

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 15, 2024

Seres Therapeutics, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware  
(State or other jurisdiction of  
incorporation)

001-37465  
(Commission  
File Number)

27-4326290  
(IRS Employer  
Identification No.)

101 Cambridgepark Drive  
Cambridge, MA  
(Address of principal executive offices)

02140  
(Zip Code)

Registrant's telephone number, including area code: (617) 945-9626

Not Applicable  
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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, par value \$0.001 per share	MCRB	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

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.

**Item 7.01. Regulation FD Disclosure**

Seres Therapeutics, Inc. (“Seres” or the “Company”) is filing this Current Report on Form 8-K to furnish its historical consolidated financial statements and the notes thereto previously included in its Annual Report on Form 10-K for the fiscal years ended December 31, 2023 and 2022 (the “Prior 10-K”) filed with the Securities and Exchange Commission on March 5, 2024 (such financial statements and notes thereto, the “2022-2023 Financial Statements”). The 2022-2023 Financial Statements, furnished as Exhibit 99.1 to this Current Report, are consistent in all respects with the financial statements for such periods included in the Prior 10-K. This Current Report does not reflect events occurring after March 5, 2024, the filing date of the Prior 10-K, and does not modify or update the disclosures set forth in the Prior 10-K in any way.

Seres expects to incorporate by reference the 2022-2023 Financial Statements in its proxy statement to be filed in connection with the sale of specified assets related to Seres’ VOWST microbiome therapeutic business. The 2022-2023 Financial Statements are being furnished solely for such purpose.

**Item 9.01. Financial Statements and Exhibits***Exhibits*

<b>Exhibit No.</b>	<b>Description</b>
<a href="#">99.1</a>	<a href="#">The audited consolidated financial statements of Seres Therapeutics, Inc., and its subsidiaries as of and for the fiscal years ended December 31, 2023 and 2022, including the consolidated balance sheets and the related consolidated statements of operations and comprehensive loss, of stockholders’ equity and of cash flows, and the related notes.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

**SIGNATURE**

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 hereunto duly authorized.

**SERES THERAPEUTICS, INC.**

Date: August 15, 2024

By: /s/ Eric D. Shaff  
Name: Eric D. Shaff  
Title: President and Chief Executive Officer

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## Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Seres Therapeutics, Inc.

### ***Opinion on the Financial Statements***

We have audited the accompanying consolidated balance sheets of Seres Therapeutics, Inc. and its subsidiaries (the “Company”) as of December 31, 2023 and 2022, and the related consolidated statements of operations and comprehensive loss, of stockholders’ (deficit) equity and of cash flows for the years then ended, including the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

### ***Substantial Doubt About the Company’s Ability to Continue as a Going Concern***

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred losses and negative cash flows from operations since its inception and needs to raise additional capital to fund future operations, which raises substantial doubt about its ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### ***Basis for Opinion***

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

### ***Critical Audit Matters***

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

#### ***Recognition of Collaboration (Profit) Loss Sharing - License Agreement with NHSc Rx License GmbH (Nestlé)***

As described in Note 15 to the consolidated financial statements, the Company recognizes collaboration (profit) loss sharing – related party arising from a license agreement with Nestlé, which totaled \$0.7 million for the year ended December 31, 2023. Under the 2021 License Agreement with Nestlé, beginning with the first commercial sale of VOWST, which occurred in June 2023, net sales of VOWST are recorded by Nestlé. The Company records its share of the profits or losses from the sales of VOWST, including commercial and medical affairs expenses incurred by the Company, on a net basis, as collaboration (profit) loss sharing - related party. The collaboration (profit) loss sharing - related party line item also includes the Company’s profit on the transfer of VOWST inventory to Nestlé, which represents the excess of the supply price paid by Nestlé over the Company’s cost to manufacture VOWST, subject to a supply price cap applicable to product manufactured prior to commercial launch.

The principal consideration for our determination that performing procedures relating to the recognition of collaboration (profit) loss sharing arising from the license agreement with Nestlé is a critical audit matter is a high degree of auditor effort in performing procedures related to the Company's recognition of collaboration (profit) loss sharing.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included, among others (i) evaluating management's collaboration (profit) loss sharing accounting policy; (ii) testing the completeness and accuracy of certain data used to calculate the collaboration (profit) loss sharing by sending a confirmation and obtaining and inspecting source documents provided by Nestlé; (iii) recalculating the Company's share of the profit or losses from the sales of VOWST; and (iv) recalculating the Company's profit on transfer of VOWST inventory to Nestlé and obtaining and inspecting source documents, such as invoices and evidence of payment.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts

March 5, 2024

We have served as the Company's auditor since 2014.

**SERES THERAPEUTICS, INC.**  
**CONSOLIDATED BALANCE SHEETS**  
(In thousands, except share and per share data)

	<b>December 31,</b>	
	<b>2023</b>	<b>2022</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 127,965	\$ 163,030
Short term investments	—	18,311
Collaboration receivable - related party	8,674	—
Inventories	29,647	—
Prepaid expenses and other current assets	9,124	13,423
Total current assets	175,410	194,764
Property and equipment, net	22,457	22,985
Operating lease assets	109,793	110,984
Restricted cash	8,185	8,185
Restricted investments	1,401	1,401
Other non-current assets (1)	41,354	10,465
Total assets	<u>\$ 358,600</u>	<u>\$ 348,784</u>
<b>Liabilities and Stockholder's Equity</b>		
Current liabilities:		
Accounts payable	\$ 3,641	\$ 17,440
Accrued expenses and other current liabilities (2)	80,611	59,840
Operating lease liabilities	6,677	3,601
Short term portion of note payable, net of discount	—	456
Deferred income - related party	7,730	—
Deferred revenue - related party	—	4,259
Total current liabilities	98,659	85,596
Long term portion of note payable, net of discount	101,544	50,591
Operating lease liabilities, net of current portion	105,715	107,942
Deferred revenue, net of current portion - related party	95,364	92,430
Warrant liability	546	—
Other long-term liabilities	1,628	1,442
Total liabilities	<u>403,456</u>	<u>338,001</u>
Commitments and contingencies (Note 16)		
Stockholders' (deficit) equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized at December 31, 2023 and 2022; no shares issued and outstanding at December 31, 2023 and 2022	—	—
Common stock, \$0.001 par value; 240,000,000 and 200,000,000 shares authorized at December 31, 2023 and 2022, respectively; 135,041,467 and 125,222,273 shares issued and outstanding at December 31, 2023 and 2022, respectively	135	125
Additional paid-in capital	933,244	875,181
Accumulated other comprehensive loss	—	(12)
Accumulated deficit	(978,235)	(864,511)
Total stockholders' (deficit) equity	<u>(44,856)</u>	<u>10,783</u>
Total liabilities and stockholders' equity	<u>\$ 358,600</u>	<u>\$ 348,784</u>

[1] Includes \$38,877 and \$8,828 as of December 31, 2023 and December 31, 2022, respectively, of milestones related to the construction of the Company's dedicated manufacturing suite at BacThera AG, or Bacthera (see Note 16, *Commitments and Contingencies*). Such amounts will form part of the right-of-use asset upon lease commencement.

[2] Includes related party amounts of \$28,053 and \$34,770 at December 31, 2023 and December 31, 2022, respectively (see Note 18)

*The accompanying notes are an integral part of these consolidated financial statements.*

**SERES THERAPEUTICS, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**  
(In thousands, except share and per share data)

	<b>Year Ended December 31,</b>	
	<b>2023</b>	<b>2022</b>
Revenue:		
Collaboration revenue - related party	\$ 126,325	\$ 7,128
Total revenue	126,325	7,128
Operating expenses:		
Research and development expenses	\$ 145,860	\$ 172,920
General and administrative expenses	87,744	79,694
Collaboration (profit) loss sharing - related party	704	1,004
Total operating expenses	234,308	253,618
Loss from operations	(107,983)	(246,490)
Other (expense) income:		
Interest income	7,301	3,058
Interest expense	(13,176)	(6,020)
Other income (expense)	134	(705)
Total other (expense) income, net	(5,741)	(3,667)
Net loss	\$ (113,724)	\$ (250,157)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.89)	\$ (2.31)
Weighted average common shares outstanding, basic and diluted	128,003,294	108,077,043
Other comprehensive income (loss):		
Unrealized gain (loss) on investments, net of tax of \$0	10	49
Currency translation adjustment	2	(1)
Total other comprehensive income (loss)	12	48
Comprehensive loss	\$ (113,712)	\$ (250,109)

*The accompanying notes are an integral part of these consolidated financial statements.*



**SERES THERAPEUTICS, INC.**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' (DEFICIT) EQUITY**  
(In thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss (Income)	Accumulated Deficit	Total Stockholders (Deficit) Equity
	Shares	Par Value				
<b>Balance at December 31, 2021</b>	91,889,418	92	745,829	(60)	(614,354)	131,507
Issuance of common stock upon exercise of stock options	326,864	—	966	—	—	966
Issuance of common stock upon vesting of RSUs and PSUs, net of tax withholdings	282,401	—	—	—	—	—
Issuance of common stock under ESPP	322,560	—	1,769	—	—	1,769
Issuance of common stock net of issuance costs of \$3,279	31,746,030	32	96,689	—	—	96,721
Issuance of common stock from at the market equity offering, net of issuance costs of \$310	655,000	1	4,446	—	—	4,447
Stock-based compensation expense	—	—	25,482	—	—	25,482
Other comprehensive income	—	—	—	48	—	48
Net loss	—	—	—	—	(250,157)	(250,157)
<b>Balance at December 31, 2022</b>	125,222,273	125	875,181	(12)	(864,511)	10,783
Issuance of common stock upon exercise of stock options	260,640	—	877	—	—	877
Issuance of common stock upon vesting of RSUs and PSUs, net of tax withholdings	1,244,663	1	(1)	—	—	—
Issuance of common stock under ESPP	602,692	2	2,149	—	—	2,151
Issuance of common stock from at the market equity offering, net of issuance costs of \$772	7,711,199	7	18,152	—	—	18,159
Issuance of warrants	—	—	2,785	—	—	2,785
Stock-based compensation expense	—	—	34,101	—	—	34,101
Other comprehensive income	—	—	—	12	—	12
Net loss	—	—	—	—	(113,724)	(113,724)
<b>Balance at December 31, 2023</b>	135,041,467	\$ 135	\$ 933,244	\$ —	\$ (978,235)	\$ (44,856)

*The accompanying notes are an integral part of these consolidated financial statements.*

**SERES THERAPEUTICS, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(In thousands)

	<b>Year Ended December 31,</b>	
	<b>2023</b>	<b>2022</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (113,724)	\$ (250,157)
<b>Adjustments to reconcile net loss to net cash provided by (used in) operating activities:</b>		
Stock-based compensation expense	34,101	25,482
Depreciation and amortization expense	6,243	6,629
Non-cash operating lease cost	8,871	5,224
Amortization of premiums on investments	(236)	688
Amortization of debt issuance costs	1,139	705
Loss on extinguishment of debt	1,625	—
Change in fair value of warrant liabilities	(1,554)	—
Collaboration (profit) loss sharing - related party	5,158	1,004
<b>Changes in operating assets and liabilities:</b>		
Prepaid expenses and other current and non-current assets	(29,124)	(12,599)
Collaboration receivable - related party	(8,674)	—
Inventories	(29,647)	—
Deferred income - related party	7,730	—
Deferred revenue - related party	(1,325)	(7,128)
Accounts payable	(11,578)	2,203
Operating lease liabilities	(2,197)	(4,203)
Accrued expenses and other current and long-term liabilities (3)	15,838	3,336
Net cash (used in) provided by operating activities	<u>(117,354)</u>	<u>(228,816)</u>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(7,975)	(9,821)
Purchases of investments	(4,426)	(48,221)
Sales and maturities of investments	22,983	140,470
Net cash provided by investing activities	<u>10,582</u>	<u>82,428</u>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of common stock, net of issuance costs	—	96,721
Proceeds from at the market equity offering, net of issuance costs	18,159	4,447
Proceeds from exercise of stock options	877	966
Issuance of common stock under ESPP	2,151	1,769
Proceeds from issuance of debt, net of issuance costs	103,378	27,606
Repayment of notes payable	(52,860)	(1,907)
Net cash provided by financing activities	<u>71,705</u>	<u>129,602</u>
<b>Net (decrease) increase in cash, cash equivalents and restricted cash</b>	<b>(35,067)</b>	<b>(16,786)</b>
Effect of exchange rate changes on cash, cash equivalents and restricted cash	2	(1)
Cash, cash equivalents and restricted cash at beginning of year	171,215	188,002
Cash, cash equivalents and restricted cash at end of year	<u>\$ 136,150</u>	<u>\$ 171,215</u>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for interest	\$ 12,547	\$ 4,926
<b>Supplemental disclosure of non-cash investing and financing activities:</b>		
Property and equipment purchases included in accounts payable and accrued expenses	\$ 16	\$ 2,276
Lease liability arising from obtaining right-of-use assets	\$ 3,046	\$ 91,412
Prepaid rent reclassified to right-of-use assets	\$ 4,634	\$ 6,822
Recognition of warrant liabilities	\$ 2,100	\$ —
Warrants issued related to Term Loan and recorded as debt discount (Note 9)	\$ 2,785	\$ —

[3] Includes related party amounts of \$(6,717) and \$3,087 at December 31, 2023 and 2022, respectively (see Note 18)

*The accompanying notes are an integral part of these consolidated financial statements.*

**SERES THERAPEUTICS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**(amounts in thousands, except share and per share data)**

**1. Nature of the Business and Basis of Presentation**

Seres Therapeutics, Inc. (the “Company”) was incorporated under the laws of the State of Delaware in October 2010 under the name Newco LS21, Inc. In October 2011, the Company changed its name to Seres Health, Inc., and in May 2015, the Company changed its name to Seres Therapeutics, Inc. The Company is a commercial-stage microbiome therapeutics company focused on the development and commercialization of a novel class of biological drugs, which are designed to treat disease by modulating the microbiome to restore health by repairing the function of a disrupted microbiome to a non-disease state.

The Company’s product, VOWST (fecal microbiota spores, live brkp), formerly called SER-109, was approved by the U.S. Food and Drug Administration (“FDA”) on April 26, 2023 and is the first and only orally administered microbiome therapeutic. VOWST is indicated to prevent the recurrence of *Clostridioides difficile* infection (“CDI”) in patients 18 or older following antibacterial treatment for recurrent CDI. The Company launched VOWST in the United States with its collaborator, Nestlé Health Science (“Nestlé”), in June 2023.

