Summit Therapeutics Inc Reports Financial Results and Operational Progress for the Fourth Quarter and Year Ended December 31, 2021

Summit Therapeutics perceives multiple opportunities to expand across the microbiome therapeutics field

Cambridge, Massachusetts, March 17, 2022 - Summit Therapeutics Inc. (NASDAQ: SMMT) ("Summit," "we," or the "Company") today reports its financial results and provides an update on its operational progress for the fourth quarter and year ended December 31, 2021.

Note: A glossary of terms is included at the end of this document to allow for the ease of understanding of terms or concepts used throughout this release.

Operational & Corporate Updates

Summit Therapeutics intends to implement a strategy that centers on microbiome-focused therapeutics. Modern medicine is pushing the boundaries of a new, increasingly patient friendly era: successfully treating disease while reducing associated adverse events. A proper-functioning and balanced microbiome is fundamental to optimum human health.

Consistent with our messaging from the J.P. Morgan Healthcare Conference, we intend to expand our pipeline product portfolio by developing new mechanism, new era product offerings that are designed to work in harmony with the human gut microbiome in the therapeutic areas of oncology and infectious diseases to optimize the condition of overall human health. Throughout the process of our clinical development of ridinilazole, we learned a substantial amount regarding the function of the microbiome as we sought to reduce *C. difficile* infection recurrence to the lowest practical levels. We plan to move forward with our stated goal of becoming a leader in the microbiome therapeutics field. We intend to enact this mission through business development activities, including possible acquisitions and/or collaborations.

On December 20, 2021, we announced topline results for the Phase III Ri-CoDIFy investigational trials evaluating ridinilazole for the treatment and Sustained Clinical Response (SCR) for patients suffering from *C. difficile* infection (*C. diff.* infection or CDI). While the pre-specified superiority primary endpoint of SCR was not achieved, several important patient effects were observed in our study results. Patients treated with ridinilazole experienced substantially less recurrence of *C. diff.* infection as compared to patients treated with vancomycin (nominal p-value = 0.0002). The study did show a numerically higher SCR rate for those patients treated with ridinilazole.

We are actively preparing and plan to present the data for submission to a major medical conference in May, subject to its acceptance by the conference. We are in the process of evaluating the future path forward for ridinilazole, including potential partnership opportunities.

We have been and plan to continue to perform IND-enabling activities for SMT-738.

Financial Highlights

- Aggregate cash, accounts receivable, and tax credits receivable on December 31, 2021 totaled $89.0 million as compared to $76.6 million on December 31, 2020. Our cash balance on December 31, 2021 was $71.8 million as compared to $66.4 million on December 31, 2020. Accounts receivable and research and development tax credits receivable on December 31, 2021 were $17.2 million as compared to $10.2 million on December 31, 2020.
- Net loss for the three months ended December 31, 2021 and 2020, was $27.1 million and $13.5 million, respectively. Net loss for the year ended December 31, 2021 and 2020, was $88.6 million and $52.7 million, respectively.
- Operating cash outflow for the year ended December 31, 2021 and 2020, was $72.6 million and $48.1 million, respectively.
- During the three months ended December 31, 2021, the Company received non-dilutive funding of $0.7 million from the Biomedical Advanced Research and Development Authority ("BARDA"), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services, in support of the Company's Ri-CoDIFy clinical trials and clinical development of ridinilazole. As of December 31, 2021, an aggregate of $56.5 million out of a potential award of $72.5 million has been received from BARDA under contract number HHSO100201700014C. (Remaining potential funding from BARDA has not been included in aggregate cash and receivables balances, above.)
- During the three months ended December 31, 2021, the Company received non-dilutive funding of $0.3 million from the Trustees of Boston University under the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator ("CARB-X") program, in support of IND-enabling activities for SMT-738. As of December 31, 2021, an aggregate of $0.5 million out of a potential of up to $7.8 million of funding has been received from CARB-X.

