



Summit Therapeutics Inc.

(‘Summit’, the ‘Company’ or the ‘Group’)

Summit Therapeutics Reports Financial Results and Operational Progress for the Second Quarter and Six Months Ended June 30, 2020

Cambridge, MA, September 29, 2020 - Summit Therapeutics Inc. (NASDAQ: SMMT) today reports its financial results and provides an update on its operational progress for the second quarter and six months ended June 30, 2020.

Ridinilazole for *C. difficile* Infection (‘CDI’)

1. Summit published data from its Phase 2 clinical trial of ridinilazole evaluating the effects of a narrow-spectrum (ridinilazole) or broad-spectrum antibiotic (vancomycin) on intestinal bile acid profiles. This was the first study to demonstrate in humans the relationships between *Clostridioides difficile* antibiotic treatment choice and bile acid metabolism both during therapy and after treatment cessation. The results indicated that ridinilazole maintained an intestinal bile acid profile associated with a lowered risk of recurrence. The data were published in the *American Journal of Physiology – Gastrointestinal and Liver Physiology*.
2. As of August 31, 2020, Summit had enrolled a total of 369 patients into its Phase 3 Ri-CoDIFy clinical trials of ridinilazole. Below is a table outlining the enrollment statistics by calendar quarter and for this past July and August since the opening of the trials in February 2019.

Quarter	Number of patients enrolled	Cumulative Patients Enrolled
Q1 2019	9	9
Q2 2019	21	30
Q3 2019	43	73
Q4 2019	78	151
Q1 2020	101	252
Q2 2020	73	325
July 2020	22	347
August 2020	22	369

3. Due to the uncertainties surrounding COVID-19, Summit is withdrawing public commentary on the timing of completion of the Phase 3 Ri-CoDIFy clinical trials. The Company plans to publicly update stakeholders quarterly as to enrollment status.
4. The Ri-CoDIFy clinical trials aim to support application for marketing approval of the precision antibiotic ridinilazole in the United States and other territories and the goal of it being used as a first-line treatment for CDI by:
 - a. 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;
 - b. generating health economic data to support ridinilazole's commercial launch, when as and if approved by regulatory authorities; and
 - c. undertaking microbiome and metabolome analysis that aims to show ridinilazole's impact on the gut microbiome and bile acids composition



5. BARDA is supporting the Phase 3 clinical trials and regulatory development of ridinilazole with a financial award of potential funding of up to \$72.5 million. As of June 30, 2020, an aggregate of \$46.6 million had been received.

Discuva Platform

Enterobacteriaceae

1. DDS-04 compound series is a new class of precision antibiotics, with new mechanism of action, which is in lead optimization that acts *via* the novel bacterial target LolCDE with the potential to treat multidrug resistant infections caused by the Gram-negative bacteria Enterobacteriaceae.

Gonorrhoea

1. Based on results from recent preclinical studies, the DDS-01 series of antibiotics against *Neisseria gonorrhoeae* was determined not to have suitable qualities for further development as it had shown toxicity in animal studies and therefore, Summit is ceasing work on the gonorrhea program. The Company expects CARB-X will cover its remaining share of the work that has been funded under the award.

