attributable to owners of the parent		(5,906)	(2,139)	(6,093)
Other comprehensive expenses				
Exchange differences on translating foreign operations		(3)	-	-
Total comprehensive loss for the period attributable to owners of the parent		(5,909)	(2,139)	(6,093)
Basic and diluted loss per ordinary share (post consolidation and subdivision)	2,4	(15.51)p	(11.93)p	(29.71)p

All of the activities of the Group are classified as continuing.

CONSOLIDATED STATEMENT OF FINANCIAL POSITION (unaudited)
As at 31 July 2014

	31 July 2014	31 January 2014	31 July 2013
	£000s	£000s	£000s
ASSETS			
Non-current assets			
Intangible assets	3,488	3,493	166
Property, plant and equipment	48	43	38
	3,536	3,536	204
Current assets			
Trade and other receivables	1,290	431	266
Current tax receivable	1,132	634	239
Cash and cash equivalents	17,442	2,030	6,004
	19,864	3,095	6,509
Total assets	23,400	6,631	6,713
LIABILITIES			
Current liabilities			
Trade and other payables	(2,630)	(1,852)	(1,460)
Provisions for other liabilities and charges	(769)	(17)	-
	(3,399)	(1,869)	(1,460)
Total liabilities	(3,399)	(1,869)	(1,460)
Net assets	20,001	4,762	5,253
EQUITY			
Share capital	13,459	10,075	9,711
Share premium account	57,495	40,177	37,166
Share-based payment reserve	2,082	1,636	1,548
Merger reserve	(1,943)	(1,943)	(1,943)
Currency translation adjustment	(3)	-	-
Retained earnings	(51,089)	(45,183)	(41,229)
Total equity attributable to the equity shareholders of the parent	20,001	4,762	5,253

CONSOLIDATED STATEMENT OF CASH FLOWS (unaudited)
For the six months ended 31 July 2014

	Six months ended 31 July 2014	Six months ended 31 July 2013	Year ended 31 January 2014
	£000s	£000s	£000s
Cash flows from operating activities			
Loss before income tax	(6,372)	(2,381)	(6,700)
Adjusted for:			
Finance income	(25)	(6)	(9)
Foreign exchange loss	3	10	18
Depreciation	10	7	17
Amortisation of intangible fixed assets	5	5	9
Profit on disposal of assets	-	(6)	(14)
Movement in provisions	752	(150)	(133)
Research and development expenditure credit	(32)	-	(29)
Share-based payment	446	138	226
Adjusted loss from operations before changes in working capital	(5,213)	(2,383)	(6,615)
(Increase)/decrease in trade and other receivables	(859)	99	(65)
Increase in trade and other payables	773	75	465
Cash used by operations	(5,299)	(2,209)	(6,215)
Taxation received	-	346	346
Net cash used in operating activities	(5,299)	(1,863)	(5,869)
Investing activities			
Proceeds from disposal of property, plant and equipment	-	101	102
Purchase of property, plant and equipment	(16)	(22)	(37)
Purchase of intangible assets	-	-	(10)
Interest received	25	6	9
Net cash generated by / (used in) investing activities	9	85	64
Financing activities			
Proceeds from issue of share capital	22,000	4,614	4,663
Transaction costs on share capital issued	(1,298)	(211)	(207)
Net cash generated from financing activities	20,702	4,403	4,456
Increase/(decrease) in cash and cash equivalents	15,412	2,625	(1,349)
Cash and cash equivalents at beginning of period	2,030	3,379	3,379
Cash and cash equivalents at end of period	17,442	6,004	2,030

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY (unaudited)
Six months ended 31 July 2014

Group	Share capital £000s	Share premium account £000s	Share-based payment reserve £000s	Merger reserve £000s	Currency translation adjustment £000s	Retained earnings £000s	Total £000s
At 1 February 2014	10,075	40,177	1,636	(1,943)	-	(45,183)	4,762
Loss for the period from continuing operations	-	-	-	-	-	(5,906)	(5,906)
Total comprehensive expense for the period	-	-	-	-	-	(5,906)	(5,906)
New share capital issued	3,384	18,616	-	-	-	-	22,000
Transaction costs on share capital issued	-	(1,298)	-	-	-	-	(1,298)
Share based payment	-	-	446	-	-	-	446
Currency translation adjustment	-	-	-	-	(3)	-	(3)
At 31 July 2014	13,459	57,495	2,082	(1,943)	(3)	(51,089)	20,001