Summit Therapeutics' Mission Statement

To build a viable, long-lasting health care organization that assumes full responsibility for designing, developing, trial execution and enrollment, regulatory submission and approval, and successful commercialization of patient, physician, caregiver, and societal-friendly medicinal therapy intended to: improve quality of life, increase potential duration of life, and resolve serious medical healthcare needs. To identify and control promising product candidates based on exceptional scientific development and administrational expertise, develop our products in a rapid, cost-efficient manner, and to engage commercialization and/or development partners when appropriate.

We accomplish this by building a team of world class professional scientists and business administrators that apply their experience and knowledge to this mission. Team Summit exists to pose, strategize, and execute a path forward in medicinal therapeutic health care that places Summit in a well-deserved, top market share, leadership position. Team Summit assumes full responsibility for stimulating continuous expansion of knowledge, ability, capability, and well-being for all involved stakeholders and highly-valued shareholders.

About Summit Therapeutics
Summit was founded in 2003 and our shares are listed on the Nasdaq Global Market (symbol 'SMMT'). We are headquartered in Cambridge, Massachusetts, and we have additional offices in Oxford, UK, Cambridge, UK, and Menlo Park, California

For more information, please visit https://www.summittxinc.com and follow us on Twitter @summitplc.

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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, potential acquisitions 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 results of our evaluation of the underlying data in connection with the topline results of our Phase III Ri-CoDIFy study evaluating ridinilazole, the outcome of discussions with regulatory authorities, including the Food and Drug Administration, the uncertainties inherent in the initiation of future clinical trials, availability and timing of data from ongoing and future clinical trials, the results of such trials, and their success, and 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, whether business development opportunities to expand the Company's pipeline of drug candidates, including without limitation, through potential acquisitions of, and/or collaborations with, other entities occur, 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. Any change to our ongoing trials could cause delays, affect our future expenses, and add uncertainty to our commercialization efforts, as well as to affect the likelihood of the successful completion of clinical development of ridinilazole. 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.

SUMMIT THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited, in thousands, except per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Revenue	$ 251	$ 185	$ 1,809	$ 860
Operating expenses:				
Research and development	23,107	13,064	85,352	53,274
General and administrative	7,780	3,040	23,611	19,232
Impairment of intangible assets	—	—	—	859
Total operating expenses	30,887	16,104	108,963	73,365
Other operating income	4,589	4,363	20,968	19,312
Operating loss	(26,047)	(11,556)	(86,186)	(53,193)
Other (expense) income, net	(1,052)	(2,006)	(2,416)	283
Loss before income tax	(27,099)	(13,562)	(88,602)	(52,910)
Income tax benefit	—	21	—	213
Net loss	$ (27,099)	$ (13,541)	$ (88,602)	$ (52,697)
Basic and diluted loss per share	$ (0.28)	$ (0.18)	$ (0.96)	$ (0.76)
Other comprehensive (loss) income:				
Foreign currency translation adjustments	1,245	3,320	1,597	970
Comprehensive loss	$ (25,854)	$ (10,221)	$ (87,005)	$ (51,727)

CONDENSED CONSOLIDATED BALANCE SHEET INFORMATION
(unaudited, in thousands, except per share data)

	December 31, 2021	December 31, 2020
Cash	$ 71,791	$ 66,417
Total assets	113,374	102,498
Total liabilities	30,090	23,045
Total stockholders' equity	$ 83,284	$ 79,453

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS INFORMATION
(unaudited, in thousands, except per share data)

	Year Ended December 31,	
	2021	2020
Net cash used in operating activities	$ (72,587)	$ (48,111)
Net cash used in investing activities	(306)	(421)
Net cash provided by financing activities	77,916	50,551
Effect of exchange rate changes on cash	351	556
Increase in cash	$ 5,374	$ 2,575

Appendix: Glossary of Critical Terms Contained Herein

Antibiotic resistance genes – Genes known to be involved in bacterial resistance; such genes may include for example beta-lactamases which can inactivate various beta-lactam antibiotics.

