

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)
☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2022
or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the transition
period from _____ to _____

Commission File Number: 001-36866

Summit Therapeutics Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

37-1979717

(I.R.S. Employer Identification
No.)

One Broadway, 14th Floor,
Cambridge, MA

(Address of principal executive offices)

02142

(Zip Code)

617-514-7149

(Registrant's telephone number, including area code)

Not Applicable

(Former name or former address and former fiscal year, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.01 par value per share	SMMT	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer”, “accelerated filer”, “smaller reporting company” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of May 4, 2022, there were 98,122,356 shares of common stock, par value \$0.01 per share, outstanding.

PART I

Item 1.	Financial Statements (Unaudited)	
	Condensed Consolidated Balance Sheets as of March 31, 2022 and December 31, 2021	4
	Condensed Consolidated Statements of Comprehensive Loss for the three months ended March 31, 2022 and 2021	5
	Condensed Consolidated Statements of Stockholders' Equity for the three months ended March 31, 2022 and 2021	6
	Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2022 and 2021	7
	Notes to Unaudited Condensed Consolidated Financial Statements	8
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	19
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	27
Item 4.	Controls and Procedures	27

PART II

Item 1.	Legal Proceedings	27
Item 1A.	Risk Factors	27
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	28
Item 3.	Defaults Upon Senior Securities	28
Item 4.	Mine Safety Disclosures	28
Item 5	Other Information	28
Item 6.	Exhibits	29
Signatures		

INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or this Report, contains forward-looking statements that involve substantial risks and uncertainties. All statements contained in this Report, other than statements of historical fact, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “target,” “potential,” “will,” “would,” “could,” “should,” “continue,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. The forward-looking statements in this Report include, among other things, statements about:

- the timing and evaluation of next steps with respect to our lead product candidate, ridinilazole (formerly SMT19969), for the treatment of patients with Clostridioides difficile infection (formerly known as Clostridium difficile infection) based upon our review of the topline results for the Phase III Ri-CoDIFy study announced in December 2021, including exploring potential partnership opportunities;
- the timing of and our ability to obtain marketing approval of ridinilazole, and the ability of ridinilazole to meet existing or future regulatory standards;
- the timing and conduct of clinical trials for any other product candidates;
- the potential benefits of our Discuva Platform to identify new bacterial targets for drug discovery and development;
- our plans to conduct research and development and advance potential new mechanism antibiotic compounds identified and developed under our Discuva Platform;
- the potential benefits and future operation of our collaboration with the Biomedical Advanced Research and Development Authority, or BARDA;
- the potential benefits and future operation of our license and commercialization agreement with Eurofarma Laboratórios SA, or Eurofarma;
- our plans with respect to possible future collaborations and partnering arrangements;
- the potential benefits of possible future acquisitions or investments in other businesses, products or technologies;
- our plans to pursue research and development of other future product candidates;
- the potential advantages of ridinilazole and our other new mechanism antibiotics;
- the rate and degree of market acceptance and clinical utility of ridinilazole and our other new mechanism antibiotics;
- our estimates regarding the potential market opportunity for ridinilazole and our other new mechanism antibiotics;
- our sales, marketing and distribution capabilities and strategy;
- our ability to establish and maintain arrangements for manufacture of ridinilazole;
- our intellectual property position;
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- the impact of government laws and regulations;
- our competitive position;
- the need to raise additional capital to fund ongoing operations and capital needs; and
- the impact of the novel coronavirus pandemic (COVID-19) and the response to it.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Report, particularly in the “Risk Factors” section in this Report, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this Report and the documents that we have filed as exhibits to this Report completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements.

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements.

Summit Therapeutics Inc. Condensed Consolidated Balance Sheets (in thousands, except share and per share data) (Unaudited)		
	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash	\$ 77,450	\$ 71,791
Accounts receivable	870	1,464
Prepaid expenses	4,350	7,161
Other current assets	1,475	1,201
Research and development tax credit receivable	15,290	15,695
Total current assets	99,435	97,312
Non-current assets:		
Research and development tax credit receivable	1,655	—
Property and equipment, net	965	694
Right-of-use assets	2,432	2,790
Goodwill	1,953	2,009
Intangible assets, net	9,866	10,399
Other assets	166	170
Total assets	\$ 116,472	\$ 113,374
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 6,959	\$ 4,374
Accrued expenses	7,569	7,197
Accrued compensation	1,514	4,125
Lease liabilities	907	1,091
Deferred revenue and other income	5,097	7,939
Other current liabilities	678	897
Total current liabilities	22,724	25,623
Non-current liabilities:		
Lease liabilities, net of current portion	1,535	1,691
Other non-current liabilities	2,751	2,776
Promissory note payable to a related party	25,055	—
Total liabilities	52,065	30,090
Commitments and contingencies (Note 14)		
Stockholders' equity:		
Common stock, \$0.01 par value: 250,000,000 shares authorized; 98,122,356 and 98,039,540 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	981	980
Additional paid-in capital	388,328	384,049
Accumulated other comprehensive loss	(3,957)	(2,197)
Accumulated deficit	(320,945)	(299,548)
Total stockholders' equity	64,407	83,284
Total liabilities and stockholders' equity	\$ 116,472	\$ 113,374

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements.

Summit Therapeutics Inc.
Condensed Consolidated Statements of Comprehensive Loss
(in thousands, except share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2022	2021
Revenue	\$ 250	\$ 192
Operating expenses:		
Research and development	20,556	18,379
General and administrative	6,659	4,185
Total operating expenses	27,215	22,564
Other operating income	4,807	5,449
Operating loss	(22,158)	(16,923)
Other income (expense), net	761	(565)
Net loss	<u>\$ (21,397)</u>	<u>\$ (17,488)</u>
Net loss per share:		
Basic and diluted	\$ (0.22)	\$ (0.21)
Weighted-average shares used to compute net loss per share:		
Basic and diluted	98,070,095	82,817,836
Comprehensive loss:		
Net loss	\$ (21,397)	\$ (17,488)
Other comprehensive (loss) income:		
Foreign currency translation adjustments	(1,760)	675
Comprehensive loss	<u>\$ (23,157)</u>	<u>\$ (16,813)</u>

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements.

Summit Therapeutics Inc.
Condensed Consolidated Statements of Stockholders' Equity
(in thousands, except share data)
(Unaudited)

	Three Months Ended March 31, 2022					
	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2021	98,039,540	\$ 980	384,049	\$ (2,197)	\$ (299,548)	\$ 83,284
Issuance of shares under stock purchase and award plans	82,816	1	186	—	—	187
Stock-based compensation	—	—	3,996	—	—	3,996
Promissory note payable to related party - imputed interest (see Note 11)	—	—	97	—	—	97
Foreign currency translation adjustment	—	—	—	(1,760)	—	(1,760)
Net loss	—	—	—	—	(21,397)	(21,397)
Balance at March 31, 2022	98,122,356	\$ 981	\$ 388,328	\$ (3,957)	\$ (320,945)	\$ 64,407

	Three Months Ended March 31, 2021					
	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2020	82,575,064	\$ 826	\$ 293,367	\$ (3,794)	\$ (210,946)	\$ 79,453
Issuance of common stock from exercise of stock options	344,458	3	894	—	—	897
Stock-based compensation	—	—	868	—	—	868
Foreign currency translation adjustment	—	—	—	675	—	675
Net loss	—	—	—	—	(17,488)	(17,488)
Balance at March 31, 2021	82,919,522	\$ 829	\$ 295,129	\$ (3,119)	\$ (228,434)	\$ 64,405

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements.

Summit Therapeutics Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands)
(Unaudited)

	Three Months Ended March 31,	
	2022	2021
Cash flows used in operating activities:		
Net loss	\$ (21,397)	\$ (17,488)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash interest expense	198	103
Unrealized foreign exchange loss (gain)	1,037	(1,719)
Amortization of operating right-of-use assets	298	152
Depreciation	69	80
Amortization of intangible assets	248	255
Stock-based compensation	3,996	868
Change in operating assets and liabilities:		
Accounts receivable	455	(114)
Prepaid expenses	2,682	1,638
Other current assets	(370)	549
Research and development tax credit receivable	(1,666)	(3,661)
Deferred revenue and other income	(2,658)	(1,200)
Accounts payable	2,759	(2,082)
Accrued liabilities	(832)	1,961
Accrued compensation	(3,523)	141
Operating lease liabilities	(297)	(152)
Net cash used in operating activities	(19,001)	(20,669)
Cash flows used in investing activities:		
Purchases of property and equipment	(361)	(39)
Net cash used in investing activities	(361)	(39)
Cash flows provided by financing activities:		
Proceeds from related party promissory note	25,000	55,000
Proceeds received related to employee stock awards	187	897
Net cash provided by financing activities	25,187	55,897
Effect of exchange rate changes on cash	(166)	588
Increase in cash	5,659	35,777
Cash at beginning of the period	71,791	66,417
Cash at end of the period	\$ 77,450	\$ 102,194

	Three Months Ended March 31,	
	2022	2021
Supplemental Disclosure of Cash Flow Information:		
Promissory note issuance costs in accrued expenses	\$ —	\$ 38
Lease assets obtained in exchange for operating lease liabilities	\$ —	\$ 1,085

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements.

