Summit Therapeutics plc

('Summit', the 'Company' or the 'Group')

Summit Therapeutics Reports Financial Results for the Fourth Period and Eleven Months Ended December 31, 2019, and Operational Progress

Oxford, UK, and Cambridge, MA, US, April 30, 2020 - Summit Therapeutics plc (NASDAQ: SMMT) today reports its financial results for the fourth period* and eleven months ended December 31, 2019, and provides an update on its operational progress.

Program Highlights

Ridinilazole for C. difficile *Infection ('CDI')*

- As of March 31, 2020, the Company had enrolled a total of 252 patients into its Phase 3 Ri-CoDIFy clinical trials. Below is a table outlining the enrollment statistics by calendar quarter since the opening of the trials in February 2019. The Company expects to report quarterly enrollment updates going forward.

Quarter	Number of patients enrolled
Q1 2019	9
Q2 2019	21
Q3 2019	43
Q4 2019	78
Q1 2020	101

- Due to the uncertainties surrounding COVID-19, the Company is withdrawing the expected timing of completion for the clinical trials.
- The Ri-CoDIFy clinical trials aim to support registration of the precision antibiotic ridinilazole in the US and other territories resulting in its intended adoption as a first-line treatment for CDI by:
    1. testing for superiority over the current standard of care, vancomycin, in the primary endpoint of sustained clinical response at 30 days after treatment has ended;
    2. generating health economic data to help support ridinilazole's commercial launch, if approved; and
    3. undertaking deep microbiome analysis that aims to show ridinilazole's preservation of the gut microbiome.
- BARDA increased the total value of its award in June 2019 and again in January 2020. The total award is now worth up to $72.5 million, with $62.4 million of that committed to date. As of December 31, 2019, an aggregate of £29.1 million ($38.6 million) of the total committed BARDA funding had been received.

Discuva Platform

Enterobacteriaceae

- DDS-04 compound series is a new class of antibiotics in lead optimization to treat infections caused by the Gram-negative bacteria, Enterobacteriaceae.
- Presented *in vivo* proof of concept data in pneumonia, sepsis and urinary tract infection at medical conferences in 2019.

Gonorrhea

- Developing a new mechanism antibiotic for the treatment of gonorrhea with published preclinical data showing compounds from the series had consistently high potency across over 200 clinically relevant strains of *Neisseria gonorrhoeae*, including numerous multi-drug resistant and extensively-drug resistant strains.
- Program supported by an award of up to $5.7 million from CARB-X.

Key Operational Updates

- In light of the COVID-19 pandemic, Summit's employees are currently working remotely with the Company's IT infrastructure helping maintain high levels of connectivity enabling the majority of day to day business operations to continue. Summit's own laboratory facilities are temporarily closed, and management continues to evaluate plans that may allow resumption of activities while not compromising the safety of the researchers. There has been a slowing of patient enrollment into the Ri-CoDIFy clinical trials, which the Company expects to continue during the pandemic.
- Mr. Robert W. Duggan was appointed as Chief Executive Officer, Dr. Elaine Stracker was appointed Interim Chief Operating Officer and Dr. Ventzislav Stefanov was appointed Executive Vice President and President of Discuva in April 2020. Mr. Glyn Edwards stepped down as Chief Executive Officer in April 2020, and he remains on the board as a Non-Executive Director.
- Dr. David Powell was promoted to Chief Scientific Officer from his previous position as Head of Research and Development in March 2020.
- Ms. Divya Chari was appointed as Head of Global Clinical Operations in March 2020. She has over 16 years of experience in clinical operations working with data management, supporting multiple successful New Drug Applications and Supplemental New Drug Applications across therapeutic areas. Ms. Chari most recently led large, global partnership clinical trials at Pharmacyclics, Inc., an AbbVie company.
- The Company's six-member board consists of Mr. Robert W. Duggan, Mr. Manmeet Soni, Dr. Elaine Stracker, Dr. Ventzislav Stefanov, Mr. Glyn Edwards and Mr. Rainer Erdtmann.