Bile acids – a collection of steroid-based gut metabolites, the balance of the amount of and types of bile acids in the gut microbiome are believed to play an important role in the development of or prevention of an initial and potential recurrent instance of *C. difficile* Infection.[i]

Bloodstream infections – an infectious disease defined by the presence of viable bacterial or fungal microorganisms in the bloodstream that elicit or have elicited an inflammatory response.[ii]

Carbapenem-Resistant Enterobacteriaceae (CRE) – Enterobacteriaceae that are resistant to carbapenems, a type of antibiotic used to treat some of the most resistant forms of gram-negative bacteria. This resistance means that there are fewer options available to treat infections caused by these bacteria, as CRE do not respond to commonly used antibiotics. In many cases, including infections such as urinary tract infections caused by CRE germs, more complex treatments are required. Instead of taking oral antibiotics at home, patients with these infections might require hospitalization and intravenous (IV) antibiotics. Occasionally CRE are resistant to all available antibiotics. CRE are a threat to public health.[iii]

Clostridia – a class of bacteria that exist within a healthy gut microbiome that likely plays a largely crucial role in microbiome homeostasis by interacting with the other resident microbe populations and providing specific and essential functions to the overall microbiome. While most groups of Clostridia have a commensal, or co-existing, relationship with the rest of the gut microbiome, some Clostridia can be pathogenic, when larger concentrations of the bacteria exist, such as *Clostridioides difficile* bacteria.[iv]

***Clostridioides difficile* (*C. difficile* or *C. diff.*)** – a germ (bacterium) that can cause severe diarrhea and colitis (an inflammation of the colon). *C. difficile* can live naturally in the intestines (gut) of humans and not cause any problem. Sometimes changes in the gut microbiome lead the bacteria to grow and produce toxins from which illness can develop.[v]

***C. diff.* Infection (CDI)** – a bacterial infection of the colon that produces toxins causing inflammation of the colon and severe watery diarrhea, very painful and persistent abdominal cramping, nausea, fever, and dehydration. CDI can also result in more serious disease complications, including bowel perforation (a tear in the gastrointestinal tract), sepsis, and death. Most cases of *C. diff.* infection occur while a person is taking antibiotics or not long after a person has finished taking antibiotics. CDI is an insidious and debilitating disease that necessitates patient isolation because of its contagious nature, making it able to be passed from one person to another either in a hospital or long-term care facility setting or in the community.[vi]

DDS-04 – a series of new mechanism antibiotics targeting Enterobacteriaceae. DDS-04 acts via LolCDE, an essential bacterial complex responsible for the transport of lipoproteins from the inner to outer membrane in gram-negative bacteria. Because this complex has not been a previous target of existing antimicrobials, bacterial resistance does not yet exist to this targeted approach, potentially allowing for the treatment of highly-resistant Enterobacteriaceae-caused infections. Some of these infections, particularly in a subset of CRE-caused infections, do not have effective treatments through currently available antibiotics.[vii]

Discuva Platform – Summit Therapeutics' proprietary platform that enables the identification of novel antimicrobials to expand Summit's pipeline of investigational drugs. The Discuva Platform focuses on identifying

new antibiotics against bacteria where increasing resistance has limited treatment via existing antibiotics currently on the market.[viii]

Enterobacteriaceae – a large family of different types of bacteria (germs) that commonly cause infections both in healthcare settings, such as hospitals and long-term care facilities, and in communities. Examples of germs in the Enterobacteriaceae family include *Escherichia coli* (commonly known as *E. coli*) and *Klebsiella pneumoniae*. Enterobacteriaceae are frequent carriers of resistance genes to many of the currently available antibiotics used to treat bacterial infections. Because they are bacteria, Enterobacteriaceae can be passed from person to person.[ix]

Escherichia coli (E. coli) – a type of Enterobacteriaceae found in the environment, foods, and intestines of people and animals. *E. coli* are a large and diverse group of bacteria. Although most strains of *E. coli* are harmless, others can make a person sick. Some kinds of *E. coli* can cause diarrhea, while others cause urinary tract infections, bloodstream infections, respiratory illness and pneumonia, and other illnesses.[x]

Gastrointestinal tract – a series of hollow organs joined in a long, twisting tube from the mouth to the anus. These organs also include the esophagus, stomach, small intestine, and large intestine.[xi]

