

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

**FORM 10-Q**

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the quarterly period ended March 31, 2021

or

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission File Number: 001-38822

**KALEIDO BIOSCIENCES, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**65 Hayden Avenue, Lexington, MA**  
(Address of principal executive offices)

**47-3048279**

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

**02421**

(Zip Code)

**(617) 674-9000**

(Registrant's telephone number, including area code)

**Not Applicable**

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

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

Title of each class  
**Common Stock, \$0.001 Par Value**

Trading Symbol(s)  
**KLDO**

Name of each exchange on which registered  
**NASDAQ Global Select Market**

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

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.

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

As of April 30, 2021, there were 42,518,653 shares of registrant's common shares outstanding.

## FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or Quarterly Report, contains forward-looking statements, which reflect our current views with respect to, among other things, our operations and financial performance. We make such forward looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plan, objectives of management and expected market growth are forward-looking statements. You can identify these forward-looking statements by the use of words such as “outlook,” “believes,” “expects,” “potential,” “continues,” “may,” “will,” “should,” “seeks,” “approximately,” “predicts,” “intends,” “plans,” “estimates,” “anticipates” or the negative version of these words or other comparable words. Such forward-looking statements are subject to various risks and uncertainties. Accordingly, there are or will be important factors that could cause actual outcomes or results to differ materially from those indicated in these statements. We believe these factors include but are not limited to those described under “Risk Factors” and include, among other things:

- our ability to continue as a going concern, including without limitation our ability to continue to advance the clinical development of our MMT candidates;
  - the success, cost and timing of our research and development activities, including statements regarding the timing of initiation and completion of clinical studies or clinical trials and related preparatory work, the period during which the results of the clinical studies or clinical trials will become available;
  - our ability to advance any product candidate into or successfully complete any clinical trial or identify an alternative commercial pathway for such product candidate;
  - our ability or the potential to successfully manufacture our product candidates for clinical studies, clinical trials or for commercial use, if approved;
  - our ability to obtain funding for our operations, when needed, including funding necessary to complete further development and commercialization of our product candidates, if approved, and to further expand our propriety product platform;
  - the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
  - the potential for our identified research priorities to advance our product candidates or allow us to identify new product candidates;
  - our expectations regarding the timing for proposed submissions of regulatory filings, including but not limited to any Investigational New Drug application filing or any New Drug Applications;
  - our ability to maintain regulatory approval, if obtained, of any of our current or future product candidates, and any related restrictions, limitations and/or warnings in the label of an approved product candidate;
  - our ability to commercialize our products in light of the intellectual property rights of others;
  - our plans to research, develop and commercialize our product candidates;
  - our ability to attract collaborators with development, regulatory and commercialization expertise;
  - the expected results pursuant to collaboration arrangements including the receipts of future payments that may arise pursuant to collaboration agreements;
  - existing and future agreements with third parties in connection with the research and development or commercialization of our product candidates;
  - the size and growth potential of the markets for our product candidates, and our ability to serve those markets either alone or in collaboration with others;
  - the rate and degree of market acceptance of our product candidates;
  - the success of competing therapies that are or become available
  - our ability to contract with third-party suppliers and manufacturers and their ability to perform their obligations adequately;
  - our ability to attract and retain key scientific or management personnel;
  - the impact of changes in existing laws, regulations and guidance or the adoption of new laws, regulations and guidance;
  - our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates and other technologies;
  - the impact of the COVID-19 outbreak on our clinical trial programs and business generally, as well as our plans and expectations with respect to the timing and resumption of any development activities that may be temporarily paused as a result of the COVID-19 outbreak;
  - the ultimate impact of the current coronavirus pandemic, or any other health epidemic, on our business, our clinical trials, our research programs, healthcare systems or the global economy as a whole; and
  - other risks and uncertainties, including those discussed in Part II, Item 1A, “Risk Factors” in this Quarterly Report.
-

All of our forward-looking statements are as of the date of this Quarterly Report only. In each case, actual results may differ materially from such forward-looking information. We can give no assurance that such expectations or forward-looking statements will prove to be correct. An occurrence of or any material adverse change in one or more of the risk factors or risks and uncertainties referred to in this Quarterly Report on Form 10-Q or included in our other public disclosures or our other periodic reports or other documents or filings filed with or furnished to the Securities and Exchange Commission, or the SEC, could materially and adversely affect our business, prospects, financial condition and results of operations. Except as required by law, we do not undertake or plan to update or revise any such forward-looking statements to reflect actual results, changes in plans, assumptions, estimates or projections or other circumstances affecting such forward-looking statements occurring after the date of this Quarterly Report on Form 10-Q, even if such results, changes or circumstances make it clear that any forward-looking information will not be realized. Any public statements or disclosures by us following this Quarterly Report that modify or impact any of the forward-looking statements contained in this Quarterly Report will be deemed to modify or supersede such statements in this Quarterly Report.