Financial Highlights

- Net proceeds of $49.1 million (£38.1 million) received from the sale of the Company's ordinary shares in a placement that completed in December 2019.
- Loss for the eleven months ended December 31, 2019, of £22.0 million compared to a profit of £7.5 million for the year ended January 31, 2019.
- Cash and cash equivalents at December 31, 2019, of £48.4 million compared to £26.9 million at January 31, 2019.
- In December 2019, the Company changed its fiscal year end from January 31 to December 31. As a result, the Company is presenting financial results for the eleven months ended December 31, 2019.

* The fourth period ended December 31, 2019, covered the two months from November 2019 to December 2019 and was due to the change in fiscal year end made in December 2019.

About *C. difficile* Infection

Clostridioides difficile, or *C. difficile*, infection (CDI) is a bacterial infection of the colon that produces toxins causing inflammation of the colon and severe diarrhea. CDI can also result in more serious disease complications, including pseudomembranous colitis, bowel perforation, toxic megacolon and sepsis.

CDI represents a serious healthcare issue in hospitals, long-term care homes and in the wider community. Summit estimates there are over one million cases of CDI each year in the United States and Europe, based on an epidemiology report on CDI that was published in 2015 by Decision Resources, a healthcare research and consulting company. In addition, from 2011-2017, CDI was associated with over 20,000 deaths each year in the United States, according to a study published in the *New England Journal of Medicine* in April 2020. The Healthcare Cost and Utilization Project, a family of databases developed through a federal-state-industry partnership, sponsored by the Agency for Healthcare Research and Quality of the US Department of Health and Human Services, reported an approximate 3.5-fold increase in hospital stays associated with CDI between 2000 and 2008. The economic impact of CDI is significant. A study published in 2016 in *BMC Infectious Diseases* estimated that the total costs attributable to the management of CDI were approximately $6.3 billion per year.

About Enterobacteriaceae

Enterobacteriaceae are a family of bacteria responsible for severe and often deadly infections. They account for a significant number of cases across a number of conditions including bloodstream infections, urinary tract infections and hospital-acquired pneumonias. Summit estimates that there are more than one million infections in the United States annually caused by Enterobacteriaceae across these three conditions based on data published in 2018 in the *Journal of Antimicrobial Chemotherapy*, 2016 in the *Journal of Molecular Science*, 2014 in the National Healthcare Safety Network, 2014 and 2018 in the *New England Journal of Medicine*, 2015 in *Nature Reviews Microbiology*, 2012 in *World Journal of Urology* and 2014 in *PLOS One*. Mechanisms of antibiotic resistance to Enterobacteriaceae are listed as both urgent and serious threats by the CDC.

About Gonorrhea

There is an urgent unmet need for the development of new antibiotics against gonorrhea, which is a sexually transmitted infection caused by an overgrowth of the bacteria *Neisseria gonorrhoeae* (*N. gonorrhoeae*). *N. gonorrhoeae* can cause infection of the genitals, throat, and eyes. Untreated infections may spread to the rest of the body, especially the joints, and in women may cause pelvic inflammatory disease and possible infertility. It is estimated by the WHO that there are approximately 78 million new cases of gonorrhea globally per year. *N gonorrhoeae* has consistently developed resistance to each class of antibiotics recommended for the treatment of gonorrhea infections, and there is now only one treatment that is recommended by the CDC, a combination of the cephalosporin antibiotic ceftriaxone and the macrolide antibiotic azithromycin. The WHO ranks gonorrhea as a “high” priority for research and development while the CDC states that additional treatment options are urgently needed.

About Summit Therapeutics

Summit Therapeutics is a leader in antibiotic innovation. Our new mechanism antibiotics are designed to become the new standards of care for the benefit of patients, subject to regulatory approvals, and create value for payors and healthcare providers. We are currently developing new mechanism antibiotics to treat infections caused by
C. difficile, Enterobacteriaceae and *N. gonorrhoeae* and are using our proprietary Discuva Platform to expand our pipeline. For more information, visit www.summitplc.com and follow us on Twitter @summitplc.