1. Nature of the Business and Operations and Recent Events

Nature of Business and Operations

The terms "Summit" and the "Company" refer to Summit Therapeutics Inc. and its subsidiaries. The Company is a biopharmaceutical company focused on the discovery, development, and commercialization of patient-, physician-, caregiver- and societal-friendly medicinal therapies intended to improve quality of life, increase life expectancy, and resolve serious unmet needs. The Company's novel mechanism pipeline of product candidates is designed with the goal to become the patient-friendly, new-era standard-of-care medicines. The Company's lead product candidate, ridinilazole, is a novel first-in-class drug that is engaged in a global Phase III clinical trial program. On December 20, 2021, the Company announced topline results for the Phase III Ri-CoDIFy study evaluating ridinilazole for treating patients suffering from *Clostridioides difficile* infection, also known as *C. difficile* infection, or CDI. The Company's second product candidate, SMT-738, was announced in May 2021 for combating multidrug resistant infections, specifically Carbapenem-resistant Enterobacteriaceae (“CRE”) infections. SMT-738 is the first of a novel class of precision antibiotics that has entered into preclinical development. The Company intends to expand its portfolio by developing further new mechanism, new era product offerings in the therapeutic areas of oncology and infectious diseases and/or product offerings that are designed to work in harmony with the human gut microbiome.

Recent Events

On May 12, 2021, the Company closed its rights offering, which was fully subscribed. The Company received aggregate gross proceeds from the rights offering of \$75,000 from the sale of 14,312,976 shares of its common stock at a price per share of \$5.24. Issuance costs associated with the rights offering were immaterial. In connection with the closing of the rights offering, a promissory note dated April 20, 2021, that was outstanding and had been issued by the Company in favor of the Company's Chairman, Chief Executive Officer, and the beneficial owner of approximately 70% of its outstanding common stock prior to this rights offering, Robert W. Duggan, in the principal amount of \$55,000, matured and became due and the Company repaid all principal and accrued interest thereunder using a portion of the proceeds from the rights offering.

On August 11, 2021, based on a thorough review of the design and enrollment status of its two ongoing blinded Phase III Ri-CoDIFy trials, the Company announced that it combined its two blinded pivotal Phase III clinical trials evaluating ridinilazole versus vancomycin into a single study and presented this decision to the United States ("U.S.") Food and Drug Administration (the "FDA") as such. During September 2021, the Company received feedback from the FDA that the FDA did not agree with the change to the primary endpoint that the Company proposed and subsequently implemented in its then ongoing Phase III Ri-CoDIFy studies when combining the trials.

On December 20, 2021, the Company announced topline results for the Phase III Ri-CoDIFy study evaluating ridinilazole, for the treatment of and Sustained Clinical Response (“SCR”), as defined below, for patients suffering from *C. difficile* infection ("C. diff. infection" or "CDI"). The study showed that ridinilazole resulted in a numerically higher SCR rate than vancomycin, but did not meet the study’s primary endpoint for superiority. The pivotal Phase III clinical trial consisted of two Phase III clinical trials combined into a single study, designed to assess, as the primary endpoint, the superiority of ridinilazole compared to vancomycin in SCR, which is defined as clinical response of the treated episode of CDI and no recurrence of CDI through 30 days after the end of treatment. Additional endpoints included safety, tolerability, analyses of the gut microbiome and metabolome, in addition to quality of life and health economic outcome measures. We are in the process of evaluating the future path forward with respect to ridinilazole, including potential partnership opportunities.

On March 10, 2022, Mr. Robert W. Duggan, entered into a Note Purchase Agreement (the “2022 Note”), pursuant to which he has loaned the Company \$25,000 in exchange for the issuance by the Company of an unsecured promissory note in the amount of \$25,000. The 2022 Note accrues interest at a rate per annum equal to the prime rate as reported in the *Wall Street Journal*, which was 3.25% as of the effective date and 3.5% as of March 31, 2022.. The 2022 Note becomes due upon the earlier of (i) the consummation of a registered public offering with net proceeds of no less than \$25,000 or (ii) 18 months from the date of issuance of the 2022 Note.

2. Basis of Presentation and Use of Estimates

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") and pursuant to the rules and regulations of the U.S. Securities and Exchange Commission. Accordingly, certain information and disclosures required by U.S. GAAP for complete consolidated financial statements are not included herein. All intercompany accounts and transactions have been eliminated in consolidation. The interim financial data as of March 31, 2022, and for the three months ended March 31, 2022 are unaudited; however, in the opinion of management, the interim data includes all adjustments, consisting of normal recurring adjustments, necessary for a fair statement of the results for the interim periods. The condensed consolidated balance sheet presented at December 31, 2021 has been derived from the consolidated audited financial statement as of that date. The results of the period are not necessarily indicative of full year results or any other interim period. These unaudited interim condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto of the Company which are included in the Summit Annual Report on Form 10-K for the year ended December 31, 2021 filed with the Securities and Exchange Commission on March 17, 2022. The financial results of the Company's activities are reported in United States Dollars.

The progression of the COVID-19 pandemic continues to evolve and its enduring impact on the Company's business remains uncertain. Management believes the estimates and assumptions underlying its unaudited interim financial statements are reasonable and supportable based on the information available as of March 31, 2022, however, the extent to which the COVID-19 pandemic impacts the Company's financial results for the remainder of 2022 and beyond will depend on future developments that are highly uncertain and cannot be predicted at this time.

Use of Estimates

The preparation of these unaudited condensed consolidated financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent liabilities at the date of the unaudited condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. On an on-going basis, management evaluates its estimates and judgments, including those related to revenue recognition, accrued research and development expenses, stock-based compensation, intangible assets, goodwill, other long-lived assets and income taxes. Management bases its estimates and judgments on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

3. Recently Issued or Adopted Accounting Pronouncements

In November 2021, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2021-10, "Government Assistance (Topic 832)." This ASU increases the transparency of government assistance including the disclosure of (1) the types of assistance, (2) an entity's accounting for the assistance, and (3) the effect of the assistance on an entity's financial statements as diversity currently exists in the recognition, measurement, presentation and disclosure of government assistance received by business entities because of the lack of specific authoritative guidance in U.S. GAAP. This ASU is effective for annual periods, and interim periods within those fiscal years, beginning after December 15, 2021. Early application of this ASU is permitted. The Company adopted and applied the amendments of this ASU to its disclosures during the fourth quarter of 2021 and the application of this ASU did not have a material impact on its financial position, results of operations or cash flows.

In October 2021, the FASB issued ASU No. 2021-08, "Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers." This ASU improves the accounting for acquired revenue contracts with customers in a business combination by addressing diversity in practice and inconsistency relating to: 1) recognition of an acquired contract liability and 2) payment terms and their effect on subsequent revenue recognized by the acquirer. The amendments in this ASU require acquiring entities to apply Topic 606 to recognize and measure contract assets and contract liabilities in a business combination, whereas current U.S. GAAP requires that the acquirer measure such assets and liabilities

Summit Therapeutics Inc.
Notes to Unaudited Condensed Consolidated Financial Statements
(in thousands, except share and per share data)

at fair value on the acquisition date. This ASU is effective for annual periods, and interim periods within those fiscal years, beginning after December 15, 2022. The Company will apply this ASU on a prospective basis for business combinations once this ASU is effective and at that time will be able to determine the potential impact on its financial position, results of operations or cash flows.

In May 2021, the FASB issued AS No. 2021-04, "Earnings Per Share (Topic 260), Debt - Modifications and Extinguishments (Subtopic 470-50), Compensation - Stock Compensation (Topic 718), and Derivatives and Hedging Contracts in Entity's Own Equity (Subtopic 815-40) - Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options." This ASU provides clarification and reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (such as warrants) that remain equity classified after modification or exchange. This ASU is effective for annual periods, and interim periods within those fiscal years, beginning after December 15, 2021. The Company adopted this ASU during the first quarter of 2022 and the adoption of this ASU did not have a material impact on its financial position, results of operations or cash flows.