Corporate Highlights

1. Mr. Michael Donaldson was appointed as Chief Financial Officer in June 2020. Previously, Mr. Donaldson served as Vice President, Finance, and Corporate Controller for Goldfinch Bio, Inc. from 2018 to 2020 and Vice President, Finance, Corporate Controller and Assistant Treasurer at ARIAD Pharmaceuticals, Inc., which was acquired by Takeda, Inc. in 2017, from 2016 to 2017. Prior to that, he was the Corporate Controller for Hittite Microwave Corporation, which was acquired by Analog Devices in 2014. Mr. Donaldson spent the first 11 years of his career at PricewaterhouseCoopers
2. Dr. Jos Houbiers was promoted to Chief Medical Officer in July 2020. Dr Houbiers brings to Summit over 20 years of experience in pharmaceutical clinical development, where he's implemented clinical development strategies, creative trial design and comprehensive medical safety monitoring across therapeutic areas, including functional urology, immunology and transplantation. He was most recently at Astellas, where he served in roles of increasing responsibility in clinical development from the Global Development hub, where he ended as Executive Medical Director and Group Head for the Medical Science Urology department. Dr. Houbiers received his MD from Leiden University Medical Center and PhD (immunology) and MSc in medicine from Leiden University.
3. Ms. Ujjwala Mahatme was appointed as a Director in July 2020.
4. Mr. Robert W. Duggan was appointed as Chief Executive Officer and Dr. Ventzislav Stefanov was appointed Executive Vice President and President of Discuva, the Company's discovery engine employing 14 people, in April 2020. Mr. Glyn Edwards stepped down as Chief Executive Officer in April 2020 and from the Board of Directors in June 2020.
5. Summit has redomiciled to the United States, effective September 18, 2020.

COVID-19

6. In light of the ongoing COVID-19 pandemic, Summit's employees continue to work remotely, enabling the majority of day to day business operations to continue. Summit's own laboratory facilities have begun to reopen to resume work on key projects; site access by staff is being monitored closely and is limited to ensure the safety of Summit researchers. There continues to be a negative impact on patient enrollment into the Ri-CoDIFy clinical trials. We are working to implement a number of initiatives and considering alternative courses of action to mitigate the impact of the COVID-19 pandemic on our clinical trials, although there can be no assurance that such actions will be successful.



Financial Highlights

1. Cash and cash equivalents at June 30, 2020, of \$36.4 million compared to \$63.8 million at December 31, 2019.
2. The Company's existing cash and cash equivalents and committed external funding are expected to be sufficient to enable the Company to fund its operating expenses and capital expenditure requirements through January 31, 2021. The Principal shareholder of the Company, Mr. Robert W. Duggan, has given his intention to the Board of Directors to participate in a future fundraise as required in order to support the Company with its clinical operations and planned research and development efforts.
3. Loss for the six months ended June 30, 2020, of \$21.6 million compared to a loss of \$13.7 million for the six months ended June 30, 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 watery diarrhea, painful abdominal cramping, nausea, fever and dehydration. CDI can also result in more serious disease complications, including bowel perforation, sepsis and death. CDI represents a serious healthcare issue in hospitals, long-term care homes and in the wider community. Summit estimates that there are over 3 million cases of CDI each year worldwide, based on a meta-analysis of 229 publications with data from 41 countries, published in the Journal of Global Health, June 2019.

About Enterobacteriaceae

Enterobacteriaceae are a family of bacteria responsible for serious infections across a number of conditions including bloodstream infections, urinary tract infections and hospital-acquired pneumonias. Multidrug resistant Enterobacteriaceae are resistant to treatment by most or occasionally all of existent antibiotics. The most difficult to treat among them are the ESBL-producing and the Carbapenem-resistant Enterobacteriaceae which according to the CDC, have collectively caused an estimated 210,500 infections and 10,200 deaths in hospitalized patients in the United States in 2017.

About Summit Therapeutics

Summit Therapeutics, empowered by its Discuva Platform, the Company's innovative antibiotic discovery engine, led by Dr. Ventzislav Stefanov and supported by BARDA and Carb-X funding, intends to be the leader in patient and physician friendly paradigm shifting antibiotic innovation. Our new mechanism antibiotics are designed to become the patient-friendly, new era standard-of-care, by working in harmony with the human microbiome to treat prospective patients suffering from infectious disease, initially focussing on Clostridioides difficile infections ("CDI") which is estimated to impact over 3 million patients worldwide annually. Commercialization of ridinilazole for the treatment of CDI is subject to regulatory approvals. The overriding objective of Summit Therapeutics is to create value for patients, hospital infectious disease care givers, community based infectious disease healthcare providers, as well as healthcare payors around the world. Currently, Summit's lead product candidate ridinilazole is engaged in two global phase III trials, Ri-CoDIFy 1 & 2, each enrolling 680 patients vs standard of care (Vancomycin) for the treatment of C. difficile infections.