Twelve months ended 31 January 2014

Group	Share capital £000s	Share premium account £000s	Share-based payment reserve £000s	Merger reserve £000s	Retained earnings £000s	Total £000s
At 1 February 2013	8,788	33,686	1,410	(1,943)	(39,090)	2,851
Loss for the year from continuing operations	-	-	-	-	(6,093)	(6,093)
Total comprehensive expense for the year	-	-	-	-	(6,093)	(6,093)
New share capital issued	1,287	6,698	-	-	-	7,985
Transaction costs on share capital issued	-	(207)	-	-	-	(207)
Share-based payment	-	-	226	-	-	226
At 31 January 2014	10,075	40,177	1,636	(1,943)	(45,183)	4,762

Six months ended 31 July 2013

Group	Share capital £000s	Share premium account £000s	Share-based payment reserve £000s	Merger reserve £000s	Retained earnings £000s	Total £000s
At 1 February 2013	8,788	33,686	1,410	(1,943)	(39,090)	2,851
Loss for the period from continuing operations	-	-	-	-	(2,139)	(2,139)
Total comprehensive expense for the period	-	-	-	-	(2,139)	(2,139)
New share capital issued	923	3,691	-	-	-	4,614
Transaction costs on share capital issued	-	(211)	-	-	-	(211)
Share-based payment	-	-	138	-	-	138
At 31 July 2013	9,711	37,166	1,548	(1,943)	(41,229)	5,253

NOTES TO THE FINANCIAL STATEMENTS

For the six months ended 31 July 2014

1. Basis of accounting

The Group's unaudited interim financial statements for the half year ended 31 July 2014 have been prepared in accordance with International Financial Reporting Standards (IFRS) as adopted by the EU including those applicable to accounting periods ending 31 January 2015 and the accounting policies set out in Summit's Annual Report for the year ended 31 January 2014. They do not include all the statements required for full annual financial statements, and should be read in conjunction with the consolidated financial statements of the Group at 31 January 2014. The Group's unaudited interim financial statements do not comply with all the disclosures in IAS 34 'Interim Financial Reporting'.

The Annual Report and Accounts for 31 January 2014 have been filed with the Registrar of Companies. The Independent Auditors' Report on the Annual Report and Accounts for 2014 was unqualified and did not include references to any matters to which the auditors drew attention by way of emphasis without qualifying their report and did not contain statements under Section 498(2) or 498 (3) of the Companies Act 2006. The Group's interim financial statements have not been audited or reviewed by the Group's auditors.

The interim financial statements have been prepared on a going concern basis. Management, having reviewed the future operating costs of the business in conjunction with the cash held at 31 July 2014, are confident about the Group's ability to continue as a going concern.

2. Loss per ordinary share calculation

The loss per ordinary share has been calculated by dividing the loss for the period by the weighted average number of shares in issue during the six month period to 31 July 2014, adjusted to reflect the share consolidation and subdivision which took effect on 3 July 2014: 38,082,944 (pre share reorganisation 761,658,884) (for the six month period ended 31 July 2013: 358,676,431 (recalculated post share reorganisation 17,933,822); for the year ended 31 January 2014: 410,192,616 (recalculated post share reorganisation 20,509,631)).

Comparative values for the loss per ordinary share have been recalculated based on the weighted average number of ordinary shares in issue at the relevant time and retrospectively applying the share consolidation and subdivision. Calculating the loss per ordinary share for the current period using the weighted average number of ordinary shares assuming the share reorganisation had not taken place would have resulted in a loss of 0.78p per share (for the six month period ended 31 July 2013: a loss of 0.60p; for the year ended 31 January 2014: a loss of 1.49p)

Since the Group has reported a net loss, diluted loss per ordinary share is equal to basic loss per ordinary share.

3. Issue of share capital

On 28 February 2014 the number of ordinary shares in issue increased to 821,228,226 following the placing of 338,461,540 ordinary 1p shares. The shares rank *pari passu* with existing ordinary shares. The equity placing raised net proceeds of £20.7 million.

On 3 July 2014 the number of ordinary shares in issue increased to 821,228,240 following the issue of 14 Ordinary 1p shares. These new shares were issued as part of the Capital Reorganisation (see Note 4) to ensure the number of shares in issue was exactly divisible by 20. The shares ranked *pari passu* with the then existing ordinary shares.

4. Share consolidation

On 3 July 2014 the shareholders approved a reorganisation of the Company's share capital. The capital reorganisation consisted of three elements; a consolidation of every 20 existing ordinary shares into one consolidated ordinary share followed by an immediate subdivision of each of those ordinary shares into one new ordinary share and 19 new deferred shares; and a capital reduction to cancel the existing and new deferred shares and a reduction of the Company's Share Premium Account.

The consolidation and sub division took place on 3 July 2014 and resulted in the issued ordinary share capital of the Company consisting of 41,061,412 ordinary shares of 1 penny each. The capital reduction took effect on 3 September 2014.