4. Liquidity and Capital Resources

During the three months ended March 31, 2022, the Company incurred a net loss of \$21,397 and cash flows used in operating activities was \$19,001. As of March 31, 2022, the Company had an accumulated deficit of \$320,945, cash of \$77,450, short-term research and development tax credits of \$15,290 and accounts receivable of \$870. The Company expects to continue to generate operating losses for the foreseeable future. Until the Company can generate substantial revenue and achieve profitability, the Company will need to raise additional capital to fund its ongoing operations and capital needs.

Based on the Company's current funding arrangements and financial resources as of March 31, 2022, the Company has the ability to fund its operating costs and working capital needs for more than twelve months from the date of issuance of this quarterly report on Form 10-Q. In order to continue to fund the operations of the Company beyond this time period, management has developed plans, which primarily consist of raising additional capital through some combination of equity or debt financings, and/or potentially entering into new collaborations. There is no assurance, however, that additional financing will be available when needed or that management of the Company will be able to obtain financing on terms acceptable to the Company. If the Company is unable to obtain funding when required in the future, the Company could be required to delay, reduce, or eliminate research and development programs, product portfolio expansion, or future commercialization efforts, which could adversely affect its business prospects.

The accompanying consolidated financial statements are prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of the business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classifications of liabilities that might result from the outcome of this uncertainty.

5. Segment Reporting

The Company's chief operating decision makers (the "CODM function"), which are the Company's Chief Executive Officer and Chief Operating Officer, utilize financial information to make decisions about allocating resources and assessing performance for the entire Company. The CODM function approves of key operating and strategic decisions, including key decisions in clinical development and clinical operating activities, entering into significant contracts, such as revenue contracts and collaboration agreements and approves the Company's consolidated operating budget. The CODM function views the Company's operations and manages its business as a single reportable operating segment. The Company's single reportable operating segment covers the Company's research and development activities, primarily comprising of the CDI program and antibiotic pipeline research activities. As the Company operates as one operating segment, all required financial segment information can be found in the condensed consolidated financial statements.

The Company operates in two geographic regions: the U.K. and the U.S. The following table summarizes the Company's long-lived assets, which include the Company's property and equipment, net and right-of-use assets by geography:

	March 31, 2022	December 31, 2021
United Kingdom	\$ 2,871	\$ 2,762
United States	526	722
	<u>\$ 3,397</u>	<u>\$ 3,484</u>

For details of revenue from external customers by geography refer to Note 6.

6. Revenue

The following table summarizes revenue by category:

	Three Months Ended March 31,	
	2022	2021
Revenue by category:		
Licensing agreements	\$ 250	\$ 192
	<u>\$ 250</u>	<u>\$ 192</u>

Revenue recognized in the period consists only of amounts received from the license and commercialization agreement with Eurofarma Laboratórios S.A.

The following table summarizes revenue by geography:

	Three Months Ended March 31,	
	2022	2021
Revenue by geography:		
Latin America	\$ 250	\$ 192
	<u>\$ 250</u>	<u>\$ 192</u>

The analysis of revenue by geography has been identified on the basis of the customer’s geographical location.

The following table summarizes the deferred revenue relating to Eurofarma Laboratórios S.A. and deferred other income relating to BARDA (as defined in Note 7), respectively:

	2022	2021
Beginning deferred revenue and other income, January 1 ⁽¹⁾	\$ 7,939	\$ 8,939
Additions	255	761
Amount of deferred revenue and other income recognized in the statement of operations	(2,884)	(1,980)
Foreign currency adjustments	(213)	86
Ending deferred revenue and other income, March 31 ⁽²⁾	<u>\$ 5,097</u>	<u>\$ 7,806</u>

(1) Beginning deferred revenue and other income as of January 1, 2022 and 2021 included \$7,939 of current and \$0 of long-term deferred revenue and other income, and \$8,370 of current and \$569 of long-term deferred revenue and other income, respectively.
(2) Ending deferred revenue and other income as of March 31, 2022 and 2021 included \$5,097 of current and \$0 of long-term deferred revenue and other income. and \$7,423 of current and \$383 of long-term deferred revenue and other income, respectively.

As of March 31, 2022, deferred revenue is comprised of \$490 and \$4,607 relating to Eurofarma and BARDA (as defined in Note 7), respectively. As of January 1, 2022, deferred revenue is comprised of \$756 and \$7,183 relating to Eurofarma and BARDA, respectively.

Refer to Note 7 below for further details regarding other income recognized under the BARDA contract.

Eurofarma Laboratórios S.A.

On December 21, 2017, Summit announced it had entered into an exclusive license and commercialization agreement with Eurofarma Laboratórios S.A. ("Eurofarma"), pursuant to which the Company granted Eurofarma the exclusive right to commercialize ridinilazole in specified countries in South America, Central America and the Caribbean. The Company has retained commercialization rights in the rest of the world.

Under the terms of the license and commercialization agreement with Eurofarma, the Company received an upfront payment of \$2,500 from Eurofarma in December 2017. In February 2020, the Company reached the first enrollment milestone and earned \$1,000. In September 2021, the Company reached the second enrollment milestone and earned \$1,250. The terms of the contract have been assessed under Accounting Standards Codification 606 and currently only the upfront payment and the first two enrollment milestone payments are included in the transaction price. These payments are initially recorded as deferred revenue in the balance sheet and are recognized as revenue ratably over the performance period.

Revenue recognized during the three months ended March 31, 2022 related to the upfront payment and the first two enrollment milestones earned in accordance with the Company's revenue recognition policy. Revenue recognized during the three months ended March 31, 2021 related to the upfront payment and the first enrollment milestone earned in accordance with the Company's revenue recognition policy. The revenue is being recognized ratably over the performance period to reflect the transfer of control to the customer occurring over the time period that the research and development services are provided by the Company. This output method is, in management’s judgment, the best measure of progress towards satisfying the performance obligation. As of March 31, 2022 and December 31, 2021, the current contract liability relating to the Eurofarma contract was \$490 and \$756, respectively, and was recorded in current deferred revenue in the condensed consolidated balance sheet.

In addition, the Company could receive an additional \$1,500 in development milestones upon the achievement of staged patient enrollment targets in the licensed territory in the combined Phase III clinical trial of ridinilazole. The Company is eligible to receive a further \$1,000 in development milestones, \$2,400 in commercial milestones and up to \$18,000 in sales milestones when cumulative net sales equal or exceed \$100,000 in the Eurofarma licensed territory. Each subsequent achievement of an additional \$100,000 in cumulative net sales will result in the Company receiving additional milestone payments, which, when combined with anticipated product supply transfer payments from Eurofarma paid to the Company in connection with a commercial supply agreement to be entered into between the two parties, will provide payments estimated to range from a mid-teens to high-teens percentage of cumulative net sales in the Eurofarma licensed territory. The Company estimates such product supply transfer payments from Eurofarma will range from a high single-digit to low double-digit percentage of cumulative net sales in the licensed territory.

7. Other Operating Income

The following table sets forth the components of other operating income by category:

Other operating income by category:	Three Months Ended March 31,	
	2022	2021
Funding income from BARDA (as defined below)	\$ 2,634	\$ 1,770
Research and development tax credits	1,696	3,679
Grant income from CARB-X (as defined below)	477	—
	<u>\$ 4,807</u>	<u>\$ 5,449</u>

BARDA (as defined below)

In September 2017, the Company was awarded a funding contract from the Biomedical Advanced Research and Development Authority ("BARDA"), part of the Office of the Assistant Secretary for Preparedness and Response at the United States Department of Health and Human Services, in support of the Company's Ri-CoDIFy clinical trials and clinical development of of ridinilazole.

The awarded contract was originally worth up to \$62,000. In June 2019 and again in January 2020, BARDA increased the value of the contract such that it is now worth up to \$72,500 and brought the total amount of committed funding to \$62,400.

The remaining federal government funding was dependent on BARDA in its sole discretion exercising the final independent option work segment, upon the achievement by the Company of certain agreed-upon milestones for ridinilazole. This option work segment was never exercised by BARDA. The contract ran through April 2022 and was extended through December 2022 as a no cost contract, solely to close out open activities. As of March 31, 2022, an aggregate of \$57,946 of the total committed BARDA funding had been received and the Company has recognized \$52,796 of cumulative income since contract inception.