Gut microbiome – within the human gastrointestinal tract, the gut microbiome is a collection of microbiota, consisting of trillions of microorganisms that inhabit the gut. The gut microbiota is considered an important partner to human cell systems, interacting extensively with other organs in the body to influence a wide range of functions from digestion to immunity. The balance of the different types of cells and microorganisms within the microbiome is considered to be important in the microbiome's ability to properly play its role within the human body. Disruption in the balance of microorganisms within the gut microbiome (known as dysbiosis) is believed to impact the gut microbiome's role in keeping a person healthy and free of certain conditions or diseases.[xii xiii]

Gut microbiota – the trillions of microorganisms, including symbiotic and pathogenic microorganisms, that inhabit the gut. Examples of these microorganisms include bacteria, fungi, viruses, protists, and archaea.

Gut resistome – within the human gastrointestinal tract, the diversity and dynamics of the antibiotic resistance genes that are harbored by the gut microbiota. Examples of the gut resistome include genes associated with resistance to carbapenem antibiotics.[xiv]

Hospital-acquired pneumonia (HAP) – pneumonia that occurs 48 hours or more after a patient has been admitted to a hospital and was not present and incubating at the time of admission. Ventilator-associated pneumonia (VAP) is a significant sub-set of HAP, often occurring in intensive care units (ICUs) with a patient on a ventilator. Common pathogens of HAP and VAP include Enterobacteriaceae and *Pseudomonas* species. Due to the presence of the bacteria in a hospital, these bacteria may be resistant to different antibiotics, potentially causing the resulting infection to be more difficult to treat.[xv]

Klebsiella pneumoniae – a type of Enterobacteriaceae that can cause different types of healthcare-associated infections, including pneumonia, bloodstream infections, wound or surgical site infections, and meningitis. Increasingly, *Klebsiella* bacteria have developed resistance to antibiotics, most recently to the class of antibiotics known as carbapenems. *Klebsiella* bacteria are normally found in the human intestines (where they do not cause disease). In healthcare settings, *Klebsiella* infections commonly occur among sick patients who are receiving treatment for other conditions. Patients whose care requires devices like ventilators (breathing machines) or

intravenous (vein) catheters, and patients who are receiving long courses of certain antibiotics are most at risk for *Klebsiella* infections. Healthy people typically do not develop *Klebsiella* infections.[xvi]

Microbiome - a community of microorganisms (such as bacteria, fungi, and viruses) that live in or on humans; the collection of microbial genomes that contribute to the broader genetic portrait, or metagenome, of a human.[xvii]

Sepsis – the body's extreme response to an infection and a life-threatening medical emergency. Sepsis occurs when an existing infection triggers a chain reaction throughout a person's body via the bloodstream. Without timely treatment, sepsis can rapidly lead to tissue damage, multi-organ failure, and death. Almost any type of infection can lead to sepsis. Infections that lead to sepsis most often start in the lung, urinary tract, skin, or gastrointestinal tract. Sepsis is a condition and is not contagious; however, the underlying cause of the infection (e.g., bacteria) can be spread from person to person. Bacterial infections cause most cases of sepsis.[xviii]

Shotgun metagenomic analysis – shotgun metagenomic sequencing sequences all genomic DNA present in a sample. This allows a more accurate taxonomic annotation of the microbiota compared to other techniques such as 16S rRNA amplicon sequencing as well as antibiotic resistance gene profiling and metabolic function profiling.

Urinary tract infections (UTI) – common infections that happen when bacteria, often from the skin or rectum, enter the urethra, and infect the urinary tract. The infections can affect several parts of the urinary tract, but the most common type is a bladder infection. Kidney infections are another type of UTI and can be more serious than bladder infections. UTIs are usually caused by bacteria and are treated with antibiotics. People who have had multiple UTIs requiring multiple courses of antibiotics are at increased risk of developing antibiotic-resistant infections that can become increasing complex to treat.[xix]

Vancomycin – an antibiotic that is used to treat CDI

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