Building upon VOWST, the Company is progressing the Phase 1b clinical trial of SER-155, a microbiome therapeutic candidate consisting of a 16-strain consortium of cultivated bacteria designed to prevent enteric-derived infections and resulting bloodstream infections, as well as induce immune tolerance responses to reduce the incidence of graft-versus-host disease (“GvHD”) in patients undergoing allogeneic hematopoietic stem cell transplantation (“allo-HSCT”). Gastrointestinal microbiome data from the first 100 days of SER-155 Phase 1b open-label study cohort 1 showed the successful engraftment of SER-155 bacterial strains, and a substantial reduction in the cumulative incidence of pathogen domination as compared to a reference cohort of patients, a biomarker associated with the risk of serious enteric infections and resulting bloodstream infections, as well as GvHD. The tolerability profile observed was favorable, with no serious adverse events attributed to SER-155 administration. Enrollment in the placebo-controlled cohort 2 portion of the study is ongoing, and the cohort 2 data readout is anticipated in the third quarter of 2024.

The Company has built and deploys a reverse translational platform and knowledge base for the discovery and development of microbiome therapeutics, and maintains extensive proprietary know-how that may be used to support future research and development efforts. This platform incorporates high-resolution analysis of human clinical data to identify microbiome biomarkers associated with disease and non-disease states; preclinical screening using human cell-based assays and in vitro/ex vivo and in vivo disease models customized for microbiome therapeutics; and microbiological capabilities and a strain library that spans broad biological and functional breadth to both identify specific microbes and microbial metabolites that are associated with disease and to design consortia of bacteria with specific pharmacological properties. In addition, the Company owns a valuable intellectual property estate related to the development and manufacture of microbiome therapeutics.

On October 29, 2023, the Company’s Board of Directors approved a restructuring plan to prioritize the commercialization of VOWST and the completion of the SER-155 Phase 1b study, while significantly reducing costs and supporting longer-term business sustainability (the “Restructuring Plan”). The Restructuring Plan included (i) a reduction of the Company’s workforce by approximately 41% across the organization, resulting in the elimination of approximately 160 positions; (ii) significantly scaling back all non-partnered research and development activities other than the completion of the SER-155 Phase 1b study; and (iii) reducing general and administrative expenses, including consolidating office space. For additional information on the Restructuring Plan, see Note 13, *Restructuring*.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the need to obtain additional financing. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval, prior to commercialization. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees and consultants.

The accompanying consolidated financial statements have been prepared on a basis that assumes that the Company will continue as a going concern and that contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. As of December 31, 2023, the Company had an accumulated deficit of \$978,235 and cash and cash equivalents of \$127,965.

The Company’s primary focus in recent months has been and will continue to be supporting commercialization, including the manufacture of VOWST, and the completion of the SER-155 Phase 1b study, which requires capital and resources. Other than VOWST, the Company’s product candidates are in development, and will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval, prior to potential commercialization. There can be no assurance that the Company’s research and development will be successfully completed, that adequate protection for the Company’s intellectual property will be obtained, or maintained, that any product candidate developed will obtain necessary government regulatory approval, or that any approved product will be commercially viable. Even if the Company’s product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales.

**SERES THERAPEUTICS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**(amounts in thousands, except share and per share data)**

Primarily as a result of the increased and costly efforts to commercialize VOWST and to continue the research and development efforts for other product candidates and preclinical programs, for the year ended December 31, 2023, the Company incurred a net loss of \$113,724, and had net operating cash outflows of \$117,354. The Company expects that its operating losses and negative cash flows will continue for the foreseeable future. Based on the Company's currently available cash resources, current and forecasted level of operations, and forecasted cash flows for the 12-month period subsequent to the date of issuance of these consolidated financial statements, the Company will require additional funding to maintain commercial production of VOWST, continue to progress the SER-155 Phase 1b study, and meet its operational obligations as they come due. These factors raise substantial doubt about the Company's ability to continue as a going concern.

The Company's ability to continue as a going concern is dependent upon its ability to obtain the necessary financing to meet its obligations and repay its liabilities arising from normal business operations when they come due, and to generate profitable operations in the future. Management plans to provide for the Company's capital requirements through financing or other transactions, including drawing the Tranche B Term Loan pursuant to the Oaktree Credit Agreement (see Note 9, *Notes Payable*), which is expected to become available to the Company based on VOWST net sales forecasts assuming continued quarter-over-quarter net sales growth, and selling shares under the Company's at the market equity offering. There can be no assurance that the Company will generate significant profit from the transfer of VOWST to Nestlé or its share of collaboration profits resulting from net sales of VOWST, or that it will be able to raise additional capital to fund operations with terms acceptable to the Company, or at all. Because certain elements of management's plans to mitigate the conditions that raised substantial doubt about the Company's ability to continue as a going concern are outside of the Company's control, including the ability to raise capital through an equity or other financing, those elements cannot be considered probable according to Accounting Standards Codification ("ASC") 205-40, *Going Concern* ("ASC 205-40"), and therefore cannot be considered in the evaluation of mitigating factors. As a result, management has concluded that substantial doubt exists about the Company's ability to continue as a going concern for 12 months from the date these consolidated financial statements are issued.

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") and include the accounts of the Company and its wholly owned subsidiaries after elimination of all intercompany accounts and transactions.

## **2. Summary of Significant Accounting Policies**

### **Use of Estimates**

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reporting periods. In these consolidated financial statements, the Company uses estimates and assumptions related to revenue recognition and the accrual of research and development expenses. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from the Company's estimates.

### **Cash Equivalents**

The Company considers all short-term, highly liquid investments with original maturities of 90 days or less at acquisition date to be cash equivalents. Cash equivalents, which consist of money market accounts, commercial paper and corporate bonds purchased with original maturities of less than 90 days from the date of purchase, are stated at fair value.

### **Investments**

The Company classifies all of its marketable debt securities as available-for-sale securities. Accordingly, these marketable debt securities are recorded at fair value and unrealized gains and losses are reported as a separate component of accumulated other comprehensive loss in stockholders' equity (deficit), unless the Company has determined that the security has experienced a credit loss, the Company expects to sell the security prior to the recovery of its unrealized losses, or it is more likely than not that the Company will be required to sell the security prior to the recovery of its amortized cost basis. When determining whether a credit loss exists, the Company considers several factors, including the estimated present value of expected cash flows from the security, whether the Company has the intent to sell the security or whether it is more likely than not that the Company will be required to sell the security prior to recovery of its amortized cost basis. If the Company has an intent to sell, or if it is more likely than not that the Company will be required to sell a debt security in an unrealized loss position before recovery of its amortized cost basis, the Company will write down the security to its fair value and record the corresponding charge to the consolidated statement of operations and comprehensive loss. The cost of securities sold is determined on a specific identification basis, and realized gains and losses are included in other income (expense) within the consolidated statement of operations and comprehensive loss. No credit losses were recorded during the years ended December 31, 2023 and 2022.

**SERES THERAPEUTICS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**(amounts in thousands, except share and per share data)**

The Company classifies its available-for-sale marketable debt securities as current assets on the consolidated balance sheet if they mature within one year from the balance sheet date. Any available-for-sale marketable debt securities with maturities greater than one year from the balance sheet date are classified as long-term assets on the consolidated balance sheet.

**Restricted Investments**

The Company held investments of \$1,401 as of December 31, 2023 and 2022, in a separate restricted bank account as a security deposit for the lease of the Company's headquarters in Cambridge, Massachusetts. The Company has classified these deposits as long-term restricted investments on its consolidated balance sheet.

**Restricted Cash**

The Company held restricted cash of \$8,185 as of December 31, 2023 and 2022, respectively, which represents cash held for the benefit of the landlord for the Company's other leases. The Company has classified the restricted cash as long-term on its consolidated balance sheet as the underlying leases are greater than 1 year.

Cash, cash equivalents and restricted cash were comprised of the following (in thousands):

	<b>December 31,</b>	
	<b>2023</b>	<b>2022</b>
Cash and cash equivalents	\$ 127,965	\$ 163,030
Restricted cash, non-current	8,185	8,185
Total cash, cash equivalents and restricted cash	\$ 136,150	\$ 171,215

**Concentration of Credit Risk**

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents and investments. The Company has all cash, cash equivalents and investments balances at accredited financial institutions, in amounts that exceed federally insured limits. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

**Fair Value Measurements**

Certain assets and liabilities are carried at fair value in accordance with GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's cash equivalents and investments are carried at fair value, determined according to the fair value hierarchy described above. The Company's investments in certificates of deposit are carried at amortized cost, which approximates fair value. The carrying values of the Company's prepaid expenses and other current and non-current assets, accounts payable and accrued expenses approximate their respective fair values due to the short-term nature of these assets and liabilities. The carrying value of the Company's long-term debt approximates its fair value (a level 2 measurement) at each balance sheet date due to its variable interest rate, which approximates a market interest rate. The warrant liabilities associated with the Company's credit facility with Oaktree for which there is no current market and the determination of fair value requires significant estimation are classified as Level 3 financial liabilities.

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**Inventories**

Inventories are stated at the lower of cost or estimated net realizable value with cost based on the first-in first-out method. Inventory that can be used in either the production of clinical or commercial products is expensed as research and development costs when identified for use in clinical trials.

Prior to the regulatory approval of its product candidates, the Company incurs expenses for the manufacture of drug product supplies to support clinical development that could potentially be available to support the commercial launch of those drugs. Until the date at which regulatory approval has been received or is otherwise considered probable, the Company records all such costs as research and development expenses.

**Property and Equipment**

Property and equipment are stated at cost less accumulated depreciation. Depreciation expense is recognized using the straight-line method over the useful life of the asset, which are as follows:

	<u>Estimated Useful Life (In Years)</u>
Laboratory equipment	5
Computer equipment, furniture and office equipment	3
Leasehold improvements	Lesser of useful life or lease term

Expenditures for repairs and maintenance of assets are charged to expense as incurred. Upon retirement or sale, the cost and related accumulated depreciation of assets disposed of are removed from the accounts and any resulting gain or loss is included in loss from operations.

**Impairment of Long-Lived Assets**

Long-lived assets consist of property and equipment and right-of-use assets associated with our lease agreements. All of the Company's long-lived assets are to be held and used and have definitive lives and accordingly are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset or asset group to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset or asset group are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its fair value, determined based on discounted cash flows. To date, the Company has not recorded any impairment losses on long-lived assets.

**Research and Development Costs**

Research and development costs are expensed as incurred. Research and development expenses include salaries, stock-based compensation and benefits of employees, third-party license fees and other operational costs related to the Company's research and development activities, including allocated facility-related expenses and external costs of outside vendors engaged to conduct both preclinical studies and clinical trials.

**Research Contract Costs and Accruals**

The Company has entered into various research and development contracts with research institutions and other companies. These agreements are generally cancelable, and related payments are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research costs based on reporting provided by third parties, typically contract research organizations. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued and prepaid balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

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**Patent Costs**

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses.

**Accounting for Stock-Based Compensation**

The Company measures all stock options and other stock-based awards granted to employees, non-employees, and directors based on the fair value on the date of the grant and recognizes compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. Generally, the Company issues stock options, restricted stock units and restricted stock awards with only service-based vesting conditions and records the expense for these awards using the straight-line method. For stock options or restricted stock units issued with performance-based vesting conditions, the stock compensation expense related to these awards is recognized based on the grant date fair value when achievement of the performance condition is deemed probable.

The Company classifies stock-based compensation expense in its consolidated statement of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipients' service payments are classified.

The Company accounts for forfeitures of stock-based awards as they occur rather than applying an estimated forfeiture rate to stock-based compensation expense.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The Company estimates its expected common stock volatility based on its historical common stock volatility for the same time period. The Company uses the simplified method prescribed by Securities and Exchange Commission Staff Accounting Bulletin No. 107, *Share-Based Payment*, to calculate the expected term of options granted to employees, non-employees and directors. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

**Revenue Recognition**

The Company recognizes revenue in accordance with the guidance under ASC 606, *Revenue from Contracts with Customers* ("ASC 606"). ASC 606 applies to all contracts with customers, except those contracts that are within the scope of other guidance, such as leases, insurance, and financial instruments. The Company enters into agreements that are within the scope of ASC 606, under which the Company licenses certain of the Company's product candidates and performs research and development services in connection with such arrangements. The terms of these arrangements typically include payment of one or more of the following: nonrefundable up-front fees, reimbursement of research and development costs, development, clinical, regulatory and commercial sales milestone payments, and royalties on net sales of licensed products. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. When determining the timing and extent of revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the Company performs the following five steps:

- a. identify the contract(s) with a customer;
- b. identify the performance obligations in the contract;
- c. determine the transaction price;
- d. allocate the transaction price to the performance obligations in the contract; and
- e. recognize revenue when (or as) the entity satisfies a performance obligation.

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The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration to which it is entitled in exchange for the goods or services transferred to the customer.

At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within the contract to determine whether each promised good or service is a performance obligation. The promised goods or services in the Company's arrangements typically consist of a license to the Company's intellectual property and/or research and development services. The Company may provide options to additional items in such arrangements, which are accounted for as separate contracts when the customer elects to exercise such options, unless the option provides a material right to the customer. Performance obligations are promises in a contract to transfer a distinct good or service to the customer that (i) the customer can benefit from on its own or together with other readily available resources, and (ii) is separately identifiable from other promises in the contract. Goods or services that are not individually distinct performance obligations are combined with other promised goods or services until such combined group of promises meet the requirements of a performance obligation.

The Company determines the transaction price based on the amount of consideration the Company expects to receive for transferring the promised goods or services in the contract. Consideration may be fixed, variable, or a combination of both. At contract inception for arrangements that include variable consideration, the Company estimates the probability and extent of consideration it expects to receive under the contract utilizing either the most likely amount method or expected amount method, whichever best estimates the amount expected to be received. The Company then considers any constraints on the variable consideration and includes in the transaction price variable consideration to the extent it is deemed probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

The Company then allocates the transaction price to each performance obligation based on the relative standalone selling price and recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) control is transferred to the customer and the performance obligation is satisfied. For performance obligations which consist of licenses and other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

The Company records amounts as accounts receivable when the right to consideration is deemed unconditional. When consideration is received, or such consideration is unconditionally due, from a customer prior to transferring goods or services to the customer under the terms of a contract, a contract liability is recorded for deferred revenue.