Research and development tax credits

Income from research and development ("R&D") tax credits, consists of R&D tax credits received in the U.K. The Company benefits from two U.K. R&D tax credit cash rebate regimes: Small and Medium Enterprise Program ("SME Program") and the Research and Development Expenditure Credit Program ("RDEC Program"). Qualifying expenditures largely comprise employment costs for research staff, consumables, a proportion of relevant, permitted sub-contract costs and certain internal overhead costs incurred as part of research projects for which the Company does not receive income. Tax credits related to the SME Program and RDEC Program are recorded as other operating income in the condensed consolidated statements of comprehensive loss. Under both schemes, the Company receives cash payments that are not dependent on the Company's pre-tax net income levels.

Based on criteria established by Her Majesty's Revenue and Customs, a portion of expenditures being carried out in relation to the Company's pipeline research and development activities are eligible for the SME regime.

As of March 31, 2022, the current and non-current research and development tax credit receivable was \$15,290 and \$1,655, respectively. As of December 31, 2021, the current and non-current research and development tax credit receivable was \$15,695 and \$0, respectively.

CARB-X (as defined below)

In May 2021, the Company announced the selection of a new preclinical candidate, SMT-738, from the DDS-04 series for development in the fight against multidrug resistant infections, specifically carbapenem-resistant Enterobacteriaceae ("CRE") infections. Simultaneously, the Company announced it had received an award from the Trustees of Boston University under the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator program ("CARB-X") to progress this candidate through preclinical development and Phase 1a clinical trials. The award commits initial funding of up to \$4,100, with the possibility of up to another \$3,700 based on the achievement of future milestones. As of March 31, 2022, \$937 of grant funding from CARB-X has been received, \$141 is in accounts receivable for amounts billed, \$555 is unbilled and included in other current assets as a contract asset and the Company has recognized \$1,633 of cumulative income since contract inception.

8. Loss per Share

The following table sets forth the computation of basic and diluted net loss per share:

	Three Months Ended March 31,	
	2022	2021
Net loss	\$ (21,397)	\$ (17,488)
Basic weighted average number of shares of common stock outstanding	98,070,095	82,817,836
Diluted weighted average number of shares of common stock outstanding	98,070,095	82,817,836
Basic net loss per share	\$ (0.22)	\$ (0.21)
Diluted net loss per share	\$ (0.22)	\$ (0.21)

Basic net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing the diluted net loss by the weighted-average number of common shares outstanding for the period, including potentially dilutive common shares. Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share for all periods as the inclusion of all potential common share equivalents outstanding would have been anti-dilutive.

The following potentially dilutive securities were excluded from the computation of the diluted net loss per share of common stock for the periods presented because their effect would have been anti-dilutive:

	As of March 31,	
	2022	2021
Options to purchase common stock	13,142,069	5,539,803
Warrants	5,821,137	5,821,137
Shares expected to be purchased under employee stock purchase plan	134,440	—
	<u>19,097,646</u>	<u>11,360,940</u>

9. Goodwill and Intangible Assets

Goodwill is measured as the excess of the cost of the acquisition over the sum of the amounts assigned to tangible and identifiable intangible assets acquired less liabilities assumed. The Company assigns assets acquired (including goodwill) and liabilities assumed to one or more reporting units as of the date of acquisition. Typically acquisitions related to a single reporting unit do not require the allocation of goodwill to multiple reporting units. If the products obtained in an acquisition are assigned to multiple reporting units, the goodwill is distributed to the respective reporting units as part of the purchase price allocation process.

Goodwill and purchased intangible assets are reviewed for impairment annually during the fourth quarter of each fiscal year and whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. The process of evaluating the potential impairment of goodwill and intangible assets requires significant judgment. The Company regularly monitors current business conditions and other factors including, but not limited to, adverse industry or economic trends and lower projections of profitability that may impact future operating results.

As of March 31, 2022 and December 31, 2021, goodwill was \$1,953 and \$2,009, respectively. Changes in goodwill during the three months ended March 31, 2022 are the result of foreign currency movements. There were no goodwill impairment

charges recognized for the quarter ended March 31, 2022 and there have been no cumulative goodwill impairment charges recognized to date. Intangible assets, net of accumulated amortization, impairment charges and adjustments are summarized as follows:

	March 31, 2022			December 31, 2021		
	Gross carrying amount	Accumulated amortization and impairment	Net	Gross carrying amount	Accumulated amortization and impairment	Net
Utrophin program acquired	\$ 4,362	\$ (4,362)	\$ —	\$ 4,487	\$ (4,487)	\$ —
Discuva platform acquired	14,014	(4,148)	9,866	14,416	(4,017)	10,399
Option over non-financial asset	887	(887)	—	912	(912)	—
Other patents and licenses	144	(144)	—	148	(148)	—
	<u>\$ 19,407</u>	<u>\$ (9,541)</u>	<u>\$ 9,866</u>	<u>\$ 19,963</u>	<u>\$ (9,564)</u>	<u>\$ 10,399</u>

Changes in the gross carrying amount of intangible assets during the three months ended March 31, 2022 was the result of foreign currency movements. For the three months ended March 31, 2022 and 2021, amortization expense was \$248 and \$255, respectively.

10. Leases

The Company has operating leases for real estate. The Company does not have any finance leases.

During the three months ended March 31, 2021, the Company recorded \$1,085 of additional right-of-use assets related to a new lease that commenced during the period for its Menlo Park, California, U.S. location. There were no new right-of-use assets recorded during the three months ended March 31, 2022. The carrying value of the right-of-use assets as of March 31, 2022 and December 31, 2021 was \$2,432 and \$2,790, respectively.

Fixed lease costs for the three months ended March 31, 2022 and 2021 were \$212 and \$139, respectively. Short-term lease costs and variable lease costs for each of the three month periods ended March 31, 2022 and 2021 were immaterial.

The weighted average discount rate and the weighted average remaining lease term were 2.7% and 4.1 years, respectively, as of March 31, 2022. The weighted average discount rate and the weighted average remaining lease term were 1.7% and 2.1 years, respectively, as of March 31, 2021.

11. Promissory Note Payable to a Related Party

On March 10, 2022, Mr. Robert W. Duggan, entered into a Note Purchase Agreement (the “2022 Note”), pursuant to which he has loaned the Company \$25,000 in exchange for the issuance by the Company of an unsecured promissory note in the amount of \$25,000. The 2022 Note accrues interest at a rate per annum equal to the prime rate as reported in the *Wall Street Journal*, which was 3.25% as of the effective date and 3.50% as of March 31, 2022. The 2022 Note, including all accrued interest, becomes due upon the earlier of (i) the consummation of a registered public offering with net proceeds of no less than \$25,000 or (ii) 18 months from the date of issuance of the 2022 Note. Debt issuance costs associated with the 2022 Note were immaterial and expensed as incurred.

The balance of the promissory note was \$25,055 and includes \$55 of accrued interest as of March 31, 2022. Interest expense incurred by the Company for the three months ended March 31, 2022 and 2021 was \$152 and \$27, respectively. The Company recorded \$97 of imputed interest on the 2022 Note to additional paid in capital for the difference between the stated rate of the note and the deemed market rate of interest. The interest incurred for the three months ended March 31, 2021 relates to the March 24, 2021 Note Purchase Agreement with Robert W. Duggan, for \$55,000 which was subsequently rescinded, replaced by a second note of the same amount, and paid in full in May 2021, as described further in Note 13.

12. Stock-Based Compensation and Warrants

The Company currently grants stock options to employees and directors under the 2020 Stock Incentive Plan (the "2020 Plan") and formerly, the Company granted stock options under the 2016 Long Term Incentive Plan (the "2016 Plan"). The 2020 Plan is administered by the Compensation Committee of the Company's Board of Directors. The 2020 Plan is intended to attract and retain employees and directors and provide an incentive for these individuals to assist the Company to achieve long-range performance goals and to enable these individuals to participate in the long-term growth of the Company.

The following table presents the stock option activity for both the 2016 Plan and the 2020 Plan as of March 31, 2022:

	Three Months Ended March 31, 2022	Weighted average exercise price
Outstanding at December 31, 2021	13,797,556	\$ 5.55
Granted	336,381	\$ 2.82
Forfeited	(979,873)	\$ 3.95
Exercised	(11,995)	\$ 1.86
Outstanding at March 31, 2022	13,142,069	\$ 5.61
Exercisable at March 31, 2022	2,135,201	\$ 4.19

The total intrinsic value of all outstanding and exercisable stock options at March 31, 2022 was \$424 and \$312, respectively.