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Forward Looking Statements

Any statements in this press release about the Company's future expectations, plans and prospects, including but not limited to, statements about the potential benefits and future operation of the BARDA or CARB-X contract, including any potential future payments thereunder, the clinical and preclinical development of the Company's product candidates, the therapeutic potential of the Company's product candidates, the potential of the Discuva Platform, the potential commercialization of the Company's product candidates, the sufficiency of the Company's cash resources, the timing of initiation, completion and availability of data from clinical trials, the potential submission of applications for marketing approvals, the impact of the COVID-19 pandemic and other statements containing the words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the ability of BARDA or CARB-X to terminate the contract for convenience at any time, the uncertainties inherent in the initiation of future clinical trials, availability and timing of data from ongoing and future preclinical studies and clinical trials and the results of such preclinical studies and clinical trials, whether preliminary results from a clinical trial will be predictive of the final results of that trial or whether results of early clinical trials or preclinical studies will be indicative of the results of later clinical trials, expectations for regulatory approvals, legal, regulatory, political and economic risks arising from or relating to global public health crises that reduce economic activity (including the recent coronavirus COVID-19 outbreak) and the enrollment in and completion of clinical trials, laws and regulations affecting government contracts, availability of funding sufficient for the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements and other factors discussed in the "Risk Factors" section of filings that the Company makes with the Securities and Exchange Commission, including the Company's Annual Report on Form 20-F for the fiscal year ended January 31, 2019. Accordingly, readers should not place undue reliance on forward-looking statements or information. In addition, any forward-looking statements included in this press release represent the Company's views only as of the date of this release and should not be relied upon as representing the Company's views as of any subsequent date. The Company specifically disclaims any obligation to update any forward-looking statements included in this press release.

The financial information in the Company's financial statements has been prepared assuming the Company will continue on a going concern basis. Based on management's forecasts, the Company's existing cash and cash equivalents, anticipated payments from BARDA under its contract for the development of ridinilazole, anticipated payments from CARB-X under its contract for the development of its gonorrhea antibiotic program, and anticipated milestone payments from its license and commercialization agreement with Eurofarma are expected to be sufficient to enable the Company to fund its operating expenses and capital expenditure requirements through January 31, 2021. The Company will need to raise additional funding in order to support, beyond this date, its planned research and development efforts, its preparatory commercialization related activities should ridinilazole receive marketing approval, as well as to support activities associated with operating as a public company in the United States. The failure of the Company to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on the Company's business, results of operations and financial condition, and may cast and raise significant doubt on the Company's ability to continue as a goingconcern.

FINANCIAL STATEMENTS

Consolidated Statement of Comprehensive Income (derived from audited information) For the eleven months ended December 31, 2019, and year ended January 31, 2019

	Eleven months ended December 31, 2019 **$000s**	Eleven months ended December 31, 2019 **£000s**	Year ended January 31, 2019 (Adjusted*) £000s
Revenue	**774**	**583**	43,012
Other operating income	**20,120**	**15,163**	15,156
Operating expenses			
Research and development	**(41,401)**	**(31,201)**	(39,182)
General and administration	**(13,106)**	**(9,877)**	(12,328)
Impairment of goodwill and intangible assets	**—**	**—**	(3,985)
Total operating expenses	**(54,507)**	**(41,078)**	(55,495)
Operating (loss) / profit	**(33,613)**	**(25,332)**	2,673
Finance income	**5**	**4**	2,788
Finance costs	**(303)**	**(228)**	(467)
(Loss) / profit before income tax	**(33,910)**	**(25,556)**	4,994
Income tax	**4,676**	**3,524**	2,496
(Loss) / profit for the period	**(29,234)**	**(22,032)**	7,490
Other comprehensive income / (loss)			
Items that may be reclassified subsequently to profit or loss			
Exchange differences on translating foreign operations	**—**	**—**	19
Total comprehensive (loss) / profit for the period	**(29,234)**	**(22,032)**	7,509
Basic and diluted (loss) / earnings per ordinary share from operations	**(18) cents**	**(13) pence**	9 pence

* Please refer to the Company's annual report as filed on Form 20-F for accompanying notes to these consolidated financial statements.