The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less. Incremental costs of obtaining a contract are expensed as and when incurred if the expected period over which the Company would have amortized the asset is one year or less, or the amount is immaterial.

#### **Collaboration Revenue**

Arrangements with collaborators may include licenses to intellectual property, research and development services, manufacturing services for clinical and commercial supply, and participation on joint steering committees. The Company evaluates the promised goods or services to determine which promises, or group of promises, represent performance obligations. In contemplation of whether a promised good or service meets the criteria required of a performance obligation, the Company considers the stage of development of the underlying intellectual property, the capabilities and expertise of the customer relative to the underlying intellectual property, and whether the promised goods or services are integral to or dependent on other promises in the contract. When accounting for an arrangement that contains multiple performance obligations, the Company must develop judgmental assumptions, which may include market conditions, reimbursement rates for personnel costs, development timelines and probabilities of regulatory success to determine the stand-alone selling price for each performance obligation identified in the contract.

When the Company concludes that a contract should be accounted for as a combined performance obligation and recognized over time, the Company must then determine the period over which revenue should be recognized and the method by which to measure revenue. The Company generally recognizes revenue using a cost-based input method.



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*Licenses of intellectual property*

If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue associated with the bundled performance obligation. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of progress and related revenue recognition.

*Milestone Payments*

At the inception of each arrangement that includes developmental and regulatory milestone payments, the Company evaluates whether the achievement of each milestone specifically relates to the Company's efforts to satisfy a performance obligation or transfer a distinct good or service within a performance obligation. If the achievement of a milestone is considered a direct result of the Company's efforts to satisfy a performance obligation or transfer a distinct good or service and the receipt of the payment is based upon the achievement of the milestone, the associated milestone value is allocated to that distinct good or service, otherwise it will be allocated to all performance obligations of the arrangement based on the initial allocation.

The Company evaluates each milestone to determine when and how much of the milestone to include in the transaction price. The Company first estimates the amount of the milestone payment that the Company could receive using either the expected value or the most likely amount approach. The Company primarily uses the most likely amount approach as that approach is generally most predictive for milestone payments with a binary outcome. Then, the Company considers whether any portion of that estimated amount is subject to the variable consideration constraint (that is, whether it is probable that a significant reversal of cumulative revenue would not occur upon resolution of the uncertainty). The Company updates the estimate of variable consideration included in the transaction price at each reporting date which includes updating the assessment of the likely amount of consideration and the application of the constraint to reflect current facts and circumstances.

*Royalties*

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any revenue related to sales-based royalties or milestone payments based on the level of sales.

*Manufacturing supply services*

For arrangements that include a promise of supply of clinical or commercial product, the Company determines if the supply is a promise in the contract or a future obligation at the customer's option. If determined to be a promise at inception of the contract, the Company evaluates the promise to determine whether it is a separate performance obligation or a component of a bundled performance obligation. If determined to be an option, the Company determines if the option provides a material right to the customer and if so, accounts for the option as a separate performance obligation. If determined to be an option but not a material right, the Company accounts for the option as a separate contract when the customer elects to exercise the option.

**Grant Revenue**

The Company generates revenue from government contracts that reimburse the Company for certain allowable costs for funded projects. For contracts with government agencies, when the Company has concluded that it is the principal in conducting the research and development expenses, and where the funding arrangement is considered central to the Company's ongoing operations, the Company classifies the recognized funding received as revenue.

The Company has concluded to recognize funding received as revenue, rather than as a reduction of research and development expenses, because the Company is the principal in conducting the research and development activities and these contracts are central to its ongoing operations. Revenue is recognized as the qualifying expenses related to the contracts are incurred. Revenue recognized upon incurring qualifying expenses in advance of receipt of funding is recorded in the Company's consolidated balance sheet as accounts receivable. The related costs incurred by the Company are included in research and development expense in the Company's consolidated statements of operations and comprehensive loss.

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**Collaboration Profit and Loss**

The Company analyzes its collaboration arrangements to assess whether they are within the scope of ASC 808, *Collaborative Arrangements* (“ASC 808”), which includes determining whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, the Company first determines which elements of the collaboration are deemed to be within the scope of ASC 808 and those that are more reflective of a vendor-customer relationship and therefore within the scope of ASC 606. For those elements of the arrangement that are accounted for pursuant to ASC 606, the Company applies the five-step model prescribed in ASC 606, as described above. For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, generally by analogy to ASC 606. The Company records its share of the profits or losses from the sales of VOWST on a net basis, as collaboration (profit) loss sharing - related party because Nestlé and the Company are both active participants in commercialization activities and are exposed to significant risks and rewards that are dependent on the commercial success of the activities in the arrangement. The collaboration (profit) loss sharing - related party line item also includes the Company’s profit on the transfer of VOWST inventory to Nestlé, which represents the excess of the supply price paid by Nestlé over our cost to manufacture VOWST.

**Income Taxes**

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company’s tax returns. Deferred taxes are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense.

The Company applies ASC 740-10, *Accounting for Uncertain Tax Positions*. The Company accounts for uncertainty in income taxes recognized in the financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

**Segment Data**

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company’s singular focus is on developing microbiome therapeutics to treat the modulation of the colonic microbiome. Revenue to date has been generated solely through the Company’s agreements with its collaborators, all of which has been earned in the United States. All tangible assets are held in the United States.

**Comprehensive Loss**

Comprehensive loss includes net loss as well as other changes in stockholders’ equity (deficit) that result from transactions and economic events other than those with stockholders. For the years ended December 31, 2023 and 2022, other comprehensive income (loss) consisted of changes in unrealized gains (losses) from available-for-sale investments and a currency translation adjustment.

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**Net Loss per Share**

Basic net loss per share is computed using the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed using the sum of the weighted average number of common shares outstanding during the period and, if dilutive, the weighted average number of potential shares of common stock, including the assumed exercise of stock options and unvested restricted stock. The Company applies the two-class method to calculate its basic and diluted net loss per share attributable to common stockholders. The two-class method is an earnings allocation formula that treats a participating security as having rights to earnings that otherwise would have been available to common stockholders. However, the two-class method does not impact the net loss per share of common stock as the Company was in a net loss position for each of the periods presented.

The Company's restricted stock awards entitle the holder of such awards to dividends declared or paid by the board of directors, regardless of whether such awards are unvested, as if such shares were outstanding common shares at the time of the dividend. However, the unvested restricted stock awards are not entitled to share in the residual net assets (deficit) of the Company. Accordingly, in periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

**Leases**

In accordance with ASC 842, *Leases*, the Company determines if an arrangement is or contains a lease at inception. A contract is or contains a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. The Company classifies leases at the lease commencement date as operating or finance leases and records a right-of-use asset and a lease liability on the consolidated balance sheet for all leases with an initial lease term of greater than 12 months. Leases with an initial term of 12 months or less are not recorded on the balance sheet, but payments are recognized as expense on a straight-line basis over the lease term. The Company has elected not to record a right-of-use asset or lease liability for leases with terms of 12 months or less.

A lease qualifies as a finance lease if any of the following criteria are met at the inception of the lease: (i) there is a transfer of ownership of the leased asset to the Company by the end of the lease term, (ii) the Company holds an option to purchase the leased asset that it is reasonably certain to exercise, (iii) the lease term is for a major part of the remaining economic life of the leased asset, (iv) the present value of the sum of lease payments equals or exceeds substantially all of the fair value of the leased asset, or (v) the nature of the leased asset is specialized to the point that it is expected to provide the lessor no alternative use at the end of the lease term.

The Company enters into contracts that contain both lease and non-lease components. Non-lease components may include maintenance, utilities, and other operating costs. The Company combines the lease and non-lease components of fixed costs in its lease arrangements as a single lease component. Variable costs, such as utilities or maintenance costs, are not included in the measurement of right-of-use assets and lease liabilities, but rather are expensed when the event determining the amount of variable consideration to be paid occurs.

Finance and operating lease assets and liabilities are recognized at the lease commencement date based on the present value of the lease payments over the lease term using the discount rate implicit in the lease. If the rate implicit is not readily determinable, the Company utilizes an estimate of its incremental borrowing rate based upon the available information at the lease commencement date. Operating lease assets are further adjusted for prepaid or accrued lease payments. Operating lease payments are expensed using the straight-line method as an operating expense over the lease term. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Finance lease assets are amortized to depreciation expense using the straight-line method over the shorter of the useful life of the related asset or the lease term. Finance lease payments are bifurcated into (i) a portion that is recorded as imputed interest expense and (ii) a portion that reduces the finance liability associated with the lease.

Right-of-use assets and lease liabilities are reassessed and remeasured when amendments to the terms of the lease agreement require reassessment and remeasurement of the lease payments and other inputs to the calculation of right-of-use assets and lease liabilities. The Company accounts for remeasurements and modifications to lease liabilities using the present value of remaining lease payments and estimated incremental borrowing rate at the date of remeasurement. The adjustment to the lease liability is recognized as a gain or loss in operating expenses, or as an adjustment to the right-of-use asset, as appropriate, based on the terms and conditions within the lease that are amended.

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**Recently Adopted Accounting Pronouncements**

In June 2016, the FASB issued Accounting Standards Update (“ASU”) No. 2016-13, *Financial Instruments—Credit Losses* (Topic 326): Measurement of Credit Losses on Financial Instruments (“ASU 2016-13”), which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss model. It also eliminates the concept of other-than-temporary impairment and requires credit losses related to available-for-sale debt securities to be recorded through an allowance for credit losses rather than as a reduction in the amortized cost basis of the securities. These changes may result in earlier recognition of credit losses. In November 2018, the FASB issued ASU No. 2018-19, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses*, which narrowed the scope and changed the effective date for non-public entities for ASU 2016-13. The FASB subsequently issued supplemental guidance within ASU No. 2019-05, *Financial Instruments—Credit Losses (Topic 326): Targeted Transition Relief* (“ASU 2019-05”). ASU 2019-05 provides an option to irrevocably elect the fair value option for certain financial assets previously measured at amortized cost basis. The Company adopted the new standard using a modified retrospective approach as of January 1, 2022. The adoption of this standard did not have a material impact on the Company’s consolidated financial statements.

**Recently Issued Accounting Pronouncements**

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which requires public entities to disclose information about their reportable segments’ significant expenses and other segment items on an interim and annual basis. Public entities with a single reportable segment are required to apply the disclosure requirements in ASU 2023-07, as well as all existing segment disclosures and reconciliation requirements in ASC 280, on an interim and annual basis. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and for interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact that the adoption of ASU 2023-07 may have on its consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* which requires public entities to disclose specific categories in the effective tax rate reconciliation, as well as additional information for reconciling items that exceed a quantitative threshold. ASU 2023-09 also requires all entities to disclose income taxes paid disaggregated by federal, state and foreign taxes, and further disaggregated for specific jurisdictions that exceed 5% of total income taxes paid, among other expanded disclosures. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact that the adoption of ASU 2023-09 may have on its consolidated financial statements.

**3. Fair Value of Financial Assets and Liabilities**

The following tables present the Company’s fair value hierarchy for its assets and liabilities that are measured at fair value on a recurring basis (in thousands):

	<b>Fair Value Measurements as of December 31, 2023 Using:</b>			
	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
Cash equivalents:				
Money market funds	\$ 81	\$ —	\$ —	\$ 81
Commercial paper	—	—	—	—
Government securities	—	—	—	—
Total assets	\$ 81	\$ —	\$ —	\$ 81
Warrant liabilities	\$ —	\$ —	\$ 546	\$ 546
Total liabilities	\$ —	\$ —	\$ 546	\$ 546

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	<b>Fair Value Measurements as of December 31, 2022 Using:</b>			
	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
<b>Cash equivalents:</b>				
Money market funds	\$ 47,863	\$ —	\$ —	\$ 47,863
Commercial paper	—	11,691	—	11,691
Government securities	—	4,966	—	4,966
<b>Investments:</b>				
Commercial paper	\$ —	\$ 2,465	\$ —	\$ 2,465
Corporate bonds	—	2,957	—	2,957
Certificate of deposits	—	—	—	—
Government securities	—	12,889	—	12,889
	<u>\$ 47,863</u>	<u>\$ 34,968</u>	<u>\$ —</u>	<u>\$ 82,831</u>

Money market funds are valued by the Company based on quoted market prices, which represent a Level 1 measurement within the fair value hierarchy. Commercial paper, corporate bonds, and government securities are valued by the Company using quoted prices in active markets for similar securities, which represent a Level 2 measurement within the fair value hierarchy.

As of December 31, 2023 and 2022 the Company held a restricted investment of \$1,401, which represents a certificate of deposit that is classified as Level 2 in the fair value hierarchy.

Level 3 financial liabilities consist of the warrant liabilities for which there is no current market such that the determination of fair value requires significant judgment or estimation. Changes in fair value measurements categorized within Level 3 of the fair value hierarchy are analyzed each period based on changes in estimates or assumptions and recorded through other income (expense). The Company uses a Monte-Carlo simulation model which includes the Black-Scholes option pricing model to value the Level 3 warrant liabilities at inception and on each subsequent reporting date. This model incorporates transaction details such as the Company's stock price, contractual terms of the underlying warrants, maturity, risk free rates, volatility, as well as the term to achievement of estimated sales targets. The unobservable inputs for all of the Level 3 warrant liabilities are volatility and the term to achievement of estimated sales targets. The Company utilizes its historical and implied volatility, using its closing common stock prices and market data, to reflect future volatility over the expected term of the warrants. The Company estimates the time to achievement of sales targets of VOWST using information and forecasts generated by the Company in consideration of the terms of the 2021 License Agreement.

On the Closing Date (as defined in Note 9, Notes Payable) and as of December 31, 2023, the Level 3 inputs to the warrant liabilities are as follows:

	<b>Closing Date</b>	<b>December 31, 2023</b>
Volatility	83.0%	101.0%
Term (in years)	1.7	1.3

A reconciliation of the beginning and ending balances for the year ended December 31, 2023 for liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) is as follows (in thousands):

	<b>Warrant Liabilities</b>
Balance as of December 31, 2022	\$ —
Issuance of warrants	2,100
Adjustment to fair value	(1,554)
Balance as of December 31, 2023	<u>546</u>

There were no assets or liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) during the year ended December 31, 2022. There were no transfers between Level 1, Level 2, or Level 3 during the years ended December 31, 2023 and 2022.