We caution readers not to place undue reliance on any forward-looking statements made by us, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

---

**KALEIDO BIOSCIENCES, INC. AND SUBSIDIARIES**  
**TABLE OF CONTENTS**

	<u>Page Number</u>	
<b><u>PART I: FINANCIAL INFORMATION</u></b>		
<u>Item 1.</u>	<u>Condensed Consolidated Financial Statements (Unaudited)</u>	2
	<u>Condensed Consolidated Balance Sheets</u>	2
	<u>Condensed Consolidated Statements of Operations</u>	3
	<u>Condensed Consolidated Statements of Stockholders' Equity</u>	4
	<u>Condensed Consolidated Statements of Cash Flows</u>	5
	<u>Notes to Condensed Consolidated Financial Statements</u>	6
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	12
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	20
<u>Item 4.</u>	<u>Controls and Procedures</u>	20
<b><u>PART II: OTHER INFORMATION</u></b>		
<u>Item 1.</u>	<u>Legal Proceedings</u>	21
<u>Item 1A.</u>	<u>Risk Factors</u>	21
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	21
<u>Item 3.</u>	<u>Defaults Upon Senior Securities</u>	21
<u>Item 4.</u>	<u>Mine Safety Disclosures</u>	21
<u>Item 5.</u>	<u>Other Information</u>	21
<u>Item 6.</u>	<u>Exhibits</u>	22
<u>Signatures</u>		23

---

**PART I—FINANCIAL INFORMATION****Item 1. Condensed Consolidated Financial Statements (Unaudited)**

**KALEIDO BIOSCIENCES, INC. AND SUBSIDIARIES**  
**Condensed Consolidated Balance Sheets (Unaudited)**  
(in thousands, except share and per share data)

	As of	
	March 31, 2021	December 31, 2020
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 92,362	\$ 46,222
Prepaid expenses and other current assets	2,670	2,499
Total current assets	95,032	48,721
Property and equipment, net	7,833	8,462
Restricted cash	2,161	2,161
Total assets	\$ 105,026	\$ 59,344
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 2,412	\$ 5,389
Accrued expenses and other current liabilities	5,702	8,636
Current term debt, net of unamortized debt discount	4,759	2,634
Total current liabilities	12,873	16,659
Long term debt, net of unamortized debt discount	16,433	18,375
Other liabilities	3,946	3,814
Total liabilities	33,252	38,848
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, \$0.001 par value, 10,000,000 authorized; no shares issued or outstanding	—	—
Common stock, \$0.001 par value, 150,000,000 shares authorized; 42,483,171 and 36,022,811 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	42	36
Additional paid-in capital	368,953	294,639
Accumulated deficit	(297,221)	(274,179)
Total stockholders' equity	71,774	20,496
Total liabilities and stockholders' equity	\$ 105,026	\$ 59,344

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

**KALEIDO BIOSCIENCES, INC. AND SUBSIDIARIES**  
**Condensed Consolidated Statements of Operations (Unaudited)**  
**(in thousands, except share and per share data)**

	Three Months Ended	
	March 31,	
	2021	2020
Revenue:		
Collaboration revenue	\$ 297	\$ —
Operating expenses:		
Research and development	17,185	13,137
General and administrative	5,460	5,917
Total operating expenses	22,645	19,054
Loss from operations	(22,348)	(19,054)
Other (expense) income:		
Interest income	21	193
Interest expense	(709)	(688)
Other expense	(6)	(2)
Total other (expense) income, net	(694)	(497)
Net loss	\$ (23,042)	\$ (19,551)
Net loss per share —basic and diluted	\$ (0.58)	\$ (0.64)
Weighted-average common shares outstanding —basic and diluted	39,692,582	30,333,283