This financial information for the eleven months ended December 31, 2019, and for the year ended January 31, 2019, does not constitute the statutory financial statements for the respective years within the meaning of Sections 434-436 of the Companies Act 2006 and is an extract from the financial statements.

Consolidated Statement of Financial Position (derived from audited information) As at December 31, 2019

	December 31, 2019	December 31, 2019	January 31, 2019 (Adjusted*)
	$000s	**£000s**	£000s
ASSETS			
Non-current assets			
Goodwill	**2,407**	**1,814**	1,814
Intangible assets	**13,203**	**9,950**	10,604
Property, plant and equipment	**1,548**	**1,167**	1,540
	17,158	**12,931**	13,958
Current assets			
Trade and other receivables	**10,769**	**8,116**	13,491
Current tax receivable	**4,855**	**3,659**	6,328
Cash and cash equivalents	**64,245**	**48,417**	26,858
	79,869	**60,192**	46,677
Total assets	**97,027**	**73,123**	60,635
LIABILITIES			
Non-current liabilities			
Deferred revenue	**(496)**	**(374)**	(831)
Lease liabilities	**(424)**	**(320)**	(647)
Provisions for other liabilities and charges	**(2,720)**	**(2,050)**	(1,851)
Deferred tax liability	**(2,070)**	**(1,560)**	(1,675)
	(5,710)	**(4,304)**	(5,004)
Current liabilities			
Trade and other payables	**(10,643)**	**(8,020)**	(8,733)
Lease liabilities	**(475)**	**(358)**	(358)
Deferred revenue and income	**(1,507)**	**(1,136)**	(3,374)
Contingent consideration	**(106)**	**(80)**	(629)
	(12,731)	**(9,594)**	(13,094)
Total liabilities	**(18,441)**	**(13,898)**	(18,098)
Net assets / (liabilities)	**78,586**	**59,225**	42,537
EQUITY			
Share capital	**4,457**	**3,359**	1,604
Share premium account	**171,316**	**129,110**	92,806
Share-based payment reserve	**1,724**	**1,299**	1,148
Merger reserve	**4,017**	**3,027**	3,027
Special reserve	**26,529**	**19,993**	19,993
Currency translation reserve	**74**	**56**	56
Accumulated losses reserve	**(129,531)**	**(97,619)**	(76,097)
Total equity / (deficit)	**78,586**	**59,225**	42,537

* Please refer to the Company's annual report as filed on Form 20-F for accompanying notes to these consolidated financial statement

Consolidated Statement of Cash flows (derived from audited information) For the eleven months ended December 31, 2019

	Year ended 31 December 2019	Year ended 31 December 2019	Year ended 31 January 2018 (Adjusted*)
	$000s	**£000s**	£000s
Cash flows from operating activities			
(Loss) / profit before income tax	**(33,910)**	**(25,556)**	4,994
	(33,910)	**(25,556)**	4,994
Adjusted for:			
Gain on remeasurement or derecognition of financial liabilities on funding arrangements	**—**	**—**	(539)
Loss on recognition of contingent consideration payable	**—**	**2**	754
Finance income	**(5)**	**(4)**	(2,788)
Finance costs	**303**	**228**	467
Unrealized foreign exchange loss / (gain)	**722**	**544**	(408)
Depreciation	**695**	**524**	644
Amortization of intangible fixed assets	**1,008**	**760**	829
Loss on disposal of assets	**14**	**10**	43
Increase / (decrease) in provisions	**2**	**1**	19
Impairment of goodwill and intangible assets	**—**	**—**	3,985
Share-based payment	**878**	**661**	4,743
Adjusted (loss) / profit from operations before changes in working capital	**(30,293)**	**(22,830)**	12,743
Decrease / (increase) in trade and other receivables	**6,186**	**4,662**	(2,210)
(Decrease) / increase in deferred revenue	**(3,577)**	**(2,696)**	(36,898)
(Decrease) / increase in trade and other payables	**(1,332)**	**(1,004)**	68
Cash used by operations	**(29,016)**	**(21,868)**	(26,297)
Contingent consideration paid	**(728)**	**(549)**	(192)
Taxation received	**8,272**	**6,234**	159
Research and development expenditure credit received	**685**	**516**	(333)
Net cash used by operating activities	**(20,787)**	**(15,667)**	(26,663)
Investing activities			
Purchase of property, plant and equipment	**(212)**	**(160)**	(119)
Purchase of intangible assets	**(142)**	**(107)**	(6)
Interest received	**5**	**4**	4
Net cash used by investing activities	**(349)**	**(263)**	(121)
Financing activities			
Proceeds from issue of share capital	**50,000**	**38,759**	34,648
Transaction costs on share capital issued	**(930)**	**(701)**	(1,313)
Proceeds from exercise of share options	**1**	**1**	102
Repayment of lease liabilities	**(435)**	**(328)**	(281)
Repayment of lease interest	**(40)**	**(30)**	(43)
Net cash generated from financing activities	**48,596**	**37,701**	33,113
Increase / (decrease) in cash and cash equivalents	**27,460**	**21,771**	6,329
Effect of exchange rates on cash and cash equivalents	**1,147**	**(212)**	427
Cash and cash equivalents at beginning of the period / year	**35,638**	**26,858**	20,102
Cash and cash equivalents at end of the period / year	**64,245**	**48,417**	26,858