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**4. Investments**

As of December 31, 2023, the Company held restricted investments of \$1,401, the cost of which approximates current fair value. The Company did not hold any other investments as of December 31, 2023.

Investments by security type consisted of the following at December 31, 2022 (in thousands):

	<b>December 31, 2022</b>			
	<b>Amortized Cost</b>	<b>Gross Unrealized Gain</b>	<b>Gross Unrealized Loss</b>	<b>Fair Value</b>
Investments:				
Commercial paper	\$ 2,465	\$ —	\$ —	\$ 2,465
Corporate bonds	2,958	—	(1)	2,957
Government securities	12,898	3	(12)	12,889
	<u>\$ 18,321</u>	<u>\$ 3</u>	<u>\$ (13)</u>	<u>\$ 18,311</u>

Excluded from the table above at December 31, 2022 are restricted investments of \$1,401, as the cost approximates current fair value. Investments with original maturities of less than 90 days are included in cash and cash equivalents on the consolidated balance sheets and are not included in the table above. Investments with maturities of less than twelve months are considered current assets and those investments with maturities greater than twelve months are considered non-current assets. As of December 31, 2022, all of the Company's investments were classified as available-for-sale and matured within 12 months of the balance sheet date.

**5. Inventories**

Capitalized inventories consist of the following at December 31, 2023 (in thousands):

	<b>December 31, 2023</b>	<b>December 31, 2022</b>
Raw materials	\$ 4,426	\$ —
Work in process	25,221	—
Finished goods	—	—
Total	<u>\$ 29,647</u>	<u>\$ —</u>

There were no inventories capitalized as of December 31, 2022, because the Company obtained approval for VOWST from the FDA on April 26, 2023. Prior to this approval, all costs for the manufacture of product supplies to support clinical development and commercial launch, including pre-launch inventory, were expensed as incurred or otherwise accounted for pursuant to the 2021 License Agreement. Pre-launch inventory manufactured prior to the FDA approval of VOWST, which was not capitalized into inventory but instead was expensed as research and development in previous periods, will be used in commercial production until it is depleted. Pre-launch inventory expensed as research and development totaled \$26,794 for the year ended December 31, 2023.

Inventory amounts written down as a result of excess, obsolescence, or unmarketability and determined not to be recoverable pursuant to the 2021 License Agreement are expensed in the period in which they are identified. There were no such write-downs during the year ended December 31, 2023.

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**6. Property and Equipment, Net**

Property and equipment, net consisted of the following:

	December 31,	
	2023	2022
Laboratory equipment	\$ 29,081	\$ 24,533
Computer equipment	4,142	3,557
Furniture and office equipment	5,430	3,491
Leasehold improvements	33,549	32,474
Construction in progress	1,393	3,970
	<u>73,595</u>	<u>68,025</u>
Less: Accumulated depreciation and amortization	(51,138)	(45,040)
	<u>\$ 22,457</u>	<u>\$ 22,985</u>

Depreciation and amortization expense was \$6,243 and \$6,629 for the years ended December 31, 2023 and 2022, respectively. During the years ended December 31, 2023 and 2022, the Company disposed of certain fully-depreciated assets with a cost basis of \$145 and \$1,857, respectively.

**7. Accrued Expenses and Other Current Liabilities**

Accrued expenses and other current liabilities consisted of the following:

	December 31,	
	2023	2022
Clinical and development costs	\$ 1,404	\$ 6,717
Manufacturing and quality costs	31,917	—
Payroll and payroll-related costs	16,465	14,709
Collaboration payable - related party (Note 18)	28,053	34,770
Facility and other	2,772	3,644
	<u>\$ 80,611</u>	<u>\$ 59,840</u>

As of December 31, 2023, the Company accrued a total of \$30,049 payable to Bacthera for the substantial completion of the Company's dedicated production suite for long-term supply of VOWST, as the milestone was achieved during the year ended December 31, 2023. This amount is included in the Manufacturing and quality costs category above.

Additionally, included within payroll and payroll-related costs is \$5,080 of accrued severance related to the Restructuring Plan. See Note 13, *Restructuring*, for further details.

**8. Leases**

The Company leases real estate, primarily laboratory, office and manufacturing space. The Company's leases have remaining terms ranging from approximately one to nine years. Certain leases include one or more options to renew, exercisable at the Company's sole discretion, with renewal terms that can extend the lease from approximately one year to ten years. The Company evaluated the renewal options in its leases to determine if it was reasonably certain that the renewal option would be exercised, given the Company's current business structure, uncertainty of future growth, and the associated impact to real estate, the Company concluded that it is not reasonably certain that any renewal options would be exercised. Therefore, the operating lease assets and operating lease liabilities only contemplate the initial lease terms. All the Company's leases qualify as operating leases.

In April 2022, the Company entered into a lease for additional laboratory and office space in Spring House, Pennsylvania, with a lease term of ten years and a renewal option, subject to certain conditions, for an additional five-year term. The undiscounted minimum lease payments were \$3,029, net of a tenant improvement allowance of \$1,184, over the original ten-year term. The lease commenced in April 2023. For the year ended December 31, 2023, the Company recorded a right-of-use asset of \$3,571, which consists of the lease liability of \$1,235, and \$2,336 of leasehold improvements that revert back to the lessor at the termination of the lease.

In December 2022, the Company amended its lease of its former corporate headquarters in Cambridge, Massachusetts (the "Lease Amendment"). The Lease Amendment reduced the office space subject to the lease while maintaining the laboratory and manufacturing space and extended the term to begin in November 2023, when the term of the original lease concludes, and continue through January 2030. The Company accounted for the Lease Amendment as a modification to the existing lease and not a new contract separate from the existing contract, and accordingly increased the associated lease liability and right-of-use asset by \$32,837. Minimum lease payments total \$60,022 throughout the term of the Lease Amendment, net of an estimated tenant improvement allowance of \$1,000.

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The Company has committed to restore the leased space subject to the Lease Amendment to the condition specified in the original lease, and the Company updated its estimate of the costs required to fulfill this obligation in accordance with ASC 410, *Asset Retirement Obligations*, at the effective date of the modification. Based on current estimates, the Company recorded an additional asset retirement obligation of \$452 in December 2022.

In June 2023, the Company entered into a lease for a donor collection facility in Irvine, California, with a lease term of approximately six years and a renewal option, subject to certain conditions, for an additional five-year term. The undiscounted minimum lease payments are \$1,079 over the original term. The lease commenced in December 2023. For the year ended December 31, 2023, the Company recorded a right-of-use asset of \$1,830, which consists of the lease liability of \$768, and \$1,062 of leasehold improvements that revert back to the lessor at the termination of the lease.

In January 2024, the Company entered into a sublease agreement with an unrelated third party to sublease a portion of its office and laboratory space in Cambridge, Massachusetts. The term of the sublease agreement commenced in March 2024 and ends on January 13, 2030. The Company will receive lease payments over the sublease term totaling \$10,400. The sublessee is obligated to pay all real estate taxes and costs related to the subleased premises, including cost of operations, maintenance, repair, replacement and property management.

The following table summarizes the presentation in the Company's consolidated balance sheets of its operating leases:

	<b>December 31,</b>	
	<b>2023</b>	<b>2022</b>
<b>Assets:</b>		
Operating lease assets	\$ 109,793	\$ 110,984
<b>Liabilities:</b>		
Operating lease liabilities	\$ 6,677	\$ 3,601
Operating lease liabilities, net of current portion	105,715	107,942
<b>Total operating lease liabilities</b>	<b>\$ 112,392</b>	<b>\$ 111,543</b>

The following table summarizes the effect of lease costs in the Company's consolidated statement of operations and comprehensive loss:

	<b>Year Ended December 31,</b>	
	<b>2023</b>	<b>2022</b>
Operating lease costs	\$ 22,324	\$ 8,830
Short-term lease costs	1,477	1,375
Variable lease costs	7,229	4,547
Sublease income	—	—
<b>Total lease costs</b>	<b>\$ 31,030</b>	<b>\$ 14,752</b>

During the years ended December 31, 2023 and 2022, the Company made cash payments for operating leases of \$15,656 and \$7,809, respectively.



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As of December 31, 2023, future payments of operating lease liabilities are as follows (in thousands):

	<b>As of December 31, 2023</b>
2024	\$ 19,869
2025	22,062
2026	22,674
2027	23,347
2028	23,580
2029 and thereafter	65,819
Total future payments of operating lease liabilities	\$ 177,351
Less: imputed interest	(64,959)
Present value of operating lease liabilities	\$ 112,392

As of December 31, 2023, the weighted average remaining lease term was 7.95 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 13%. As of December 31, 2022, the weighted average remaining lease term was 8.92 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 13%.

## 9. Notes Payable

On October 29, 2019 (“Hercules Closing Date”), the Company entered into a Loan and Security Agreement (the “Hercules Loan Agreement”) with Hercules Capital, Inc. (“Hercules”) pursuant to which a term loan in an aggregate principal amount of up to \$50,000 (the “Original Credit Facility”) was available to the Company in three tranches, subject to certain terms and conditions. Effective as of February 24, 2022 (the “Effective Date”), the Company entered into an Amendment to the Hercules Loan Agreement (the “Amendment”), with the lenders party thereto (the “Hercules Lenders”), and Hercules in its capacity as the administrative agent and the collateral agent for the Hercules Lenders, which amended the Original Credit Facility. Pursuant to the Amendment, a term loan facility in an amount of \$100,000 (the “Hercules Credit Facility”) became available to the Company in five tranches, including the first tranche of \$25,000 previously drawn under the Original Credit Facility, subject to certain terms and conditions.

The first tranche in an aggregate principal amount of \$25,000 was outstanding as of the Effective Date, after taking into account reborrowing by the Company on the Effective Date of a previously-repaid principal amount of approximately \$2,900. The second tranche in an aggregate principal amount of \$12,500 and the third tranche in an aggregate principal amount of \$12,500 were advanced to the Company and were outstanding as of the Effective Date. The fourth and fifth tranches, in an aggregate principal amounts of \$25,000 each, were available upon satisfaction of certain conditions, but were not drawn before the repayment and extinguishment of the Hercules Credit Facility.

All advances outstanding under the Hercules Credit Facility bore interest at a rate equal to the greater of either (i) the Prime Rate (as reported in The Wall Street Journal) plus 6.40%, or (ii) 9.65%. The Company had the option to prepay advances under the Hercules Credit Facility, in whole or in part, at any time subject to a prepayment charge, and the Hercules Loan Agreement included an end of term charge of 4.85% of the aggregate amount of the advances made under the Original Credit Facility, as well as an additional end of term charge of 1.75% of the aggregate amount of the advances under the Hercules Credit Facility (including the first tranche of \$25,000), each due as specified in the Amendment.

The Hercules Credit Facility was secured by substantially all of the Company’s assets, other than the Company’s intellectual property. The Company agreed to not pledge or secure its intellectual property to others.

The Company accounted for the Amendment as a modification in accordance with the guidance in ASC 470-50, *Debt* (“ASC 470”). Amounts paid to the lenders were recorded as debt discount and a new effective interest rate was established. Upon issuance, the Hercules Credit Facility was recorded as a liability with an initial carrying value of \$50,586, net of debt issuance costs. The initial carrying value was accreted to the repayment amount, which includes the outstanding principal plus the end of term charge, through interest expense using the effective interest rate method over the term of the debt. As of December 31, 2022, the carrying value of the debt was \$51,047.

On April 27, 2023 (the “Closing Date”), the Company entered into the Credit Agreement and Guaranty (the “Oaktree Credit Agreement”) among the Company, the subsidiary guarantors from time to time party thereto, the lenders from time to time party thereto (the “Lenders”), and Oaktree Fund Administration, LLC, in its capacity as administrative agent for the Lenders (in such capacity, the “Agent”). The Oaktree Credit Agreement establishes a term loan facility of \$250,000 (the “Term Loan”) consisting of (i) \$80,000 (“Tranche A-1”) and (ii) \$30,000 (“Tranche A-2” and collectively, “Tranche A Loan”), funded on the Closing Date. The Term Loan also consists of (i) \$45,000 (the “Tranche B Loan”) and (iii) \$45,000 (the “Tranche C Loan”), each of which the Company may borrow subject to certain conditions, and (iv) \$50,000 (the “Tranche D Loan”) available in Oaktree’s sole discretion. The Tranche B Loan may be drawn by the Company until September 30, 2024, if VOWST net sales for the trailing six consecutive months are at least \$35,000 and at least 4.5% greater in the calendar quarter prior to the Applicable Funding Date (as defined in the Oaktree Credit Agreement) over the calendar quarter immediately preceding it. The Tranche C Loan may be drawn until September 30, 2025, if VOWST net sales for the trailing 12 consecutive months are at least \$120,000 and at least 4.5% greater in each of the two calendar quarters prior to the Applicable Funding Date relative, in each case, to the calendar quarter immediately preceding it. The Term Loan has a maturity date of April 27, 2029 (the “Maturity Date”).

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Of the \$110,000 Tranche A Loan advanced by the Lenders at closing, approximately \$53,380 repaid the Company's existing credit facility with Hercules. After deducting other transaction expenses and fees, the Company received net proceeds of approximately \$50,446. The Company accounted for the repayment of the Hercules Credit Facility as an extinguishment in accordance with the guidance in ASC 470-50, and recognized a loss on extinguishment of \$1,625 in other income (expense) in the accompanying consolidated statements of operations and comprehensive loss for the year ended December 31, 2023.

Borrowings under the Term Loan bear interest at a rate per annum equal to the three-month term Secured Overnight Financing Rate ("SOFR") (subject to a 2.50% floor and a 5.00% cap), plus an applicable margin of 7.875%, payable quarterly in arrears. If certain VOWST net sales targets are met, the applicable margin will be reduced from 7.875% to 7.50% through the Maturity Date. The Company is required to make quarterly interest-only payments on the Term Loan for the first three years after the Closing Date. Beginning on June 30, 2026, the Company will be required to make quarterly payments of interest, plus repay 7.50% of the outstanding principal of the Term Loan in quarterly installments until the Maturity Date, unless the interest only period is extended based upon the achievement of certain VOWST net sales targets.