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

**KALEIDO BIOSCIENCES, INC. AND SUBSIDIARIES**  
**Condensed Consolidated Statements of Stockholders' Equity (Unaudited)**  
(in thousands, except share data)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Stockholders' Equity (Deficit)
	Shares	Amount			
<b>Balance at January 1, 2021</b>	36,022,811	\$ 36	\$ 294,639	\$ (274,179)	\$ 20,496
Issuance of common stock, net of issuance costs \$4,512	6,347,156	6	69,919	—	69,925
Exercise of stock options	63,331	—	352	—	352
Stock-based compensation	—	—	4,229	—	4,229
Common stock issued upon vesting of restricted stock units, net of 21,452 shares withheld for employee taxes	49,873	—	(186)	—	(186)
Net loss	—	—	—	(23,042)	(23,042)
<b>Balance at March 31, 2021</b>	42,483,171	\$ 42	\$ 368,953	\$ (297,221)	\$ 71,774

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Stockholders' Equity (Deficit)
	Shares	Amount			
<b>Balance at January 1, 2020</b>	30,127,846	\$ 30	\$ 241,412	\$ (192,559)	\$ 48,883
Exercise of stock options	334,444	—	1,561	—	1,561
Stock-based compensation	—	—	2,725	—	2,725
Vesting of restricted shares	1,250	—	3	—	3
Net loss	—	—	—	(19,551)	(19,551)
<b>Balance at March 31, 2020</b>	30,463,540	\$ 30	\$ 245,701	\$ (212,110)	\$ 33,621

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

**KALEIDO BIOSCIENCES, INC. AND SUBSIDIARIES**  
**Condensed Consolidated Statements of Cash Flows (Unaudited)**  
(in thousands)

	Three Months Ended March 31,	
	2021	2020
<b>Operating activities:</b>		
Net loss	\$ (23,042)	\$ (19,551)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation and amortization	577	369
Stock-based compensation	4,229	2,725
Amortization of debt discount	183	173
Non-cash interest expense	181	173
Loss on disposal of fixed assets	10	—
Changes in:		
Prepaid expenses and other assets	(173)	(1,627)
Accounts payable	(2,977)	(792)
Accrued expense and other liabilities	(2,962)	631
Net cash used in operating activities	(23,974)	(17,899)
<b>Investing activities:</b>		
Purchase of property and equipment	(30)	(1,075)
Net cash and restricted cash used in investing activities	(30)	(1,075)
<b>Financing activities:</b>		
Proceeds from exercise of stock options	352	1,561
Payments related to capital lease	—	(22)
Issuance of common stock, net of issuance costs	69,978	—
Net settlement of vested restricted stock units to fund related employee statutory tax withholdings	(186)	—
Net cash provided by financing activities	70,144	1,539
Net (decrease) increase in cash, cash equivalents, and restricted cash	46,140	(17,435)
Cash, cash equivalents, and restricted cash, beginning of period	48,383	73,526
Cash, cash equivalents, and restricted cash, end of period	\$ 94,523	\$ 56,091
<b>Supplemental cash flow information</b>		
Interest paid	\$ 526	\$ 342
<b>Supplemental disclosure of non-cash investing and financing activities</b>		
Issuance costs in accounts payable and accrued expenses	\$ 53	\$ —
Vesting of restricted stock	\$ —	\$ 3

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



**KALEIDO BIOSCIENCES, INC. AND SUBSIDIARIES**  
**Notes to Condensed Consolidated Financial Statements (Unaudited)**  
**(Amounts in thousands, except share and per share amounts)**

**1. Nature of the Business, Basis of Presentation, and Going Concern**

Kaleido Biosciences, Inc. and its wholly owned subsidiaries (the “Company”) is a clinical-stage healthcare company that was incorporated in Delaware on January 27, 2015 and has a principal place of business in Lexington, Massachusetts. The Company was formed to use its differentiated, chemistry-driven approach to leverage the potential of the microbiome to treat disease and improve human health.

The Company is subject to risks common to companies in the biotechnology industry, including, but not limited to, successful development of technology, obtaining additional funding, protection of proprietary technology, compliance with government regulations, risks of failure of preclinical studies (including *ex vivo* assays), clinical studies and clinical trials, the need to obtain marketing approval for its drug candidates and if applicable, its consumer products, fluctuations in operating results, economic pressure impacting therapeutic pricing, dependence on key personnel, risks associated with changes in technologies, development by competitors of technological innovations and the ability to supply sufficient amounts of Microbiome Metabolic Therapies, (“MMT” or “MMTs”) at an acceptable quality level.