The total stock-based compensation expense included in the Company's condensed consolidated statements of comprehensive loss was as follows:

	Three Months Ended March 31,	
	2022	2021
Research and development	\$ 1,874	\$ 323
General and administrative	2,122	546
Total stock-based compensation expense	\$ 3,996	\$ 869

Warrants

The Company had outstanding and exercisable warrants of 5,821,137 with a weighted average exercise price of \$1.56 as of March 31, 2022 and December 31, 2021.

13. Related Party Transactions

March, 24, 2021 Note Purchase Agreement

On March 24, 2021, Mr. Duggan, the Company's Executive Chairman and Chief Executive Officer and primary stockholder, entered into a Note Purchase Agreement (the “Initial Purchase Agreement”) pursuant to which he loaned the Company \$55,000 in exchange for the issuance by the Company of an unsecured promissory note (the “Initial Note”) in the amount of \$55,000. The Initial Note was to accrue interest at a rate per annum equal to 150% of the applicable 10 Year US Treasury rate, as adjusted monthly. The rate was initially estimated to be approximately 2.4%. The terms of the Initial Note were that it would mature and become due upon the earlier of (i) the consummation of a registered public offering with net proceeds of no less than \$55,000, or (ii) 13 months from the date of issuance of the Initial Note. On April 20, 2021, the Company determined, with Mr. Duggan’s agreement, to rescind both the Initial Purchase Agreement and the Initial Note issued thereunder, and repaid the principal amount of the Initial Note in full, without interest or penalty.

March 26, 2021 Sublease Agreement with Dr. Maky Zanganeh and Associates, Inc.

On March 26, 2021, the Company entered into a sublease with Dr. Maky Zanganeh and Associates, Inc. ("MZA") consisting of 4,500 square feet of office space at 2882 Sand Hill Road, Menlo Park, CA (the "Sublease"). Dr. Maky Zanganeh, the Company's Chief Operating Officer, is the sole owner of MZA. The sublease runs until September 2022, The sublease runs until September 2022. The rent payable under the terms of the sublease is equivalent to the proportionate share of the rent payable by MZA to the third-party landlord, based on the square footage of office space sublet by the Company, and no mark-up has been applied. During the three months ended March 31, 2022 and 2021 payments of \$179 and \$29, respectively, were made pursuant to the sublease.

April 20, 2021 Note Purchase Agreement

On April 20, 2021, subsequent to the repayment of the Initial Note, Mr. Duggan entered into a second Note Purchase Agreement (the "Second Purchase Agreement") pursuant to which he loaned the Company \$55,000 in exchange for the issuance by the Company of an unsecured promissory note (the "Second Note") in the amount of \$55,000. The Second Note accrued interest at a rate per annum equal to 150% of the applicable 10 Year US Treasury rate, as adjusted monthly (initially estimated to be approximately 2.4%). The Company was permitted to prepay any portion of the Second Note at its option without penalty.

May 12, 2021 Rights Offering

On May 12, 2021, the Company closed its rights offering, which was fully subscribed. Aggregate gross proceeds from the rights offering of \$75,000 from the sale of 14,312,976 shares of the Company's common stock, of which 11,365,921 shares were purchased by Mr. Robert W. Duggan and 389,977 shares were purchased by Dr. Maky Zanganeh, at price of \$5.24 per share. In connection with the closing of the rights offering, the Second Note, issued by the Company in favor of Mr. Robert W. Duggan, matured and became due and was repaid using a portion of the proceeds from the rights offering.

March 10, 2022 Note Purchase Agreement

On March 10, 2022, the Company entered into a Note Purchase Agreement (the "2022 Note"), with Mr. Duggan, pursuant to which Mr. Duggan loaned the Company \$25,000 in exchange for the issuance by the Company of an unsecured promissory note in the amount of \$25,000. The 2022 Note accrued interest at a rate per annum equal to the prime rate as reported in the *Wall Street Journal*, which was 3.25% as of the effective date and 3.5% as of March 31, 2022. The 2022 Note, including accrued interest, becomes due upon the earlier of (i) the consummation of a registered public offering with net proceeds of no less than \$25,000 or (ii) 18 months from the date of issuance of the 2022 Note.

14. Commitments and Contingencies

Fixed Asset Purchase Commitments

As of March 31, 2022 and December 31, 2021, the Company had no capital commitments.

Lease Commitments

The Company leases office and laboratory space. There have been no material changes to the Company's lease commitments as of December 31, 2021 which were disclosed in the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 17, 2022.

Other Commitments

The Company enters into contracts in the normal course of business with various third parties for clinical trials, preclinical research studies and testing, manufacturing and other services and products for operating purposes. Most contracts provide for termination upon notice, and therefore are cancellable contracts. There have been no material changes to the Company's contractual commitments as of December 31, 2021 which were disclosed in the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 17, 2022.

Indemnifications

The Company has entered into its standard form Indemnification Agreement for directors and executive officers, which was filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 18, 2020, and is incorporated by reference herein. The Indemnification Agreement provides that, subject to the provisions of the Delaware General Corporation Law, the Company is required, among other things, to indemnify its directors or executive officers for certain expenses, including attorneys' fees, judgments, fines, and settlement amounts of the types customarily incurred by them in connection with any action or proceeding arising out of their service as one of the Company's directors or executive officers. The Company believes the fair value for these indemnification obligations is minimal. Accordingly, the Company has not recognized any liabilities relating to these obligations at March 31, 2022 and December 31, 2021.

Legal Proceedings

The Company is not currently subject to any material legal proceedings.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes included herein and our audited consolidated financial statements and related notes for the year ended December 31, 2021 included in our Form 10-K, filed on March 17, 2022. Some of the information contained in this discussion and analysis or set forth elsewhere in this filing, including information with respect to our plans and strategy for our business, includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that involve risks and uncertainties. All statements other than statements relating to historical matters including statements to the effect that we “believe,” “expect,” “anticipate,” “plan,” “target,” “intend” and similar expressions should be considered forward-looking statements. As a result of many factors, including those factors set forth in the risks identified the “Risk Factors” section of our other filings with the Securities and Exchange Commission, or the SEC, our actual results could differ materially from the results, performance or achievements expressed in or implied by these forward-looking statements.

Company Overview

We are a biopharmaceutical company focused on the discovery, development, and commercialization of patient-, physician-, caregiver- and societal-friendly medicinal therapies intended to improve quality of life, increase life expectancy, and resolve serious unmet needs. Our novel mechanism pipeline of product candidates is designed with the goal to become the patient-friendly, new-era standard-of-care medicines. Our lead product candidate, ridinilazole, is a novel first-in-class drug that is engaged in a global Phase III clinical trial program. On December 20, 2021, we announced topline results for the Phase III Ri-CoDIFy study evaluating ridinilazole for treating patients suffering from *Clostridioides difficile* infection, also known as *C. difficile* infection, or CDI. Our second product candidate, SMT-738, was announced in May 2021 for combating multidrug resistant infections, specifically Carbapenem-resistant Enterobacteriaceae (“CRE”) infections. SMT-738 is the first of a novel class of precision antibiotics that has entered into preclinical development. We intend to expand our portfolio by developing further new mechanism, new era product offerings in the therapeutic areas of oncology and infectious diseases and/or product offerings that are designed to work in harmony with the human gut microbiome.

To date, we have financed our operations primarily through issuances of our common stock, payments to us under our license and commercialization agreement with Eurofarma Laboratórios SA, or Eurofarma, development funding and other assistance from government entities, philanthropic, non-government and not-for-profit organizations for our product candidates and promissory notes from related parties. In particular, we have received funding from BARDA, CARB-X, Innovate UK, Wellcome Trust and a number of not-for-profit organizations.

We have devoted substantially all of our efforts to research and development, including clinical trials. We have not completed the development of any drugs. We expect to continue to incur significant expenses and increasing operating losses for at least the next few years. The net losses we incur may fluctuate significantly from quarter to quarter and year to year, due to the nature and timing of our research and development activities. We expect that our research and development and general and administrative expenses will continue to be significant in connection with our ongoing research and development efforts. In addition, if we obtain marketing approval of ridinilazole in the U.S. or other jurisdictions where we retain commercial rights, and if we choose to maintain those rights, we would expect to incur significant sales, marketing, distribution and outsourced manufacturing expenses, as well as ongoing research and development expenses.