Summit's vision and mission is to extend our pipeline through the development of new mechanism, narrow spectrum, microbiome sparing antibiotics targeting C. difficile, Gram-negative Enterobacteriaceae such as Escherichia coli and Klebsiella pneumoniae and other bacterial infections with high unmet medical need.



For more information, visit www.summitplc.com and follow us on Twitter @summitplc. For more information on the Company's Discuva Platform, visit <https://www.summitplc.com/our-science/discuva-platform>.

Contacts Summit Press Office

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Summit 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 clinical and preclinical development of the Company's product candidates, the therapeutic potential of the Company's product candidates, the potential commercialization of the Company's product candidates, 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 on the Company's operations and clinical trials 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 uncertainties inherent in the initiation of future clinical trials, availability and timing of data from ongoing and future clinical trials and the results of such trials, global public health crises, including the coronavirus COVID-19 outbreak, that may affect timing and status of our clinical trials and operations, 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, laws and regulations affecting government contracts and funding awards, 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. 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.



CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND OTHER COMPREHENSIVE LOSS
(Unaudited)

In thousands, except share and per share data

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenue:				
Licensing agreements	\$ 170	\$ 156	\$ 494	\$ 647
Total revenue	<u>170</u>	<u>156</u>	<u>494</u>	<u>647</u>
Operating expenses:				
Research and development	14,105	11,257	26,592	22,635
General and administrative	<u>5,299</u>	<u>2,136</u>	<u>5,970</u>	<u>5,234</u>
Total operating expenses	<u>19,404</u>	<u>13,393</u>	<u>32,562</u>	<u>27,869</u>
Loss from operations	<u>(19,234)</u>	<u>(13,237)</u>	<u>(32,068)</u>	<u>(27,222)</u>
Other operating income	<u>3,867</u>	<u>6,494</u>	<u>10,640</u>	<u>13,585</u>
Operating loss	(15,367)	(6,743)	(21,428)	(13,637)
Interest expense, net	<u>(55)</u>	<u>(79)</u>	<u>(120)</u>	<u>(156)</u>
Loss before income tax	<u>(15,422)</u>	<u>(6,822)</u>	<u>(21,548)</u>	<u>(13,793)</u>
Income tax benefit (expense)	<u>191</u>	<u>139</u>	<u>(6)</u>	<u>124</u>
Net loss	<u><u>\$(15,231)</u></u>	<u><u>\$(6,683)</u></u>	<u><u>\$(21,554)</u></u>	<u><u>\$(13,669)</u></u>
Basic loss per share	\$ (0.23)	\$ (0.21)	\$ (0.32)	\$ (0.44)
Diluted loss per share	\$ (0.23)	\$ (0.21)	\$ (0.32)	\$ (0.44)
Other comprehensive income/(loss):				
Foreign currency translation adjustment	<u>(45)</u>	<u>(1,255)</u>	<u>(4,567)</u>	<u>(44)</u>
Total comprehensive loss	<u><u>\$(15,276)</u></u>	<u><u>\$(7,938)</u></u>	<u><u>\$(26,121)</u></u>	<u><u>\$(13,713)</u></u>



CONDENSED CONSOLIDATED BALANCE SHEET INFORMATION
(Unaudited)
In thousands

	June 30, 2020	December 31, 2019
Cash and cash equivalents	\$ 36,410	\$ 63,842
Total assets	\$ 70,949	\$ 96,679
Total liabilities	\$ 19,003	\$ 19,442
Total stockholders' equity	\$ 51,946	\$ 77,237

CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS INFORMATION
(Unaudited)
In thousands

	Six months ended June 30,	
	2020	2019
Net cash used in operating activities	\$ (23,491)	\$ (9,235)
Net cash used in investing activities	(327)	(225)
Net cash provided by financing activities	3	24,503
Effect of exchange rates in cash and cash equivalents	(3,617)	29
Net (decrease) / increase in cash and cash equivalents	\$ (27,432)	\$ 15,072