On June 4, 2020, the Company completed a public offering (the “Offering”), pursuant to which it issued and sold 4,750,000 shares of the common stock. The aggregate net proceeds received by the Company from the Offering were \$33,182. On July 1, 2020, 185,000 shares were exercised under the Underwriters’ over-allotment option for net proceeds of \$1,260.

On August 4, 2020, the Company entered into an Equity Distribution Agreement (the “Sales Agreement”) with a sales agent for the sale of up to \$50,000 of the Company’s shares of common stock, from time to time in an at-the-market public offering (the “ATM”). The sales agent is entitled to compensation at a fixed commission rate of 3.0% of the gross proceeds from the sale of the Company’s common stock pursuant to the Sales Agreement. During the year ended December 31, 2020, the Company sold 361,299 shares of its common stock under the ATM which resulted in aggregate net proceeds of \$3,432 after payment of related commissions. During the quarter ended March 31, 2021, the Company sold 309,656 shares of its common stock which resulted in aggregate net proceeds of \$4,860. As of March 31, 2021, there was \$41,451 available under the ATM.

On February 8, 2021, the Company completed a public offering (the “2021 Offering”), pursuant to which the Company issued and sold 6,037,500 shares of common stock for net proceeds of \$65,265, which included the full exercise of the Underwriters’ over-allotment option.

The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. As of March 31, 2021, the Company had an accumulated deficit of \$297,221. The Company expects to continue to generate operating losses and use cash in operations in the foreseeable future. As of March 31, 2021, the Company had cash and cash equivalents of \$92,362, and management expects that the cash and cash equivalents at March 31, 2021 will be sufficient to fund its operating expenses and capital expenditure requirements into the first quarter of 2022. Based on its recurring losses from operations incurred since inception, expectation of continuing operating losses for the foreseeable future, and need to raise additional capital to finance its future operations, the Company has concluded that there is substantial doubt regarding the Company’s ability to continue as a going concern within one year after the date that these consolidated financial statements are issued. These financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company will require substantial additional capital to fund its research and development and ongoing operating expenses. These capital requirements are expected to be funded through debt and equity offerings as well as possible strategic collaborations with other companies. If the Company is unable to raise additional funds when needed, it may be required to delay, reduce or eliminate its product development or future commercialization efforts, or grant rights to develop and market product candidates that the Company would otherwise prefer to develop and market itself. While there can be no assurance the Company will be able to successfully reduce operating expenses or raise additional capital, management believes the historical success in managing cash flows and obtaining capital will continue in the foreseeable future.

A novel strain of coronavirus (COVID-19) was first identified in late 2019, and subsequently declared a global pandemic by the World Health Organization on March 11, 2020. As a result of the outbreak, many companies have experienced disruptions in their operations and in markets served. The Company has instituted some and may take additional temporary precautionary measures intended to help minimize the risk of the virus to its employees, including implementing a work-at-home policy, providing flexibility for working parents, implementing safety measures for those employees who continue to go into the office to complete their work and suspending all non-essential business-related travel. The full extent of the future impacts of COVID-19 on our operations, including the timing and ability of the Company to complete certain clinical trials and other efforts to advance the development of our MMTs, is uncertain.

## 2. Summary of Significant Accounting Policies

### ***Unaudited interim financial information***

The condensed consolidated financial statements of the Company included herein have been prepared, without audit, pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"). Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") have been condensed or omitted from this report, as is permitted by such rules and regulations. Accordingly, these consolidated financial statements should be read in conjunction with the financial statements and notes thereto included in the annual report on Form 10-K filed with the SEC on March 3, 2021.

All intercompany transactions and balances of the subsidiaries have been eliminated in consolidation. In the opinion of management, the information furnished reflects all adjustments, all of which are of a normal and recurring nature, necessary for a fair representation of the results for the reported interim periods.

### ***Use of Estimates***

The preparation of the consolidated financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

### ***Collaboration Revenue***

The Company analyzes its collaboration arrangements to assess whether they are within the scope of ASC Topic 808, *Collaborative Arrangements* (ASC 808), to determine 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 that are dependent on the commercial success of such activities. To the extent the arrangement is within the scope of ASC 808, the Company will assess whether aspects of the arrangement between it and their collaboration partner are within the scope of other accounting literature. If the Company concludes that some or all aspects of the arrangement represent a transaction with a customer, it will account for those aspects of the arrangement within the scope of ASC 606, *Revenue from Contracts with Customers*, by applying the five-step model described below. If the Company concludes that some or all aspects of the arrangement are within the scope of ASC 808 and do not represent a transaction with a customer, the Company will recognize its allocation of the shared costs incurred with respect to the jointly conducted activities as a component of the related expense in the period incurred.