Recent Events

On May 12, 2021, we closed our rights offering, which was fully subscribed. We received aggregate gross proceeds from the rights offering of \$75 million from the sale of 14,312,976 shares of our common stock at a price per share of \$5.24. Issuance costs associated with the rights offering were immaterial. In connection with the closing of the rights offering, we issued a promissory note dated April 20, 2021, in favor of the Company's Chairman, Chief Executive Officer, and the beneficial owner of approximately 70% of our outstanding common stock prior to this rights offering, Robert W. Duggan, in the principal amount of \$55 million, which matured and became due and we repaid all principal and accrued interest thereunder using a portion of the proceeds from the rights offering.

On August 11, 2021, based on a thorough review of the design and enrollment status of its two ongoing blinded Phase III Ri-CoDIFy trials, we announced that we combined our two blinded pivotal Phase III clinical trials evaluating ridinilazole versus vancomycin into a single study and presented this decision to the United States ("U.S.") Food and Drug Administration (the

"FDA") as such. During September 2021, we received feedback from the FDA that the FDA did not agree with the change to the primary endpoint that we proposed and subsequently implemented in our then ongoing Phase III Ri-CoDIFy studies when combining the trials.

On December 20, 2021, we announced topline results for the Phase III Ri-CoDIFy study evaluating ridinilazole, for the treatment of and Sustained Clinical Response (“SCR”), as defined below, for patients suffering from *C. difficile* infection ("C. diff. infection" or "CDI"). The study showed that ridinilazole resulted in a numerically higher SCR rate than vancomycin, but did not meet the study’s primary endpoint for superiority. The pivotal Phase III clinical trial consisted of two Phase III clinical trials combined into a single study, designed to assess, as the primary endpoint, the superiority of ridinilazole compared to vancomycin in SCR, which is defined as clinical response of the treated episode of CDI and no recurrence of CDI through 30 days after the end of treatment. Additional endpoints included safety, tolerability, analyses of the gut microbiome and metabolome, in addition to quality of life and health economic outcome measures. We are in the process of evaluating the future path forward with respect to ridinilazole, including potential partnership opportunities.

On March 10, 2022, Mr. Robert W. Duggan, entered into a Note Purchase Agreement (the “2022 Note”), pursuant to which he has loaned us \$25 million in exchange for the issuance of an unsecured promissory note in the amount of \$25 million. The 2022 Note accrues interest at a rate per annum equal to the prime rate as reported in the *Wall Street Journal*, which was 3.25% as of the effective date of the 2022 Note, and currently 3.5% as of March 31, 2022. The 2022 Note becomes due upon the earlier of (i) the consummation of a registered public offering with net proceeds of no less than \$25 million or (ii) 18 months from the date of issuance of the 2022 Note.

COVID-19 Pandemic

The progression of the COVID-19 pandemic continues to evolve and its enduring impact on our business remains uncertain. There may be other material adverse impacts on our business, operations and financial condition that are unpredictable at this time, including delays in the development and regulatory approval of our product candidates and difficulties in retaining qualified personnel during the pandemic and once it subsides. The extent to which the pandemic may impact our business will depend on future developments, such as the duration of the pandemic, quarantines, travel restrictions and other measures in the United States, the United Kingdom and around the world, business closures or business disruptions and the effectiveness of actions taken to contain the pandemic.

Results of Operations

Comparison of the three months ended March 31, 2022 to the three months ended March 31, 2021

(in millions)	Three Months Ended March 31,		Change March 31, 2022 vs. March 31, 2021
	2022	2021	Increase/(Decrease)
Revenue	\$ 0.3	\$ 0.2	\$ 0.1
Operating expenses:			
Research and development	20.6	18.4	2.2
General and administrative	6.7	4.2	2.5
Total operating expenses	27.3	22.6	4.7
Other operating income	4.8	5.4	(0.6)
Operating loss	(22.2)	(17.0)	(5.2)
Other income (expense), net	0.8	(0.6)	1.4
Net loss	<u>\$ (21.4)</u>	<u>\$ (17.6)</u>	<u>\$ (3.8)</u>

Revenue

Revenue increased by \$0.1 million for the three months ended March 31, 2022, compared to the same period in the prior year. Revenue for the three months ended March 31, 2022 and 2021 relates to revenue from our license and commercialization agreement with Eurofarma. The increase is primarily attributed to the recognition of revenues relating to the achievement of the second enrollment milestone of \$1.25 million in September of 2021. This revenue is recognized ratably over the performance period the research and development services are provided. Note for the three months ended March 31, 2022, the revenues recognized related to the upfront milestone and the first enrollment milestone only.

Operating Expenses

Research and Development Expenses

The table below summarizes our research and development expenses by category for the three months ended March 31, 2022 and 2021. Our CDI program expenses and antibiotic pipeline development activities include costs paid to contract research organizations, manufacturing costs for our clinical trials, laboratory testing costs and research related expenses. Other research and development costs include staff and travel costs primarily for our CDI and antibiotic development teams, research and development related legal costs, patent registration fees, an allocation of facility-related costs and other non-core program related expenses.

(in millions)	Three Months Ended March 31,		Change March 31, 2022 vs. March 31, 2021
	2022	2021	Increase/(Decrease)
CDI program	\$ 11.6	\$ 13.0	\$ (1.4)
Antibiotic pipeline research and development costs	0.9	0.2	0.7
Other research and development costs	<u>\$ 8.1</u>	<u>\$ 5.2</u>	<u>\$ 2.9</u>
Total	<u>\$ 20.6</u>	<u>\$ 18.4</u>	<u>\$ 2.2</u>

Investment in our CDI program decreased by \$1.4 million for the three months ended March 31, 2022, compared to the same period in the prior year, primarily due to the lack of actively enrolling pivotal trials associated with the ridinilazole Phase III clinical program.

Investment in our antibiotic pipeline development activities was \$0.9 million for the three months ended March 31, 2022, which reflects costs associated with the development of our preclinical candidate, SMT-738, from the DDS-04 series for development in the fight against multidrug resistant infections, specifically carbapenem-resistant Enterobacteriaceae ("CRE")

infections. Investment in our antibiotic pipeline development activities was \$0.2 million for the three months ended March 31, 2021, which reflects early development costs associated with SMT-738.

Other research and development costs are comprised of the following:

(in millions)	Three Months Ended March 31,		Change March 31, 2022 vs. March 31, 2021
	2022	2021	Increase/(Decrease)
Compensation related costs, excluding stock-based compensation	\$ 5.0	\$ 4.1	\$ 0.9
Stock-based compensation	1.9	0.3	1.6
Other research and development costs	1.2	0.8	0.4
Total	<u>\$ 8.1</u>	<u>\$ 5.2</u>	<u>\$ 2.9</u>

Other research and development costs increased by \$2.9 million for the three months ended March 31, 2022, compared to the same period in the prior year, due primarily to an increase of \$0.9 million in compensation related costs and an increase of \$1.6 million in stock-based compensation as a result of an increase in headcount.

General and Administrative Expenses

(in millions)	Three Months Ended March 31,		Change March 31, 2022 vs. March 31, 2021
	2022	2021	Increase/(Decrease)
Compensation related costs, excluding stock-based compensation	2.6	\$ 2.1	\$ 0.5
Stock-based compensation	2.0	0.5	1.5
Legal and Professional Fees	1.0	0.6	0.4
Other general and administrative expenses	1.1	1.0	0.1
Total	<u>\$ 6.7</u>	<u>\$ 4.2</u>	<u>\$ 2.5</u>

General and administrative expenses were \$6.7 million and \$4.2 million for the three months ended March 31, 2022 and 2021, respectively.

General and administrative expenses increased by \$2.5 million, compared to the same period in the prior year, primarily due to an increase of \$1.5 million in stock-based compensation due to an increase in headcount.

Other Operating Income

Other operating income was \$4.7 million and \$5.4 million for the three months ended March 31, 2022 and 2021, respectively.

The decrease in other operating income of \$0.7 million for the three months ended March 31, 2022, compared to the same period in the prior year is attributed to a decrease of \$2.0 million related to U.K. research and development tax credits for research and development expenses incurred that are not funded by third parties, offset by an increase of \$0.8 million in funding income from BARDA in support of our Ri-CoDiFy clinical trials and regulatory development of ridinilazole and an increase of \$0.5 million in grant income received from CARB-X to progress the preclinical candidate SMT-738 from the DDS-04 series for development in the fight against multidrug resistant infections.

Other Income (Expense), net

Other income (expense), net was \$0.8 million and (\$0.6) million for the three months ended March 31, 2022 and 2021, respectively, was primarily comprised of gains (losses) from fluctuations in foreign currency.