* Please refer to the Company's annual report as filed on Form 20-F for accompanying notes to these consolidated financial statements.

Consolidated Statement of Changes in Equity (derived from audited information)

Eleven months ended December 31, 2019

Group	Share capital £000s	Share premium account £000s	Share-based payment reserve £000s	Merger reserve £000s	Special reserve £000s	Currency translation reserve £000s	Accumulated losses reserve £000s	Total £000s
At February 1, 2019 (as previously reported)	1,604	92,806	1,148	3,027	19,993	56	(76,092)	42,542
Change in accounting policy (full retrospective application IFRS 15)	—	—	—	—	—	—	(5)	(5)
At February 1, 2019 (Adjusted*)	1,604	92,806	1,148	3,027	19,993	56	(76,097)	42,537
Loss for the period	—	—	—	—	—	—	(22,032)	(22,032)
Total comprehensive loss for the period	—	—	—	—	—	—	(22,032)	(22,032)
New share capital issued	1,754	37,005	—	—	—	—	—	38,759
Transaction costs on share capital issued	—	(701)	—	—	—	—	—	(701)
Warrant expense	—	—	15	—	—	—	—	15
Share options exercised	1	—	—	—	—	—	—	1
Share-based payment	—	—	646	—	—	—	—	646
Transfer	—	—	(510)	—	—	—	510	—
At December 31, 2019	3,359	129,110	1,299	3,027	19,993	56	(97,619)	59,225

Year ended January 31, 2019

Group	Share capital £000s	Share premium account £000s	Share-based payment reserve £000s	Merger reserve £000s	Special reserve £000s	Currency translation reserve £000s	Accumulated losses reserve £000s	Total £000s
At February 1, 2018	736	60,237	6,743	3,027	19,993	37	(93,957)	(3,184)
Change in accounting policy (full retrospective application (IFRS 16)	—	—	—	—	—	—	32	32
At February 1, 2018 (Adjusted*)	736	60,237	6,743	3,027	19,993	37	(93,925)	(3,152)
Profit for the year	—	—	—	—	—	—	7,490	7,490
Currency translation adjustment	—	—	—	—	—	19	—	19
Total comprehensive profit for the year	—	—	—	—	—	19	7,490	7,509
New share capital issued	864	33,784	—	—	—	—	—	34,648
Transaction costs on share capital	—	(1,313)	—	—	—	—	—	(1,313)
Share options exercised	4	98	—	—	—	—	—	102
Share-based payment	—	—	4,743		—	—	—	4,743
Transfer			(10,338)				10,338	—
At January 31, 2019 (Adjusted*)	1,604	92,806	1,148	3,027	19,993	56	(76,097)	42,537

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