The Company recognizes revenue after applying the following five steps:

- 1) Identification of the contract, or contracts, with a customer,
- 2) Identification of the performance obligations in the contract, including whether they are distinct within the context of the contract
- 3) Determination of the transaction price, including the constraint on variable consideration
- 4) Allocation of the transaction price to the performance obligations in the contract
- 5) Recognition of revenue when, or as, performance obligations are satisfied

If a contract is determined to be within the scope of ASC 606 at inception, the Company assesses the goods or services promised within such contract, determines which of those goods and services are performance obligations, and assesses whether each promised good or service is distinct. Promised goods and services are considered distinct provided that: (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (that is, the good or service is capable of being distinct) and (ii) the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (that is, the promise to transfer the good or service is distinct within the context of the contract). In assessing whether a promised good or service is distinct, the Company considers factors such as the research, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. The Company also considers the intended benefit of the contract in assessing whether a promised good or service is separately identifiable from other promises in the contract. If a promised good or service is not distinct, an entity is required to combine that good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct.

The Company may provide options to additional goods or services in such arrangements exercisable at a customer's discretion. The Company assesses if these options provide a material right to the customer and if so, they are considered performance obligations. The identification of material rights requires judgments related to the determination of the value of the underlying good and services to the option exercise price.

The Company determines 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. The Company then allocates the transaction price to each performance obligation based on the relative standalone selling prices (“SSP”). SSP is determined at contract inception and is not updated to reflect changes between contract inception and when the performance obligations are satisfied. In developing the SSP for a performance obligation, the Company considers applicable market conditions and relevant entity-specific factors, including factors that were contemplated in negotiating the agreement with the customer and estimated costs.

If the consideration promised in a contract includes a variable amount, the Company estimates the amount of consideration to which it will be entitled by using the expected value method or the most likely amount method. The Company includes the unconstrained amount of estimated variable consideration in the transaction price. The amount included in the transaction price is constrained to the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur. At the end of each subsequent reporting period, the Company re-evaluates the estimated variable consideration included in the transaction price and any related constraint, and if necessary, adjusts its estimate of the overall transaction price.

The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied, either at a point in time or over time, and if over time recognition is based on the use of an output or input method.

Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue in the Company’s condensed consolidated balance sheets. If the related performance obligation is expected to be satisfied within the next twelve months this will be classified in current liabilities. Amounts recognized as revenue prior to receipt are recorded as other current assets in the Company’s balance sheets. If the Company expects to have an unconditional right to receive the consideration in the next twelve months, this will be classified in other current assets.

### Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, Leases (“ASU 2016-02”), which applies to all leases and will require the Company to record most leases on the balance sheet. The Company will use a modified retrospective approach of adoption for ASU 2016-02. As an emerging growth company, this standard is required to be adopted on January 1, 2022, and the Company is evaluating the impact that the adoption of ASU 2016-02 will have on its consolidated financial statements. The Company expects to recognize a significant lease obligation and right to use asset upon adoption.

### 3. Fair Value Measurements

The following tables set forth by level, within the fair value hierarchy, the assets carried at fair value on a recurring basis:

	Fair Value Measurements as of March 31, 2021			
	Level 1	Level 2	Level 3	Total
<b>Assets:</b>				
Money market funds included within cash and cash equivalents	\$ 25,412	—	—	\$ 25,412
<b>Total</b>	<b>\$ 25,412</b>	<b>—</b>	<b>—</b>	<b>\$ 25,412</b>
	Fair Value Measurements as of December 31, 2020			
	Level 1	Level 2	Level 3	Total
<b>Assets:</b>				
Money market funds included within cash and cash equivalents	\$ 45,410	—	—	\$ 45,410
<b>Total</b>	<b>\$ 45,410</b>	<b>—</b>	<b>—</b>	<b>\$ 45,410</b>

The fair value of money market funds was measured by the Company based on quoted market prices.

**Financial Instruments Not Recorded at Fair Value** – The carrying value of cash, cash equivalents, restricted cash, accounts payable and accrued expenses that are reported on the condensed consolidated balance sheets approximate their fair value due to the short-term nature of these assets and liabilities. The carrying value of the long-term debt approximates fair value as evidenced by the recent refinancings.