Liquidity and Capital Resources

Sources of Liquidity

To date, we have financed our operations primarily through issuances of our common stock, payments to us under license, collaboration, and commercialization arrangements, for example, our license and commercialization agreement with Eurofarma Laboratórios SA, or Eurofarma, and development funding and other assistance from government entities, philanthropic, non-government and not-for-profit organizations for our product candidates and promissory notes from related parties. In particular, we have received funding from BARDA, CARB-X, Innovate UK, Wellcome Trust and a number of not-for-profit organizations.

Following the issuance of an unsecured promissory note on March 24, 2021 to our CEO, we received net proceeds of \$55.0 million. Such note was later repaid without interest or penalty, rescinded and replaced by a new note on April 20, 2021, pursuant to a second unsecured promissory note we received net proceeds of \$55.0 million. Subsequently, on May 12, 2021, we received proceeds of \$75.0 million in the aggregate from the sale of 14,312,976 shares of Common Stock at a price per share of \$5.24 from our rights offering, the proceeds of which were used in part to repay amounts outstanding on the second unsecured promissory note. On March 10, 2022, we received net proceeds of \$25.0 million from the issuance of an unsecured promissory note (the "2022 Note") to our CEO which becomes due upon the earlier of (i) the consummation of a registered public offering with net proceeds of no less than \$25,000 or (ii) 18 months from the date of issuance of the 2022 Note.

We have devoted substantially all of our efforts to research and development, including clinical trials. We have not completed the development of any drugs. Since our inception, we have incurred significant operating losses. We anticipate that we will continue to incur losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter and year to year, due to the nature and timing of our research and development activities. We expect that our research and development and general and administrative expenses will continue to be significant in connection with our ongoing research and development efforts. In addition, if we obtain marketing approval of ridinilazole in the United States or other jurisdictions where we retain commercial rights, and if we choose to retain those rights, we would expect to incur significant sales, marketing, distribution and outsourced manufacturing expenses, as well as ongoing research and development expenses. In addition, our expenses will increase if and as we:

- continue the research and development of ridinilazole, as well as our early-stage programs targeting infections caused by Enterobacteriaceae;
- seek to identify and develop additional future product candidates, including through our bacterial genetics-based Discuva Platform for the discovery and development of new mechanism antibiotics, and specifically our research activities against a group of bacteria that collectively are known as the ESKAPE pathogens;
- seek marketing approvals for any product candidates that successfully complete clinical development;
- ultimately establish a sales, marketing and distribution infrastructure in jurisdictions where we have retained commercialization rights and scale up external manufacturing capabilities to commercialize any product candidates for which we receive marketing approval;
- acquire or in-license other product candidates and technology;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, regulatory and scientific personnel;
- expand our physical presence; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and potential planned future commercialization efforts.

During the three months ended March 31, 2022, we incurred a net loss of \$21.4 million and cash flows used in operating activities was \$19.0 million. As of March 31, 2022, we had an accumulated deficit of \$320.9 million, cash of \$77.5 million, research and development tax credits of \$16.9 million and accounts receivable of \$0.9 million. We expect to continue to generate operating losses for the foreseeable future. Based on our current funding arrangements and financial resources as of March 31, 2022, the Company has the ability to fund its operating costs and working capital needs into the third quarter of

2023. Until we can generate substantial revenue and achieve profitability, we will need to raise additional capital to fund ongoing operations and capital needs. We will continue to review our data, including performing additional analyses on the microbiome and the relative impacts of ridinilazole and vancomycin in order to submit our data to the FDA. We have also determined that we may seek one or more third-party partnership opportunities for ridinilazole. In addition, we may consider and/or pursue business development opportunities to expand our pipeline of product candidates, including without limitation, potential acquisitions of and/or collaborations with other entities. While these capital resources will allow us to continue to evaluate our next steps, we will need additional capital to prepare for regulatory filings and commercial readiness, consider commencing additional trials, or consider other strategic alternatives with respect to ridinilazole or pursue other business development opportunities. Our failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations and financial condition.

We have based the foregoing estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. This estimate assumes, among other things, that we do not obtain any additional funding through grants and clinical trial support or through new collaboration arrangements. Our future capital requirements will depend on many factors, including:

- the timing and evaluation of the data from our Phase III Ri-CoDIFy clinical trial for our lead product candidate, ridinilazole (formerly SMT19969), the next steps we will take with ridinilazole based upon our review, and the costs associated with these decisions, including completing our review of the data associated with Ri-CoDIFy and any partnerships into which we may enter to continue the advancement of ridinilazole;
- the number and development requirements of other future product candidates that we pursue;
- the costs, timing and outcome of regulatory review of ridinilazole and our other product candidates we develop;
- the costs and timing of commercialization activities, including product sales, marketing, distribution and manufacturing, for any of our product candidates that receive marketing approval;
- subject to receipt of marketing approval, revenue received from commercial sales of ridinilazole or any other product candidates;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against any intellectual property-related claims;
- our contract with BARDA and any future funding from BARDA;
- the amounts we receive from Eurofarma under our license and commercialization agreement, including for the achievement of development, commercialization and sales milestones and for product supply transfers;
- our ability to establish and maintain third-party partnerships or other arrangements and the financial terms of such arrangements;
- the extent to which we acquire or invest in other businesses, products and technologies;
- the rate of the expansion of our physical presence;
- the extent to which we change our physical presence

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of some, or all, of the following: equity and debt offerings, collaborations, strategic alliances, grants and clinical trial support from government entities, philanthropic, non-government and not-for-profit organizations and, marketing, distribution or licensing arrangements. We do not have any committed external source of funds other than amounts we may receive from Eurofarma, BARDA, CARB-X and under our arrangements with them and our research and development tax credits receivable.

Because we expect to reduce the amount of spending on the clinical development of ridinilazole in 2022 as compared to 2021 as our Phase III Ri-CoDIFy clinical trial completed in 2021, we would expect to generate less costs that would be eligible for R&D tax credits in the UK, which may materially reduce the UK R&D tax credits generated in 2022.

We will be entitled to receive an additional \$1.5 million from Eurofarma for the achievement of various development milestones and we are eligible to receive up to \$21.4 million in development, commercial and sales milestones when cumulative net sales equal or exceed \$100.0 million in the Eurofarma licensed territory. Each subsequent achievement of an additional \$100.0 million in cumulative net sales will result in the Company receiving additional milestone payments, which, when combined with anticipated product supply transfer payments from Eurofarma paid to the Company in connection with a commercial supply agreement to be entered into between the two parties, will provide payments estimated to range from a mid-teens to high-teens percentage of cumulative net sales in the territories where we have granted Eurofarma commercialization rights. As of March 31, 2022, we have recognized \$4.2 million of cumulative income since inception.

The total amount of committed BARDA funding is \$62.4 million. As of March 31, 2022, an aggregate of \$57.9 million of the total committed BARDA funding has been received and we have recognized \$52.8 million of cumulative income since contract inception. The remaining federal government funding was dependent on BARDA in its sole discretion exercising the final independent option work segment, upon the achievement by the Company of certain agreed-upon milestones for ridinilazole. This option work segment was never exercised by BARDA. The contract ran through April 2022 and was extended through December 2022 as a no cost contract, solely to close out open activities.

The total amount of committed CARB-X funding is \$4.1 million, with the possibility of up to another \$3.7 million based on the achievement of future milestones. As of March 31, 2022, an aggregate of \$0.9 million of grant funding from CARB-X has been received and we have recognized \$1.6 million of cumulative income since inception.

We will need additional capital to fund our operations. Additional capital, when needed, may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends or other distributions. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we will be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Cash Flows

The following table summarizes the results of our cash flows for the three months ended March 31, 2022 and 2021:

(in millions)	Three Months Ended March 31,	
	2022	2021
Net cash used in operating activities	\$ (19,001)	\$ (20,669)
Net cash used in investing activities	\$ (361)	\$ (39)
Net cash provided by financing activities	\$ 25,187	\$ 55,897

Operating Activities

Net cash used in operating activities for the three months ended March 31, 2022 was \$19.0 million and resulted from a net loss of \$21.4 million, which included non-cash charges of \$5.8 million, which is primarily comprised of \$4.0 million of non-cash charges related to stock-based compensation, and a net increase in working capital of \$3.5 million. The net increase in working capital was primarily due to a decrease of \$3.5 in accrued compensation, a decrease of \$2.7 million in deferred revenue and other income, an increase of \$1.7 million in the research and development tax credit receivable, a decrease of \$0.8 in accrued liabilities, and an increase of \$0.4 million in other current assets, partially offset by an increase of \$2.8 million in accounts payable, a decrease of \$2.7 million in prepaid expenses and a decrease of \$0.5 million in accounts receivable.