The Company is obligated to pay the Lenders an exit fee equal to 1.50% of the aggregate amount of the Term Loan funded, such exit fee to be due and payable upon the earliest to occur of (1) the Maturity Date, (2) the acceleration of the outstanding Term Loan, and (3) the prepayment of the outstanding Term Loan. The Company may voluntarily prepay the outstanding Term Loan, subject to a customary make-whole for the first two years following the Closing Date plus 4.0% of the principal amount of the Term Loan prepaid, and thereafter a prepayment premium equal to (i) 4.0% of the principal amount of the Term Loan prepaid, if prepaid after the second anniversary of the Closing Date through and including the third anniversary of the Closing Date, (ii) 2.0% of the principal amount of the Term Loan if prepaid after the third anniversary of the Closing Date through and including the fourth anniversary of the Closing Date, (iii) 1.0% of the principal amount of the Term Loan if prepaid after the fourth anniversary of the Closing Date through and including the fifth anniversary of the Closing Date, with no prepayment premium due after the fifth anniversary of the Closing Date through the Maturity Date.

The Company's obligations under the Oaktree Credit Agreement and the other Loan Documents (as defined in the Oaktree Credit Agreement) will be guaranteed by any domestic subsidiaries of the Company that become Guarantors (as defined in the Oaktree Credit Agreement), subject to certain exceptions. The Company's and the Guarantors' (collectively, the "Loan Parties") respective obligations under the Oaktree Credit Agreement and the other Loan Documents are secured by first priority security interests in substantially all assets of the Loan Parties, including intellectual property, subject to certain customary thresholds and exceptions. As of December 31, 2023, there were no Guarantors.

The Oaktree Credit Agreement contains customary representations, warranties and affirmative and negative covenants, including a financial covenant requiring the Company to maintain certain levels of cash and cash equivalents in accounts subject to a control agreement in favor of the Agent of at least \$30,000 at all times commencing from 30 days after the Closing Date and decreasing to \$25,000 of cash and cash equivalents in such controlled accounts after the Company borrows any Tranche B Loan. As of December 31, 2023, the Company was in compliance with all financial covenants pursuant to the Oaktree Credit Agreement.

In addition, the Oaktree Credit Agreement contains certain events of default that entitle the Agent to cause the Company's indebtedness under the Oaktree Credit Agreement to become immediately due and payable, and to exercise remedies against the Loan Parties and the collateral securing the Term Loan, including cash. In an event of default and for its duration, as defined in the Oaktree Credit Agreement, an additional default interest rate equal to 2.0% per annum may apply to all obligations owed under the Oaktree Credit Agreement.

On the Closing Date, the Company issued to the Lenders warrants to purchase 647,589 shares (subject to certain adjustments) of the Company's common stock (the "Tranche A Warrant"), at an exercise price per share of \$6.69. The Tranche A Warrant is immediately exercisable and the exercise period expires on April 26, 2030. Upon the funding of each of the Tranche B Loan and the Tranche C Loan, the Company is required to issue to the Lenders warrants to purchase 264,922 shares (subject to certain adjustments) of the Company's common stock on each such funding date at an exercise price equal to the trailing volume weighted average price of the Company's common stock for the 30 trading days prior to the funding date for each tranche (the "Tranche B Warrant" and the "Tranche C Warrant," respectively, and together the "Additional Warrants"). The Additional Warrants will be immediately exercisable upon issuance, and the exercise period will expire seven years from the date of issuance.

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The Company determined that the Tranche A Loan, the Tranche A Warrant, the commitment by the Lenders to fund the Tranche B Loan and the Tranche C Loan, and the Tranche B Warrant and Tranche C Warrant, are all freestanding financial instruments. On the Closing Date, the Company evaluated the Tranche A Warrant and determined that it meets the requirements for equity classification under ASC 815, Derivatives and Hedging (“ASC 815”). The net proceeds from the Tranche A Loan were allocated to the Tranche A Warrant and the Tranche A Loan using the relative fair value method, and the relative fair value of the Tranche A Warrant, \$2,785, is recorded as an increase to additional paid-in-capital on the consolidated statements of stockholder’s equity (deficit), and as a discount to the Tranche A Loan that will be amortized over the life of the Tranche A Loan using the effective interest method. The Company used the Black-Scholes option pricing model to determine the fair value of the Tranche A Warrant. Assumptions used in the Black-Scholes model included the fair market value per share of common stock on the valuation date of \$5.32, the exercise price per warrant equal to \$6.69, the expected volatility of 111.6%, the risk-free interest rate of 3.57%, the expected term of 7 years and the absence of a dividend.

The Additional Warrants are considered outstanding instruments at the Closing Date of the Oaktree Credit Agreement and in accordance with ASC 815, are initially recognized at their respective fair values as derivative liabilities given the variable settlement amount of their respective aggregate exercise prices. The Company adjusts the carrying values of the Additional Warrants to their respective fair values at each reporting period, until such time that the Additional Warrants are issued and their respective exercise prices become fixed, and the value of the Additional Warrants is reclassified to additional paid-in capital. The Company uses a simulation model to determine the fair value of the Additional Warrants, as described in Note 3, Fair Value Measurements. The fair value of the Tranche B Warrant and Tranche C Warrant derivative liabilities was \$1,077, \$1,023, \$276, and \$270 on the Closing Date and at December 31, 2023, respectively.

Changes in the fair values of the Additional Warrants are recorded as other income (expense) in the consolidated statements of operations and comprehensive loss. In addition to the relative fair value of the Tranche A Warrant, the original issue discount and certain debt issuance costs were recorded as a discount to the Tranche A Loan, the total of which will be accreted to the Tranche A Loan as interest expense over the life of the Tranche A Loan using the effective interest method. The fair values of the derivative liabilities associated with the Tranche B Warrant and Tranche C Warrant are recorded as loan commitment prepaid assets on the Closing Date, which are included in the consolidated balance sheets in other non-current assets, and will be reclassified as discounts to the associated Term Loan balances at such time that they are drawn.

The effective interest rate in effect as of December 31, 2023 was 15.9%. As of December 31, 2023, the carrying value of the Term Loan was \$101,544, which is classified as a long-term liability on the consolidated balance sheets. The future principal payments due under the Oaktree Credit Agreement, excluding interest and the end of term charge, are as follows:

<b>Year Ending December 31,</b>	<b>Principal</b>
2024	\$ —
2025	—
2026	24,750
2027	33,000
2028	33,000
Thereafter	19,250
<b>Total</b>	<b>\$ 110,000</b>

During the year ended December 31, 2023, the Company recognized \$2,468 and \$10,708 of interest expense under the Hercules Credit Facility and Oaktree Credit Agreement, respectively, which is reflected in interest expense on the consolidated statement of operations and comprehensive loss. During the year ended December 31, 2022, the Company recognized \$6,020 of interest expense related to the Hercules Credit Facility.

**10. Preferred Stock**

On July 1, 2015, in connection with the closing of the initial public offering of the Company’s common stock (“IPO”), the Company effected its Restated Certificate of Incorporation, which authorizes the Company to issue 10,000,000 shares of preferred stock, \$0.001 par value per share.

## **11. Common Stock and Stock-Based Awards**

On July 1, 2015, in connection with the closing of the IPO, the Company effected its Restated Certificate of Incorporation, which authorizes the Company to issue 200,000,000 shares of common stock, \$0.001 par value per share. On March 29, 2023, the Company's board of directors adopted a resolution to amend the Restated Certificate of Incorporation, subject to stockholder approval, by increasing the number of authorized shares of the Company's Common Stock from 200,000,000 shares to 240,000,000 shares (the "Share Increase Amendment"). At the Company's annual meeting of stockholders held on June 22, 2023, the Company's stockholders approved the Share Increase Amendment. On June 27, 2023, the Company amended its Restated Certificate of Incorporation to reflect the Share Increase Amendment.

In November 2019, the Company entered into a common stock sales agreement, or the 2019 Sales Agreement, with Cowen to sell shares of the Company's common stock with aggregate gross sales proceeds of up to \$25,000, from time to time, through an "at the market" equity offering program, or ATM, under which Cowen acts as sales agent. In March 2020, the Company entered into a new common stock sales agreement, or the 2020 Sales Agreement, with Cowen on substantially the same terms as the 2019 Sales Agreement and terminated the 2019 Sales Agreement. In May 2021, the Company entered into a new common stock sales agreement, or the 2021 Sales Agreement, with Cowen to sell shares of its common stock with aggregate gross sales proceeds of up to \$150,000, from time to time, through an ATM under which Cowen acts as sales agent, and terminated the 2020 Sales Agreement. During the year ended December 31, 2023, the Company sold 7,711,199 shares of common stock under the 2021 Sales Agreement, at an average price of approximately \$2.46 per share, raising aggregate net proceeds of approximately \$18,159 after deducting an aggregate commission of approximately 3% and other issuance costs. During the year ended December 31, 2022, the Company sold 655,000 shares of common stock under the 2021 Sales Agreement, at an average price of approximately \$7.26 per share, raising aggregate net proceeds of approximately \$4,447 after deducting an aggregate commission of approximately 3% and other issuance costs.

Between December 31, 2023 and February 29, 2024, the Company sold 15,366,630 shares of common stock under the 2021 Sales Agreement, at an average price of approximately \$1.23 per share, raising aggregate net proceeds of approximately \$18,484 after deducting an aggregate commission of approximately 3% and other issuance costs.

On June 29, 2022, the Company entered into securities purchase agreements with new and existing investors and certain directors and officers in a registered direct offering, or the Registered Direct Offering, of an aggregate of 31,746,030 shares of its common stock at a purchase price of \$3.15 per share for total net proceeds of approximately \$96,721, after deducting placement agent's fees and other estimated offering expenses. Net proceeds included an aggregate of \$27,525 received from Flagship Pioneering Fund VII, L.P. and Nutritional Health LTP Fund, L.P., affiliates of Flagship Pioneering, or Flagship, one of its significant stockholders, in exchange for 8,738,243 shares. The closing date of the Registered Direct Offering was July 5, 2022.

### **2012 Stock Incentive Plan**

The Company's 2012 Stock Incentive Plan, as amended, (the "2012 Plan") provided for the Company to sell or issue common stock or restricted common stock, or to grant incentive stock options or nonqualified stock options for the purchase of common stock, to employees, members of the board of directors and consultants of the Company. The 2012 Plan is administered by the board of directors, or at the discretion of the board of directors, by a committee of the board of directors. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors, or their committee if so delegated, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the share of common stock on the date of grant and the term of stock option may not be greater than ten years. The Company generally granted stock-based awards with service conditions only ("service-based" awards).

Stock options granted under the 2012 Plan generally vest over four years and expire after ten years, although options have been granted with vesting terms less than four years. As of December 31, 2023, there were no shares available for future grant under the 2012 Plan.

### **2015 Incentive Award Plan**

On June 16, 2015, the Company's stockholders approved the 2015 Incentive Award Plan (the "2015 Plan"), which became effective on June 25, 2015. The 2015 Plan was subsequently amended on December 14, 2022, and provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards. The number of shares initially reserved for issuance under the 2015 Plan was the sum of (i) 2,200,000 shares of common stock and (ii) the number of shares subject to awards outstanding under the 2012 Plan that expire, terminate or are otherwise surrendered, canceled, forfeited or repurchased by the Company on or after the effective date of the 2015 Plan. In addition, the number of shares of common stock that may be issued under the 2015 Plan is subject to increase on the first day of each calendar year, beginning in 2016 and ending in 2025, equal to the lesser of (i) 4% of the number of shares of the Company's common stock outstanding on the last day of the preceding applicable calendar year and (ii) an amount determined by the Company's board of directors.

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Stock awards granted under the 2015 Plan generally vest over four years and expire after ten years, although options have been granted with vesting terms less than four years. As of December 31, 2023, there were 2,545,586 shares available for future grant under the 2015 Plan.

**2015 Employee Stock Purchase Plan**

On June 16, 2015, the Company's stockholders approved the 2015 Employee Stock Purchase Plan (the "ESPP"), which became effective on June 25, 2015. A total of 365,000 shares of common stock were reserved for issuance under the ESPP. In addition, the number of shares of common stock that may be issued under the ESPP automatically increase on the first day of each calendar year, beginning in 2016 and ending in 2025, by an amount equal to the lesser of (i) 400,000 shares, (ii) 1% of the number of shares of the Company's common stock outstanding on the last day of the applicable preceding calendar year and (iii) an amount determined by the Company's board of directors. Offering periods under the ESPP will commence when determined by the plan administrator. During the year ended and as of December 31, 2023, there were 602,692 shares issued and 2,266,512 shares were reserved and available for issuance under the ESPP, respectively.

The ESPP provides that eligible employees may contribute up to 15% of their eligible earnings toward the semi-annual purchase of the Company's common stock. Purchase rights issued under the ESPP are intended to be qualified under Section 423 of the Internal Revenue Code ("IRC"). The employee's purchase price is derived from a formula based on the closing price of the common stock on the first day of the offering period versus the closing price on the date of purchase (or, if not a trading day, on the immediately preceding trading day). The offering period under the ESPP has a duration of six months, and the purchase price with respect to each offering period beginning on or after such date is, until otherwise amended, equal to 85% of the lesser of (i) the fair market value of the Company's common stock at the commencement of the applicable six-month offering period or (ii) the fair market value of the Company's common stock on the purchase date.

**2022 Employment Inducement Award Plan**

On December 14, 2022, the Company's board of directors approved the 2022 Employment Inducement Award Plan (the "2022 Plan"), which became effective on such date without stockholder approval pursuant to Rule 5635(c)(4) of The Nasdaq Stock Market LLC listing rules ("Rule 5635(c)(4)"). The 2022 Plan provides for the grant of nonqualified stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock- or cash-based awards. In accordance with Rule 5635(c)(4), awards under the 2022 Plan may only be made to a newly hired employee who has not previously been a member of our board of directors, or an employee who is being rehired following a bona fide period of non-employment by us as a material inducement to the employee's entering into employment with us. A total of 2,500,000 shares of common stock were reserved for issuance under the 2022 Plan. Any shares subject to awards previously granted under the 2022 Plan that expire, terminate or are otherwise surrendered, canceled, or forfeited in any case, in a manner that results in the Company acquiring the shares covered by the award at a price not greater than the price (as adjusted to reflect any equity restructuring) paid by the Participant for such shares or not issuing any shares covered by the award, the unused shares covered by the award will again be available for award grants under the 2022 Plan.