#### 4. Property and Equipment, net

Property and equipment consist of the following:

	As of	
	March 31, 2021	December 31, 2020
Laboratory equipment	\$ 7,302	\$ 6,843
Office and computer equipment	1,590	1,590
Leasehold improvements	1,910	1,910
Construction in process	1,087	1,612
Property and equipment – at cost	11,889	11,955
Less accumulated depreciation and amortization	(4,056)	(3,493)
Property and equipment – net	\$ 7,833	\$ 8,462

Depreciation and amortization expense for the three months ended March 31, 2021 and 2020 was \$577 and \$369, respectively. During the quarter ended March 31, 2021, the Company recorded gross fixed asset disposal of \$24 and related accumulated depreciation of \$14.

#### 5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	As of	
	March 31, 2021	December 31, 2020
Payroll and benefits	\$ 834	\$ 2,943
Consulting service	513	1,049
Legal service	133	173
Research and development	2,742	3,010
Interest	181	181
Deferred revenue	281	498
Other	1,018	782
Accrued expenses and other current liabilities	\$ 5,702	\$ 8,636

#### 6. Debt Financing

On December 31, 2019, the Company entered into a Credit Agreement (the “Credit Agreement”) with Hercules Capital, Inc. (the “Lender”). Under the Credit Agreement, the Company borrowed \$22,500, and the Company has the option to draw down an additional \$12,500 if certain milestones and conditions are met. The Company incurred fees of \$410, which was paid to the Lender on the closing date. These amounts were recorded as a debt discount and are being amortized as interest expense using the effective interest method over the life of the Credit Agreement. The Credit Agreement also includes an end of term charge equal to 7.55% of the aggregate principal amount of all advances. The end of term charge, totaling \$1,698 at March 31, 2021, was recognized as a debt discount and is reflected as a reduction in the carrying value of the debt and recorded in other long-term liabilities. The debt discount created by the end of term charge is being accreted and will be recognized as additional interest expense over the term of the Credit Agreement using the effective interest method.

The Credit Agreement contains customary representations and warranties, events of default and affirmative and negative covenants, including, among others, covenants that limit or restrict the Company’s ability to, among other things, incur additional indebtedness, merge or consolidate, make acquisitions, pay dividends or other distributions or repurchase equity, make investments, dispose of assets and enter into certain transactions with affiliates, in each case subject to certain exceptions. As security for its obligations under the Credit Agreement, the Company granted the Lender a first priority security interest on substantially all of the Company’s assets (other than intellectual property), and subject to certain exceptions.

The outstanding principal under the Credit Agreement has a 48-month term with interest only payments for the first 15 months, which period can be extended to up to 24 months, depending on the achievement of certain performance milestones. The principal bears interest at a rate equal to the greater of (i) 8.95% plus the prime rate minus 4.75% and (ii) 8.95%. The Credit Agreement includes mandatory prepayment provisions that require prepayment upon the occurrence of a change in control event.

On June 15, 2020, the Company entered into a Second Amendment to Loan and Security Agreement (the “Amendment”). The Amendment was entered into for the primary purpose of amending the Credit Agreement as follows: (i) the second tranche of the term loan (the “Term Loan”) is terminated; (ii) amounts available under Tranche 3 of the Term Loan is increased to \$12,500 from the previous \$7,500 availability amount and its availability period is extended through December 15, 2021, subject to future approval by the Agent’s investment committee; (iii) the interest-only period is extended through July 31, 2021; (iv) the interest rate on borrowings is increased by 0.4%, such that the per annum interest rate on outstanding borrowings will be the greater of (a) 9.35% and (b) 9.35% plus the Wall Street Journal prime rate minus 3.25%; (v) the variable amount and duration of a minimum cash covenant in the Agreement are amended. The Amendment has been accounted for as a modification and the Company incurred fees of \$79, which was paid to the lender on the closing date and were recorded as a debt discount, which will be amortized as interest expense using the effective interest method.