Net cash used in operating activities for the three months ended March 31, 2021 was \$20.7 million and resulted from a net loss of \$17.5 million, which included net non-cash income of \$0.3 million and a net increase in working capital of \$2.9 million. The net increase in working capital was primarily due to an increase of \$3.7 million in the research and development tax credit receivable, a decrease of \$2.1 million in accounts payable, and a decrease of \$1.2 million in deferred revenue and other income, partially offset by an increase of \$2.0 million in accrued liabilities, a decrease of \$1.6 million in prepaid expenses and a decrease of \$0.5 million in other current assets.

Investing Activities

Net cash used in investing activities for the three months ended March 31, 2022 and March 31, 2021 was for the purchase of property and equipment.

Financing Activities

Net cash provided by financing activities was \$25.2 million for the three months ended March 31, 2022 and primarily resulted from proceeds from a promissory note from a related party of \$25.0 million and proceeds received related to employee stock awards of \$0.2 million. Net cash provided by financing activities was \$55.9 million for the three months ended March 31, 2021 and primarily resulted from proceeds from a promissory note from a related party of \$55.0 million and net receipts related to employee stock awards of \$0.9 million.

Critical Accounting Policies and Significant Judgments and Estimates

Our management’s discussion and analysis of our financial condition and results of operations are based on our condensed consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of our financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue recognition, research and development costs, intangible assets, stock-based compensation and income taxes. We base our estimates on historical experience, known trends and events, and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations, Critical Accounting Policies and Significant Judgments and Estimates in our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission on March 17, 2022. There have been no material changes to our critical accounting policies and estimates since the date of issuance of those audited financial statements.

Contractual obligations and commitments

The Company leases office and laboratory space. There have been no material changes to the Company's lease commitments as of December 31, 2021 which were disclosed in our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission on March 17, 2022. There have been no material changes to our lease commitments as of December 31, 2021 which were disclosed in our Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 17, 2022.

We also have contingent payment obligations which primarily consist of commitments under our agreements with the Wellcome Trust, the University College London and certain employees, former employees and former directors of Discuva, pursuant to which we will be required to pay royalties or make milestone payments. As of March 31, 2022, we were unable to estimate the amount, timing or likelihood of achieving the milestones or making future product sales that these contingent payment obligations relate to. For additional information regarding these agreements, see “Business - Our Collaborations and Funding Arrangements” in our Annual Report on Form 10-K, filed with the U.S. Securities and Exchange Commission on March 17, 2022.

Additionally, we enter into contracts in the normal course of business with various third parties for clinical trials, preclinical research studies and testing, manufacturing and other services and products for operating purposes. Most contracts provide for termination upon notice, and therefore are cancellable contracts. There have been no material changes to the Company's contractual commitments as of December 31, 2021 which were disclosed in our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission on March 17, 2022.

Off-Balance Sheet Arrangements

Other than the contractual obligations and commitments described above, we did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the Securities and Exchange Commission.

Recently Issued Accounting Pronouncements

For a discussion of recently issued accounting pronouncements, refer to Note 3, *Recently Issued or Adopted Accounting Pronouncements*, to our condensed consolidated financial statements included in this report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 4. Controls and Procedures.

We have carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) under the supervision and the participation of the company’s management, which is responsible for the management of the internal controls, and which includes our Chief Executive Officer and Executive Chairman (our principal executive officer and our principal financial officer). The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities Exchange Act of 1934 is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. There are inherent limitations to the effectiveness of any system of disclosure controls and procedures, including the possibility of human error and the circumvention or overriding of the controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives. Based upon our evaluation of our disclosure controls and procedures as of March 31, 2022, our Chief Executive Officer concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable level of assurance.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors.

Information regarding risk factors affecting the Company's business are discussed in the section entitled "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2021 (the "Annual Report") filed with the Securities and Exchange Commission on March 17, 2022. There have been no material changes to the risk factors as previously disclosed in our Annual Report, except for the risk factor shown below. The risks referenced above are not the only risks facing our Company. Additional risk and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

Recent and potential future changes to U.S. and non-U.S. tax laws could materially adversely affect our company and holders of our shares of common stock.

Recent changes in tax law may adversely affect our business or financial condition. On December 22, 2017, the U.S. government enacted the Tax Cuts and Jobs Act, or the TCJA, which significantly reformed the U.S. Internal Revenue Code of 1986, as amended, or the Code. The TCJA, among other things, contained significant changes to corporate taxation, including a reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, the limitation of the tax deduction for net interest expense to 30% of adjusted taxable income (except for certain small businesses), the limitation of the deduction for net operating losses arising in taxable years beginning after December 31, 2017 to 80% of current year taxable income and elimination of net operating loss carrybacks for losses arising in taxable years ending after December 31, 2017 (though any such net operating losses may be carried forward indefinitely), the imposition of a one-time taxation of

offshore earnings at reduced rates regardless of whether they are repatriated, the elimination of U.S. tax on foreign earnings (subject to certain important exceptions), the allowance of immediate deductions for certain new investments instead of deductions for depreciation expense over time, and the modification or repeal of many business deductions and credits.

As part of Congress’ response to the COVID-19 pandemic, the Families First Coronavirus Response Act, or FFCR Act, was enacted on March 18, 2020, and the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, was enacted on March 27, 2020. Both contain numerous tax provisions. In particular, the CARES Act retroactively and temporarily (for taxable years beginning before January 1, 2021) suspends application of the 80%-of-income limitation on the use of net operating losses, which was enacted as part of the TCJA. It also provides that net operating losses arising in any taxable year beginning after December 31, 2017, and before January 1, 2021 are generally eligible to be carried back up to five years. The CARES Act also temporarily (for taxable years beginning in 2019 or 2020) relaxes the limitation of the tax deductibility for net interest expense by increasing the limitation from 30% to 50% of adjusted taxable income.

Regulatory guidance under the TCJA, the FFCR Act and the CARES Act is and continues to be forthcoming, and such guidance could ultimately increase or lessen impact of these laws on our business and financial condition. It is also likely that Congress will enact additional legislation in connection with the COVID-19 pandemic, some of which could have an impact on our company. In addition, it is uncertain if and to what extent various states will conform to the TCJA, the FFCR Act or the CARES Act.

Recent and proposed changes to U.K. tax legislation, may place limitations on the value of the tax credit which can be claimed if the Company does not meet certain specified criteria. These limitations, coupled with a reduction in clinical development activities with respect to ridinilazole may materially reduce the amount of U.K. R&D credit cash rebates to be recognized and received by the Company in the future.

Future changes in tax laws, regulations and treaties, or the interpretation thereof, in addition to initiatives related to the Base Erosion and Profit Shifting, or BEPS, Project of the Organisation for Economic Co-Operation and Development, or OECD; the European Commission’s “state aid” investigations; and other developments could have an adverse effect on the taxation of international businesses, including our own. Furthermore, countries where we are subject to taxes, including the United States, evaluate their tax policies and rules on a regular basis, and we may see significant changes in legislation and regulations concerning taxation.

We are unable to predict what tax changes may be enacted in the future or what effect such changes would have on our business, but such changes could affect our effective tax rates in countries where we have operations and could have an adverse effect on our overall tax position in the future, along with increasing the complexity, burden and cost of tax compliance.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Index

Exhibit No.	Description
31.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to §302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)
*	Filed herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: May 11, 2022

SUMMIT THERAPEUTICS INC.

By:	<u>/s/ Robert W. Duggan</u>
Name:	Robert W. Duggan
Title	Chief Executive Officer and Executive Chairman; Principal Executive Officer and Principal Financial Officer

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO RULES 13a-14(a) AND 15d-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED**

I, Robert W. Duggan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Summit Therapeutics Inc.;
 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
 4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
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5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
- a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: May 11, 2022

By: /s/ Robert W. Duggan

Name:

Title:

Robert W. Duggan

Chief Executive Officer

(Principal Executive Officer and Principal Financial Officer)

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Summit Therapeutics Inc. (the “Company”) for the period ended March 31, 2022, as filed with the U.S. Securities and Exchange Commission on the date hereof (the “Report”), the undersigned Robert W. Duggan, as Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

- 1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- 2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 11, 2022

By: /s/ Robert W. Duggan

Name:

Title:

Robert W. Duggan

Chief Executive Officer

(Principal Executive Officer and Principal Financial Officer)