As of December 31, 2023, there were 2,382,884 shares available for future grant under the 2022 Plan.

**Stock Options**

The following table summarizes the Company's stock option activity for the year ended December 31, 2023:

	<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Term (in years)</u>	<u>Aggregate Intrinsic Value</u>
Outstanding as of December 31, 2022	14,940,034	\$ 10.03	7.25	\$ 11,608
Granted	2,508,553	5.44		
Exercised	(260,640)	3.36		
Forfeited	(2,343,835)	8.30		
Outstanding as of December 31, 2023	14,844,112	\$ 9.64	5.71	\$ —
Vested or expected to vest as of December 31, 2023	14,844,112	\$ 9.64	5.66	\$ —
Options exercisable as of December 31, 2023	10,488,694	\$ 10.09	4.61	\$ —

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The weighted average grant-date fair value of stock options granted during the years ended December 31, 2023 and 2022 was \$4.51 and \$5.53 per share, respectively. The total intrinsic value of stock options exercised during the years ended December 31, 2023 and 2022 was \$438 and \$981, respectively.

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock.

During the year ended December 31, 2021, the Company granted performance-based stock options to employees for the purchase of an aggregate of 562,000 shares of common stock with a grant date fair value of \$5.53 per share. These stock options are exercisable only upon achievement of specified performance targets. In April 2023, the performance target associated with 50% of the performance-based stock options was achieved. Accordingly, the Company recorded \$2,051 of compensation expense during the year ended December 31, 2023, with respect to these performance-based stock options, which represents a cumulative catch-up from the grant date through the achievement of the performance targets, and vesting of the remaining 50% of the options beginning in April 2023, partially offset by the reversal of stock-based compensation expense associated with the forfeiture of unvested awards. The remaining compensation expense associated with these performance-based stock options will be recognized ratably through April 2024, for all such options for which ongoing performance targets are achieved and service requirements are met.

**Restricted Stock Units**

The Company has granted restricted stock units with service-based vesting conditions ("RSUs") and restricted stock units with performance-based vesting conditions ("PSUs"). RSUs and PSUs represent the right to receive shares of common stock upon meeting specified vesting requirements. Restricted stock units may not be sold or transferred by the holder and vest according to the vesting conditions of each award. The table below summarizes the Company's RSU and PSU activity for the year ended December 31, 2023:

	<b>Number of Shares</b>	<b>Weighted Average Grant Date Fair Value</b>
Unvested restricted stock units as of December 31, 2022	1,549,540	\$ 9.37
Granted	4,424,479	\$ 4.14
Forfeited	(1,071,571)	\$ 6.94
Vested	(1,524,644)	\$ 7.22
Unvested restricted stock units as of December 31, 2023	<u>3,377,804</u>	<u>\$ 4.26</u>

During the years ended December 31, 2023 and 2022, the Company granted 3,101,764 and 1,302,844 RSUs, respectively. During the year ended December 31, 2023 and 2022, the Company granted 1,322,715 and 0 PSUs, respectively. RSUs generally vest over four years, with 25% vesting after one year, and the remaining 75% vesting quarterly over the next 3 years, subject to continued service to the Company through the applicable vesting date. PSUs vest according to the performance requirements of the awards, generally when the Company has determined that the specified performance targets have been achieved.

The aggregate intrinsic value of RSUs, including PSUs for which the performance conditions have been met, that vested during the years ended December 31, 2023 and 2022 was \$4,729 and \$1,809, respectively.

In November 2023, as part of the corporate restructuring described in Note 13, *Restructuring*, the Company issued retention awards to employees of the Company in the form of RSUs which vest in two tranches on August 15, 2024, and May 15, 2025, subject to remaining actively employed with the Company through such date. The \$1,255 in compensation expense associated with these awards will be recognized ratably over the vesting period. For the year ended December 31, 2023, the Company recognized \$92 in compensation expense with respect to the retention awards.

In connection with the Restructuring Plan, the Company elected to accelerate the vesting of certain RSUs and PSUs previously granted to employees who were terminated as part of the Restructuring Plan. The Company accounted for the acceleration as a modification under applicable accounting standards, in which awards that were previously deemed not probable of vesting due to the employees' terminations became probable. Accordingly, the Company reversed \$1,191 of compensation cost that had previously been recognized during the year ended December 31, 2023 on these awards and recorded the incremental fair value of the awards on the modification date of \$261.

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During the year ended December 31, 2021, the Company granted PSUs to two employees covering an aggregate of 85,000 shares of common stock with a grant date fair value of \$9.59 per share and 40,000 shares with a grant date fair value of \$20.35 per share. These PSUs vest only upon achievement of specified performance targets. In October 2022, 42,500 of the awards with a grant date fair value of \$9.59, and 20,000 of the awards with a grant date fair value of \$20.35, vested fully, as the associated performance targets were achieved. Accordingly, the Company recorded \$815 in compensation expense during the year ended December 31, 2022, with respect to these awards. In April 2023, the remaining PSUs underlying these awards vested because the associated targets were achieved. Accordingly, the Company recorded the remaining \$815 in compensation expense during the year ended December 31, 2023, with respect to these PSUs.

During the year ended December 31, 2023, the Company granted PSUs to employees covering an aggregate of 1,322,715 shares of common stock with a grant date fair value of \$5.50. These PSUs begin to vest ratably only upon achievement of specified performance targets, which were achieved in April 2023. Accordingly, the Company recorded \$4,293 in compensation expense during the year ended December 31, 2023, with respect to these PSUs. The remaining \$1,092 in compensation expense associated with these PSUs will be recognized ratably through October 2024.

**Stock-based Compensation Valuation**

The assumptions that the Company used to determine the fair value of the stock options granted to employees and directors were as follows, presented on a weighted average basis:

	<b>Year Ended December 31,</b>	
	<b>2023</b>	<b>2022</b>
Risk-free interest rate	3.64%	1.67%
Expected term (in years)	6.0	6.0
Expected volatility	107.2%	104.0%
Expected dividend yield	0%	0%

The Company estimates the fair value of rights to acquire common stock under the ESPP using a Black-Scholes valuation model on the date of grant and the straight-line attribution approach to recognize the expense. The assumptions that the Company used to determine the fair value of rights to acquire common stock under the ESPP were as follows, presented on a weighted average basis:

	<b>Year Ended December 31,</b>	
	<b>2023</b>	<b>2022</b>
Risk-free interest rate	5.01%	2.11%
Expected term (in years)	0.5	0.5
Expected volatility	79.1%	99.0%
Expected dividend yield	0%	0%

**Stock-based Compensation**

The Company recorded stock-based compensation expense related to stock options and restricted stock units in the following expense categories of its consolidated statements of operations and comprehensive loss:

	<b>Year Ended December 31,</b>	
	<b>2023</b>	<b>2022</b>
Research and development expenses	\$ 19,341	\$ 13,429
General and administrative expenses	14,760	12,053
	<u>\$ 34,101</u>	<u>\$ 25,482</u>

As of December 31, 2023, the Company had an aggregate of \$35,036 of unrecognized stock-based compensation cost, which is expected to be recognized over a weighted average period of 2.1 years.



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**12. Net Loss per Share**

Basic and diluted net loss per share attributable to common stockholders was calculated as follows:

	<b>Year Ended December 31,</b>	
	<b>2023</b>	<b>2022</b>
Numerator:		
Net loss attributable to common stockholders	\$ (113,724)	\$ (250,157)
Denominator:		
Weighted average common shares outstanding, basic and diluted	128,003,294	108,077,043
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.89)	\$ (2.31)
Anti-dilutive potential common stock equivalents excluded from the calculation of net loss per share:		
Stock options to purchase common stock	14,844,112	14,940,034
Unvested restricted stock units	3,377,804	1,549,540
Shares issuable under employee stock purchase plan	297,784	89,593
Warrants to purchase common stock	1,177,433	—

The Company's potential dilutive securities, which include stock options, unvested restricted common stock and shares issuable under the ESPP, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share and therefore been anti-dilutive. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. Additionally, for the year ended December 31, 2023, the warrants to purchase common stock were excluded because the exercise price of the Tranche A Warrants is greater than the average fair value of the Company's common shares, and the necessary conditions for exercise of the Tranche B and Tranche C Warrants had not been met.

**13. Restructuring**

On November 2, 2023, the Company announced the Restructuring Plan to prioritize the commercialization of VOWST and the completion of the SER-155 Phase 1b study, while significantly reducing costs and supporting longer-term business sustainability. The Restructuring Plan included (i) a reduction of the Company's workforce by approximately 41% across the organization, resulting in the elimination of approximately 160 positions; (ii) significantly scaling back all non-partnered research and development activities other than the completion of the SER-155 Phase 1b study; and (iii) reducing general and administrative expenses, including consolidating office space.

During the year ended December 31, 2023, the Company recognized a restructuring charge of \$5,606, which was incurred entirely in the fourth quarter of 2023, and which represents all restructuring charges expected to be incurred. Restructuring charges included approximately \$5,345 of employee related termination costs in the form of salary continuation and cash severance payments, and \$261 related to the acceleration of vesting of certain previously granted RSUs and PSUs. The following tables summarize the restructuring related charges and classification by line item within the Company's consolidated statements of operations during the year ended December 31, 2023:

	<b>Year Ended December 31, 2023</b>		
	<b>Research and development</b>	<b>General and administrative</b>	<b>Total</b>
Severance and other employee costs	3,318	2,027	5,345
Acceleration of unvested equity awards	163	98	261
Total restructuring charges	3,481	2,125	5,606



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The restructuring charge is included in accrued expenses and other current liabilities in the Company's consolidated balance sheets. The following table presents changes in the restructuring liability for the year ended December 31, 2023 (in thousands):

	<b>As of December 31, 2023</b>
Restructuring expenses	\$ 5,606
Less: stock-based compensation	\$ (261)
Cash payments made	(265)
Remaining liability included in accrued expenses and other current liabilities	\$ 5,080

The Company expects that substantially all of the accrued restructuring charges as of December 31, 2023 will be paid in cash by March 31, 2024.

**Retention Awards**

In November 2023, upon recommendation of the Company's Compensation Committee, the Board of Directors approved retention awards for employees of the Company in the form of RSUs which vest in two tranches on August 15, 2024, and May 15, 2025, subject to remaining actively employed with the Company through such date. The \$1,255 in compensation expense associated with these awards will be recognized ratably over the vesting period.

**14. Revenue from Contracts with Customers**

***License Agreement with NHSc Rx License GmbH (Nestlé)***

*Summary of Agreement*

In July 2021, the Company entered into the 2021 License Agreement with NHSc Pharma Partners, succeeded by NHSc Rx License GmbH (together with Société des Produits Nestlé S.A., their affiliates, and their subsidiaries, "Nestlé") (the "2021 License Agreement"). Under the terms of the 2021 License Agreement, the Company granted Nestlé a co-exclusive, sublicensable (under certain circumstances) license to develop, commercialize and conduct medical affairs activities for (i) therapeutic products based on the Company's microbiome technology (including VOWST, previously the Company's SER-109 product candidate) that are developed by the Company or on the Company's behalf for the treatment of CDI and recurrent CDI, as well as any other indications pursued for the products upon mutual agreement of the parties (the "2021 Field") in the United States and Canada (the "2021 Licensed Territory"), and (ii) VOWST and any improvements and modifications thereto developed pursuant to the terms of the 2021 License Agreement (the "2021 Collaboration Products") for any indications in the 2021 Licensed Territory. The Company is responsible for completing development of the first 2021 Collaboration Product, which is VOWST, in the 2021 Field in the United States until first regulatory approval, which was obtained on April 26, 2023.

Nestlé has the sole right to commercialize the 2021 Collaboration Products in the 2021 Licensed Territory in accordance with a commercialization plan. Both parties will perform medical affairs activities in the 2021 Licensed Territory in accordance with a medical affairs plan. The Company is responsible for the manufacturing and supply for commercialization under a supply agreement that has been executed between the parties. Both parties performed pre-launch activities of VOWST prior to the first commercial sale in the United States, which occurred in June 2023. The Company was responsible for funding the pre-launch activities until first commercial sale of VOWST in the 2021 Licensed Territory and in accordance with a pre-launch plan, up to a specified cap. The Company is entitled to share equally in the commercial profits and losses of VOWST.

In connection with the 2021 License Agreement, the Company received an upfront payment of \$175,000, and the Company received an additional \$125,000 milestone payment in May 2023 after FDA approval of VOWST. The Company is eligible to receive additional payments of up to \$235,000 if certain regulatory and sales milestones are achieved. The potential future milestone payments include up to \$10,000 for the achievement of specified regulatory milestones and up to \$225,000 for the achievement of specified net sales milestones.

The 2021 License Agreement continues in effect until all development and commercialization activities for all 2021 Collaboration Products in the 2021 Licensed Territory have permanently ceased. The 2021 License Agreement may be terminated by either party upon sixty days' written notice for the other party's material breach that remains uncured during such sixty-day period, or immediately upon written notice for the other party's insolvency. Nestlé may also terminate the 2021 License Agreement at-will with twelve months' prior written notice, effective only on or after the third anniversary of first commercial sale of VOWST in the 2021 Licensed Territory. The Company may also terminate the 2021 License Agreement immediately upon written notice if Nestlé challenges any licensed patent in the 2021 Licensed Territory. Upon termination of the 2021 License Agreement, all licenses granted to Nestlé by the Company will terminate. If the Company commits a material breach of the 2021 License Agreement, Nestlé may elect not to terminate the 2021 License Agreement but instead apply specified adjustments to the payment terms and other terms and conditions of the 2021 License Agreement.

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*Accounting Analysis*

The 2021 License Agreement represents a separate contract between Nestlé and the Company. The 2021 License Agreement is within the scope of Accounting Standard Update 2018-18, *Collaborative Arrangements (Topic 808)* (see Note 15, *Collaboration Profit and Loss*), and has elements that are within the scope of ASC 606 - *Revenue From Contracts with Customers (Topic 606)* and Topic 808.

The Company identified the following promises in the 2021 License Agreement that were evaluated under the scope of Topic 606: (i) delivery of a co-exclusive license for VOWST to develop, commercialize and conduct medical affairs in the United States and Canada; (ii) services to be performed in accordance with the development and regulatory activity plan to obtain regulatory approval of VOWST in the United States. The Company also evaluated whether certain options outlined within the 2021 License Agreement represented material rights that would give rise to a performance obligation and concluded that none of the options convey a material right to Nestlé and therefore are not considered separate performance obligations within the 2021 License Agreement.

The Company assessed the above promises and determined that the co-exclusive license for VOWST and the services to obtain regulatory approval of VOWST in the United States are reflective of a vendor-customer relationship and therefore represent performance obligations within the scope of Topic 606. The co-exclusive license for VOWST in the United States and Canada is considered functional intellectual property and distinct from other promises under the contract as Nestlé can benefit from the license on its own or together with other readily available resources. The services performed by the Company to obtain regulatory approval of VOWST were not complex or specialized, could be performed by another qualified third party, were not expected to significantly modify or customize the license given that VOWST was late-stage intellectual property that completed clinical development and the services were performed over a short period of time. Therefore, the license and the services each represents a separate performance obligation within a contract with a customer under the scope of Topic 606 at contract inception.

The up-front payment of \$175,000 compensated the Company for: (i) the co-exclusive license for VOWST to develop, commercialize and conduct medical affairs in the United States and Canada, (ii) services performed in accordance with the development and regulatory activity plan to obtain regulatory approval of VOWST in the United States and (iii) pre-launch activities performed by Nestlé and the Company until the first commercial sale of VOWST in the United States. The commercialization activities, which include the commercial manufacturing, participation on joint steering committees and medical affairs work, that occur after regulatory approval of VOWST in the United States, are part of the 50/50 sharing of commercial profits. Therefore, the up-front payment of \$175,000 does not compensate the Company for these activities.

The Company allocated the \$175,000 between the Topic 606 unit of account and the Topic 808 unit of account by determining the standalone selling price (SSP) of each good or service. The selling price of each good or service was determined based on the Company's SSP with the objective of determining the price at which it would sell such an item if it were to be sold regularly on a standalone basis. The Company determined the transaction price under Topic 606 to be \$139,500 and the Topic 808 amount to be \$35,500 at the inception of the 2021 License Agreement (see Note 15, *Collaboration Profit and Loss*).

The Topic 606 transaction price of \$139,500 was allocated to the co-exclusive license for VOWST and the services performed in accordance with the development and regulatory activity plan to obtain regulatory approval of VOWST in the United States based on the Company's SSP. The Company recognized revenue for the license performance obligation at a point in time, that is upon transfer of the license to Nestlé. As control of the license was transferred in July 2021, the Company recognized \$131,343 of collaboration revenue - related party during the year ended December 31, 2021 pertaining to the license performance obligation. The remaining amount of the Topic 606 transaction price of \$8,157 was allocated to the services performance obligation and was recognized over time as the Company performed the services, which it completed in April 2023. During the years ended December 31, 2023 and 2022, the Company recognized \$1,975 and \$4,114 of collaboration revenue - related party, respectively, related to the services performance obligation under the 2021 License Agreement.

The Company determined that any variable consideration related to the remaining regulatory milestones is deemed to be fully constrained and therefore excluded from the transaction price due to the high degree of uncertainty and risk associated with these potential payments, as the Company determined that it could not assert that it was probable that a significant reversal in the amount of cumulative revenue recognized will not occur. The Company also determined that sales milestones relate solely to the license of intellectual property and are therefore excluded from the transaction price under the sales- or usage-based royalty exception of Topic 606. Revenue related to these sales milestones will only be recognized when the associated sales occur, and relevant thresholds are met.

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The Company recognized the \$125,000 regulatory milestone payment received in May 2023, which was fully allocated to the license performance obligation, as revenue in the consolidated statements of operations and comprehensive loss during the year ended December 31, 2023.

***Collaboration and License Agreement with Société des Produits Nestlé S.A. (Nestlé)***

*Summary of Agreement*

In January 2016, the Company entered into a collaboration and license agreement with Nestec Ltd., succeeded by Société des Produits Nestlé S.A. (together with NHSc Rx License GmbH, their affiliates and their subsidiaries, “Nestlé”) (the “2016 License Agreement”) for the development and commercialization of certain product candidates for the treatment and management of CDI and inflammatory bowel disease (“IBD”), including UC and Crohn’s disease. The 2016 License Agreement supports the development of the Company’s portfolio of products for CDI and IBD in markets outside of the United States and Canada (the “2016 Licensed Territory”).

Under the 2016 License Agreement, the Company granted to Nestlé an exclusive, royalty-bearing license to develop and commercialize, in the 2016 Licensed Territory, certain products based on its microbiome technology that are being developed or commercialized, as applicable, for the treatment of CDI and IBD, including VOWST, SER-262, SER-287 and SER-301 (collectively, the “2016 Collaboration Products”). The 2016 License Agreement sets forth the Company’s and Nestlé’s respective obligations for development, commercialization, regulatory and manufacturing and supply activities for the 2016 Collaboration Products with respect to the licensed fields and the 2016 Licensed Territory.

Under the 2016 License Agreement, Nestlé agreed to pay the Company an upfront cash payment of \$120,000, which the Company received in February 2016. The Company is eligible to receive up to \$285,000 in development milestone payments, \$375,000 in regulatory payments and up to an aggregate of \$1,125,000 for the achievement of certain commercial milestones related to the sales of the 2016 Collaboration Products. Nestlé also agreed to pay the Company tiered royalties, at percentages ranging from the high single digits to high teens, of net sales of 2016 Collaboration Products in the 2016 Licensed Territory.

Under the 2016 License Agreement, the Company is entitled to receive a \$20,000 milestone payment from Nestlé following initiation of a SER-287 Phase 2 study and a \$20,000 milestone payment from Nestlé following the initiation of a SER-287 Phase 3 study. In November 2018, the Company entered into a letter agreement with Nestlé which modified the 2016 License Agreement to address the current clinical plans for SER-287. Pursuant to the letter agreement, the Company and Nestlé agreed that following initiation of the SER-287 Phase 2b study, the Company would be entitled to receive \$40,000 in milestone payments from Nestlé, which represent the milestone payments due to the Company for the initiation of a SER-287 Phase 2 study and a Phase 3 study. The SER-287 Phase 2b study was initiated and the \$40,000 of milestone payments were received in December 2018.

The 2016 License Agreement continues in effect until terminated by either party on the following bases: (i) Nestlé may terminate the 2016 License Agreement in the event of serious safety issues related to any of the 2016 Collaboration Products; (ii) the Company may terminate the 2016 License Agreement if Nestlé challenges the validity or enforceability of any of the Company’s licensed patents; and (iii) either party may terminate the 2016 License Agreement in the event of the other party’s uncured material breach or insolvency. Upon termination of the 2016 License Agreement, all licenses granted to Nestlé by the Company will terminate, and all rights in and to the 2016 Collaboration Products in the 2016 Licensed Territory will revert to the Company. If the Company commits a material breach of the 2016 License Agreement, Nestlé may elect not to terminate the 2016 License Agreement but instead apply specified adjustments to its payment obligations and other terms and conditions of the 2016 License Agreement.

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*Accounting Analysis*

The Company assessed the 2016 License Agreement in accordance with Topic 606 and concluded that Nestlé is a customer. The Company identified the following promises under the contract: (i) a license to develop and commercialize the 2016 Collaboration Products in the 2016 Licensed Territory, (ii) obligation to perform research and development services, (iii) participation on a joint steering committee, and (iv) manufacturing services to provide clinical supply to complete future clinical trials. In addition, the Company identified a contingent obligation to perform manufacturing services to provide commercial supply if commercialization occurs, which is contingent upon regulatory approval. This contingent obligation is not a performance obligation at inception and has been excluded from the initial allocation as it represents a separate buying decision at market rates, rather than a material right in the contract. The Company assessed the promised goods and services to determine if they are distinct. Based on this assessment, the Company determined that Nestlé cannot benefit from the promised goods and services separately from the others as they are highly interrelated and therefore not distinct. Accordingly, the promised goods and services represent one combined performance obligation and the entire transaction price will be allocated to that single combined performance obligation.

At contract inception, the Company determined that the \$120,000 non-refundable upfront amount constituted the entirety of the consideration to be included in the transaction price as the development, regulatory, and commercial milestones were fully constrained. During the year ended December 31, 2016, the Company received \$10,000 from Nestlé in connection with the initiation of the Phase 1b study for SER-262 in CDI. During the year ended December 31, 2017, the Company received \$20,000 from Nestlé in connection with the initiation of the Phase 3 study for VOWST, then SER-109. During the year ended December 31, 2018, the Company received \$40,000 from Nestlé in connection with the initiation of the Phase 2b study for SER-287. During the year ended December 31, 2020, the Company received \$10,000 from Nestlé in connection with the initiation of the Phase 1b SER-301 study. As of December 31, 2023, the aggregate amount of the transaction price allocated to the performance obligation of the 2016 License Agreement was approximately \$200,000.

During the years ended December 31, 2023 and 2022, using the cost-to-cost method, which best depicts the transfer of control to the customer, the Company recognized (\$650) and \$3,014 of collaboration revenue – related party, respectively, relating to the 2016 License Agreement.

As of December 31, 2023 and 2022, there was \$95,364, and \$96,689 of deferred revenue related to the unsatisfied portion of the performance obligation under the Nestlé agreements. As of December 31, 2023, deferred revenue is classified as current or non-current in the consolidated balance sheets based on the Company's estimate of revenue that will be recognized within the next twelve months, which is determined by the cost-to-cost method which measures the extent of progress towards completion based on the ratio of actual costs incurred to the total estimated costs expected upon satisfying the performance obligation. All costs associated with the 2016 License Agreement are recorded in research and development expense in the consolidated statements of operations and comprehensive loss.

***Contract Balances from Contracts with Customers***

The following tables present changes in the Company's contract liabilities during the year ended December 31, 2023 and 2022:

	<b>Balance as of December 31, 2022</b>	<b>Additions</b>	<b>Deductions</b>	<b>Balance as of December 31, 2023</b>
<b>Year ended December 31, 2023</b>				
Contract liabilities:				
Deferred revenue - related party	\$ 96,689	1,644	(2,969)	\$ 95,364
	<b>Balance as of December 31, 2021</b>	<b>Additions</b>	<b>Deductions</b>	<b>Balance as of December 31, 2022</b>
<b>Year ended December 31, 2022</b>				
Contract liabilities:				
Deferred revenue - related party	\$ 103,817	—	(7,128)	\$ 96,689

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During the year ended December 31, 2023, the Company recognized the following revenues as a result of changes in the contract liability balances in the respective periods (in thousands):

	Year Ended December 31,	
	2023	2022
<b>Revenue recognized in the period from:</b>		
Amounts included in the contract liability at the beginning of the period	\$ 1,325	\$ 7,128

When consideration is received, or such consideration is unconditionally due, from a customer prior to transferring goods or services to the customer under the terms of a contract, a contract liability is recorded. Revenue is recognized from the contract liability over time using the cost-to-cost method.

**15. Collaboration Profit and Loss**

*License Agreement with NHSc Rx License GmbH (Nestlé)*

*Accounting Analysis*

The 2021 License Agreement represents a separate contract between Nestlé and the Company. The 2021 License Agreement is within the scope of Topic 808, and has elements that are within the scope of Topic 606 (see Note 14, *Revenue from Contracts with Customers*) and Topic 808.

The Company considers the collaborative pre-launch activities and commercialization activities to be separate units of account within the scope of Topic 808 and are not performance obligations under Topic 606. The Company and Nestlé were both active participants in the pre-launch activities and commercialization activities and were exposed to significant risks and rewards that were dependent on the commercial success of the activities in the arrangement. The amount allocated to the Topic 808 unit of accounting relates to the pre-launch activities performed prior to the first commercial sale of VOWST and was determined to be \$35,500 based on standalone selling price.

The Company recorded the \$35,500 in total liabilities on its consolidated balance sheets at the inception of the arrangement. On a quarterly basis, the Company and Nestlé provided financial information about the pre-launch activities performed by both parties. The Company reduced the \$35,500 liability as the pre-launch activities were performed and it made payments to Nestlé for the pre-launch costs Nestlé incurred. As of December 31, 2023 and 2022, there was \$10,064 and \$34,770, respectively, included in accrued expenses and other current liabilities which represents costs incurred by Nestlé for pre-launch activities that have not yet been reimbursed by Seres.

The cost associated with pre-launch activities performed by the Company is recorded within total operating expenses in the Company's consolidated statements of operations and comprehensive loss. In the years ended December 31, 2023 and 2022, the Company recognized \$1,446 and \$6,102 in research and development expenses and \$4,242 and \$8,953 in general and administrative expenses, respectively, associated with pre-launch activities performed. The pre-launch activities were completed prior to the first commercial sale of VOWST, which occurred in June 2023.

Under the 2021 License Agreement with Nestlé, beginning with the first commercial sale of VOWST, which occurred in June 2023, net sales of VOWST are recorded by Nestlé and include gross sales net of discounts, rebates, allowances, and other applicable deductions. These amounts include the use of estimates and judgments, which could be adjusted based on actual results in the future. The Company records its share of the profits or losses from the sales of VOWST, including commercial and medical affairs expenses incurred by the Company, on a net basis, as collaboration (profit) loss sharing - related party. This treatment is in accordance with the Company's revenue recognition and collaboration policy, given that Nestlé and the Company are both active participants in commercialization activities and are exposed to significant risks and rewards that are dependent on the commercial success of the activities in the 2021 License Agreement. Nestlé provides the Company with reporting related to net sales of VOWST in accordance with U.S. generally accepted accounting principles in order to calculate and record collaboration profit or loss.

The collaboration (profit) loss sharing - related party line item also includes the Company's profit on the transfer of VOWST inventory to Nestlé, which represents the excess of the supply price paid by Nestlé over the Company's cost to manufacture VOWST, subject to a supply price cap applicable to product manufactured prior to commercial launch.

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The collaboration (profit) loss sharing - related party line item also includes the collaboration loss related to pre-launch activities, which were completed prior to the first commercial sale of VOWST.

The components of the collaboration profit (loss) sharing for the years ended December 31, 2023 and 2022 are as follows:

	<b>For the Year Ended</b>	
	<b>December 31,</b>	
	<b>2023</b>	<b>2022</b>
Share of VOWST net loss	\$ 18,873	\$ —
Profit on transfer of VOWST inventory to Nestlé	(23,327)	—
Collaboration (profit)/loss related to pre-launch activities	5,158	1,004
Total collaboration (profit) loss sharing - related party	\$ 704	\$ 1,004

**16. Commitments and Contingencies**

***Leases***

Refer to Note 8 “Leases” for discussion of the commitments associated with the Company’s lease portfolio.

***Indemnification Agreements***

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third-parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and its officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company does not believe that the outcome of any claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its consolidated financial statements as of December 31, 2023 or 2022.

***Legal Contingencies***

The Company accrues a liability for legal contingencies when it believes that it is both probable that a liability has been incurred and that the Company can reasonably estimate the amount of the loss. The Company reviews these accruals and adjusts them to reflect ongoing negotiations, settlements, rulings, advice of legal counsel and other relevant information. To the extent new information is obtained and the views on the probable outcomes of claims, suits, assessments, investigations or legal proceedings change, changes in the Company’s accrued liabilities would be recorded in the period in which such determination is made.

In addition, in accordance with the relevant authoritative guidance, for any matters in which the likelihood of material loss is at least reasonably possible, the Company will provide disclosure of the possible loss or range of loss. If a reasonable estimate cannot be made, however, the Company will provide disclosure to that effect. The Company expenses legal costs as they are incurred.

The Company did not accrue any liabilities related to legal contingencies in its consolidated financial statements as of December 31, 2023 and 2022.

***BacThera Long Term Manufacturing Agreement***

On November 8, 2021, the Company entered into a Long Term Manufacturing Agreement with BacThera AG (“BacThera”), a joint venture between Chr. Hansen and a Lonza Group affiliate, which was amended on December 14, 2022 (the “BacThera Agreement”). The BacThera Agreement governs the general terms under which BacThera, or one of its affiliates, will (i) construct a dedicated full-scale production suite for the Company at BacThera’s Microbiome Center of Excellence in Visp, Switzerland, which is substantially complete; and (ii) provide manufacturing services to the Company for its then SER-109 product candidate (now VOWST) and other products, as agreed to by the parties.

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Under the terms of the Bacthera Agreement, the Company agreed to pay Bacthera a total of at least 256,000 CHF (or approximately \$301,000) for the initial term of the agreement, inclusive of the construction fees and annual operating fees. Bacthera is funding the majority of the construction costs and will own and control the manufacturing suite during construction. The construction fees that the Company is responsible for represent a small percentage of the overall construction costs and are payable upon the achievement of certain milestones related to the construction of the dedicated manufacturing suite. The annual operating fee includes the cost of a baseline annual batch production volume. The Company has also agreed to pay certain other ancillary fees and a per-batch fee in excess of the baseline batches. These fees are subject to adjustment during construction for certain items outside of Bacthera's control and annually against an agreed index. The Company will supply the active pharmaceutical ingredients to Bacthera to enable it to perform the services and pay for certain other raw materials and manufacturing components, which will be acquired by Bacthera.

The Bacthera Agreement has an initial term that continues until the tenth anniversary of the earlier of (a) successful completion of construction and demonstration of Bacthera's readiness for commercial production or (b) the commencement of manufacturing.

The initial term is subject to renewals, which could extend the term to 16 years, and additional three-year terms thereafter. Each party has the ability to terminate the Bacthera Agreement upon the occurrence of certain customary conditions. The Company may also terminate the Bacthera Agreement for convenience after a defined period. In the event of a termination, the Company has certain financial obligations that would apply, and Bacthera has agreed to grant a license to Bacthera-developed manufacturing know how, if any, and provide technical assistance to the Company, so that the Company could transfer the manufacturing operations to itself or a third party. The Bacthera Agreement also contains representations, warranties and indemnity obligations as well as limitations of liability that are customary for agreements of this type.

The Bacthera Agreement represents a lease as the Company will have the right to use the dedicated manufacturing suite for a period of time following completion of the construction of the manufacturing suite and approval by regulatory authorities. As of December 31, 2023, the lease commencement date has not occurred and therefore the Company has not recorded an operating lease asset or an operating lease liability on its consolidated balance sheets. As of December 31, 2023, the Company has paid Bacthera \$12,276 related to the construction of the dedicated manufacturing suite. As of December 31, 2023, the Company recorded \$38,877 in other non-current assets in the accompanying consolidated balance sheet, including \$30,049 related to the achievement of the substantial completion milestone that occurred in late 2023. These amounts will be recorded as part of the right-of-use asset upon lease commencement.

**17. Income Taxes**

During the years ended December 31, 2023 and 2022, the Company recorded no income tax benefits for the net operating losses incurred in each year or interim period, due to its uncertainty of realizing a benefit from those items.

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	<b>Year Ended December 31,</b>	
	<b>2023</b>	<b>2022</b>
Federal statutory income tax rate	(21.0)%	(21.0)%
Research and development tax credits	(4.3)	(3.1)
State taxes, net of federal benefit	(7.8)	(4.3)
Stock-based compensation	1.4	0.6
Uncertain tax position reserves	0.8	4.6
Other	(0.3)	0.3
Change in deferred tax asset valuation allowance	31.2	22.9
Effective income tax rate	<u>—%</u>	<u>—%</u>



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Net deferred tax assets as of December 31, 2023 and 2022 consisted of the following:

	December 31,	
	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	\$ 142,506	\$ 132,560
Research and development tax credit carryforwards	52,843	48,854
Section 174 capitalized research and development expenses	55,572	38,894
Stock-based compensation expense	25,898	20,048
Lease liability	29,855	29,717
Deferred revenue	27,452	29,922
Accrued expenses	3,540	4,044
Section 163(j) limitation	3,741	2,303
Depreciation and amortization	398	396
Other	169	200
Total deferred tax assets	\$ 341,974	\$ 306,938
Deferred tax liabilities:		
Depreciation and amortization	—	—
Right of use assets	(29,165)	(29,568)
Total deferred tax liabilities	(29,165)	(29,568)
Valuation allowance	\$ (312,809)	\$ (277,370)
Net deferred tax assets	\$ —	\$ —

The Tax Cuts and Jobs Act (“TCJA”) requires taxpayers to capitalize and amortize research and experimental expenditures under IRC Section 174 for tax years beginning after December 31, 2021. This rule became effective for the Company during the year ended December 31, 2022 and resulted in the capitalization of research and development costs of \$102,558 and \$160,586 for the years ended December 31, 2023 and 2022, respectively. The Company will amortize these costs for tax purposes over five years if the research and development was performed in the U.S. and over 15 years if the research and development was performed outside the U.S.

As of December 31, 2023, the Company had net operating loss carryforwards (“NOLs”) for federal and state income tax purposes of \$527,065 and \$504,215, respectively. Federal NOLs of \$119,800, generated before 2018, will begin expiring in varying amounts in 2035 unless utilized. The remaining federal NOLs of \$407,265, generated after 2017, will be carried forward indefinitely and could be used to offset up to 80% of taxable income in future tax years. The Company’s state NOLs will expire at various times starting in 2035. As of December 31, 2023, the Company also had available gross research and development tax credit carryforwards for federal and state income tax purposes of \$53,928 and \$11,455, respectively, which begin to expire in 2031 and 2028, respectively. The federal research and development tax credits include an orphan drug credit carryforward of \$25,873.

Utilization of the NOLs and research and development tax credit carryforwards may be subject to a substantial annual limitation under Sections 382 and 383 of the IRC due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50% over a three-year period. Since its formation, the Company has raised capital through the issuance of capital stock on several occasions. These financings, combined with the purchasing shareholders' subsequent disposition of those shares, may have resulted in a change of control or could result in a change of control in the future upon subsequent disposition. The Company conducted an analysis to determine if historical changes in ownership through December 31, 2020 would limit or otherwise restrict its ability to utilize these NOLs and research and development credit carryforwards. As a result of this analysis, the Company does not believe there are any significant limitations on its ability to utilize these carryforwards. However, future changes in ownership after December 31, 2020 could affect the limitation in future years. Any limitation may result in expiration of a portion of the NOLs or research and development credit carryforwards before utilization.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management has considered the Company’s history of cumulative net losses incurred since inception and its lack of commercialization of any products or generation of any revenue from product sales since inception and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the deferred tax assets as of December 31, 2023 and 2022. Management reevaluates the positive and negative evidence at each reporting period.



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Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2023 and 2022 related primarily to the increases in NOLs, research and development tax credit carryforwards and capitalized research and development expenses pursuant to IRC Section 174, and stock-based compensation were as follows:

	<b>Year Ended December 31,</b>	
	<b>2023</b>	<b>2022</b>
Valuation allowance at beginning of year	\$ (277,370)	\$ (220,114)
Decreases recorded as benefit to income tax provision	—	—
Increases recorded to income tax provision	(35,439)	(57,256)
Valuation allowance as of end of year	<u>\$ (312,809)</u>	<u>\$ (277,370)</u>

During the year ended December 31, 2023, the Internal Revenue Service (“IRS”) concluded their examination of the Company for the period ended December 31, 2018 related to the Company’s 2018 research and development tax credits (“R&D Credit(s)”). The Company has adjusted its 2018 R&D Credits and its overall federal and state R&D Credit carryforward balance from the Company’s inception to December 31, 2023 to account for the conclusions drawn by the IRS. Also, the Company has reviewed each of its overall filing positions since inception and has not identified any additional positions that do not meet the more likely than not threshold. The Company does not anticipate a material change to its uncertain tax position reserves in the next 12 months. The changes in the Company’s unrecognized tax benefits for the years ended December 31, 2023 and 2022 were as follows:

	<b>Year Ended December 31,</b>	
	<b>2023</b>	<b>2022</b>
Balance at beginning of year	\$ 12,528	\$ —
Increase in unrecognized tax benefits as a result of tax positions taken during the year	1,001	12,528
Reduction to unrecognized tax benefits	—	—
Balance at end of year	<u>\$ 13,529</u>	<u>\$ 12,528</u>

The Company has not yet conducted a study of its research and development credit carry forwards. This study may result in further adjustment to the Company’s R&D Credits; however, a full valuation allowance has been provided against the Company’s R&D Credits, and if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the consolidated balance sheet or statement of operations if an adjustment were required. The Company had no other unrecognized tax benefits accrued for the years ended December 31, 2023 and 2022, or related interest and penalties as of such dates. The Company will recognize any interest and penalties related to uncertain tax positions in income tax expense.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. The Company’s tax years are still open under statute from 2011 to present. All years may be examined to the extent the tax credit or net operating loss carryforwards are used in future periods.

**18. Related Party Transactions**

As described in Notes 14 and 15, in July 2021, the Company entered into the 2021 License Agreement with NHSc Pharma Partners, succeeded by NHSc Rx License GmbH (together with Société des Produits Nestlé S.A., their affiliates, and their subsidiaries, “Nestlé”). NHSc Rx License GmbH is an affiliate of one of the Company’s significant stockholders, Société des Produits Nestlé S.A. During the years ended December 31, 2023 and 2022, the Company recognized \$126,975 and \$4,114 of related party revenue, respectively, associated with the 2021 License Agreement. As of the years ended December 31, 2023 and 2022, there was \$0 and \$1,976 of deferred revenue related to the 2021 License Agreement, respectively, which is classified as current in the consolidated balance sheets. As of December 31, 2023 and 2022 there was \$28,053 and \$34,770 included in accrued expenses and other liabilities, which represents amounts due to Nestlé pursuant to the 2021 License Agreement. As of December 31, 2023 and 2022, there was \$7,730 and \$0 of deferred income - related party included on the accompanying consolidated balance sheets, which represents the inventory transferred to Nestlé that Nestlé has not yet sold through to customers or transferred as free goods. The Company recognizes deferred income - related party as collaboration profit upon Nestlé’s sale or transfer of such inventory to third parties. During the years ended December 31, 2023 and 2022, the Company paid Nestlé \$37,387 and \$0 for Nestlé’s share of the collaboration expenses pursuant to the 2021 License Agreement. During the years ended December 31, 2023 and 2022, the Company received \$31,243 and \$0 in payments from Nestlé for the transfer of VOWST to Nestlé. As of December 31, 2023 and 2022, there is \$8,674 and \$0 due from Nestlé pursuant to the 2021 License Agreement.

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As described in Note 14, *Revenue from Contracts with Customers*, in January 2016, the Company entered into the 2016 License Agreement with Nestec, Ltd, succeeded by Société des Produits Nestlé S.A. for the development and commercialization of certain product candidates in development for the treatment and management of CDI and IBD, including UC and Crohn's disease. Société des Produits Nestlé S.A. is one of the Company's significant stockholders. During the years ended December 31, 2023 and 2022, the Company recognized (\$650) and \$3,014, respectively, of related party revenue associated with the 2016 License Agreement. As of December 31, 2023 and 2022, there was \$95,364 and \$94,713, respectively, of deferred revenue related to the 2016 License Agreement, which is classified as current or non-current in the consolidated balance sheets. The Company did not make any payment to or receive any payment from Nestlé during the years ended December 31, 2023 and 2022 pursuant to the 2016 License Agreement. There was no amount due from Nestlé pursuant to the 2016 License Agreement as of December 31, 2023 and 2022.

As described in Note 11, the Company entered into a securities purchase agreement with Flagship Pioneering Fund VII, L.P. and Nutritional Health LTP Fund, L.P., affiliates of Flagship, one of the Company's significant stockholders, for the sale of 8,738,243 shares of its common stock at a purchase price of \$3.15 per share as part of the Registered Direct Offering, which closed on July 5, 2022. The Company received proceeds from Flagship of \$27,525.

In July 2022, the Company entered into a Pledge and Utilization Agreement with Flagship Pioneering Labs TPC, Inc., an affiliate of Flagship, for an option to lease certain manufacturing space. The Company paid \$833 for this option which is classified in other non-current assets on the Company's consolidated balance sheet as of December 31, 2022. In June 2023, the Company elected not to renew the option and accordingly at such time, expensed the \$833 option payment.

**19. 401(k) Savings Plan**

The Company has a defined contribution savings plan under Section 401(k) of the IRC. This plan covers substantially all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Effective January 1, 2016, the Company elected to match 50% of the first 6% of an employee's deferral. Company contributions are expensed in the year for which they are declared. During the years ended December 31, 2023 and 2022 the Company recorded expense of \$2,003 and \$1,921, respectively, for 401(k) match contributions.