Future principal payments under the Credit Agreement as of March 31, 2021 are as follows (in thousands):

2021	3,379
2022	8,686
2023	9,547
2024	888
Total future principal payments	22,500
Less unamortized debt discount	1,308
Total balance	<u>\$ 21,192</u>

On April 30, 2021, the Company entered into a Third Amendment to Loan and Security Agreement (the “Amendment”). The Amendment was entered into for the primary purpose of amending the Agreement as follows: (i) the interest-only period was extended through January 31, 2022; (ii) the second tranche of the term loan (the “Term Loan”) was reinstated and the related \$5,000 is available to be drawn at the Company’s option on or before June 1, 2021; and (iii) the Minimum Cash Covenant was reduced from \$22,500 to \$15,000. The Company incurred fees of \$20, which was paid to the lender on the closing date.

## 7. Commitments and contingencies

### *Facilities Leases*

In March 2018, the Company entered into a non-cancelable ten-year lease agreement for laboratory and office space in Lexington, Massachusetts. In March 2019, the Company exercised its option to lease additional space in the building. The lease expires in 2029, subject to one option to extend the lease for 10 years.

Rent expense for the three months ended March 31, 2021 and 2020 totaled \$1,623 and \$1,779, respectively. Future minimum lease payments under the non-cancelable operating leases consisted of the following as of March 31, 2021:

<b><u>Year Ending December 31,</u></b>	
2021	\$ 4,532
2022	6,207
2023	6,393
2024	6,584
2025	6,782
Thereafter	25,502
	<u>\$ 56,000</u>

## 8. Stockholders’ Equity

### *Modification of equity awards*

On January 20, 2021, the Company entered into a separation agreement with the former Chief Medical Officer and Head of Research and Development of the Company, which amended an existing employment agreement and provided for changes in the term of service and compensation under the agreement. The outstanding options and restricted stock units held by the former Chief Medical Officer were modified to accelerate certain vesting provisions and the period of exercisability. As a result, the Company recorded stock-based compensation expense of \$1,968 related to the incremental fair value of the modified awards during the three months ended March 31, 2021.

## 9. Net Loss per Share

Basic and diluted net loss per common share is determined by dividing net loss by the weighted-average common shares outstanding during the period. The Company has computed diluted net loss per common share after giving consideration to all potentially dilutive

common shares, including options to purchase common stock and unvested restricted common stock, outstanding during the period determined using the treasury stock method, except where the effect of including such securities would be anti-dilutive. Because the Company has reported net losses since inception, these potential common shares have been anti-dilutive and therefore basic and diluted net loss per share have been equivalent.

The following table presents securities that have been excluded from the computations of diluted weighted-average shares outstanding as they would be anti-dilutive:

	As of March 31,	
	2021	2020
Options to purchase common stock	6,206,765	6,644,275
Restricted stock units	272,296	50,000
	<u>6,479,061</u>	<u>6,694,275</u>

## 10. Revenue

In December 2019, the Company entered into a research collaboration agreement with Janssen's World Without Disease Accelerator ("Janssen"), part of the Janssen Pharmaceutical Companies of Johnson & Johnson, to explore the potential for MMT to prevent the onset of childhood allergy and other atopic, immune and metabolic conditions.

The collaboration includes three milestones of research and development with deliverables due to Janssen at end of the milestone at which point Janssen will have 60 days to decide to proceed with the next milestone.

The Company assessed the Janssen collaboration agreement in accordance with ASC 808 and ASC 606 and concluded that it represents a contract with a customer and is within the scope of ASC 606. The promised goods and services represent one combined performance obligation and the entire transaction price will be allocated to that single combined performance obligation. In addition, the Company concluded the right to proceed with the following milestones does not provide any discounts to Janssen if it decides to proceed with the next milestones. As such, the Company concluded the milestone is not considered to be a material right. Each milestone is considered a separate contract and will reflect applicable standalone selling prices.

Under the Janssen collaboration agreement, Janssen is obligated to reimburse the Company for the costs incurred under an agreed upon research plan. Costs incurred are billed by the Company to Janssen at completion of each milestone. The Company recognizes revenue over the research period and as the performance obligation is satisfied using total estimated hours to be incurred throughout each milestone. For the quarter ended March 31, 2021, the Company recognized \$297 as collaboration revenue under the agreement with Janssen. Additionally, as of March 31, 2021, the Company recognized \$218 of previously recorded deferred revenue within current liabilities on the Company's condensed consolidated balance sheets related to the Janssen collaboration agreement. The expected research term of this arrangement is expected to be completed during 2021, and the aggregate consideration is not expected to be material.

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

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with (i) our condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report and audited financial statements the notes thereto contained in our current report on Form 10-K filed with the Securities and Exchange Commission (the “SEC”), on March 3, 2021.*

*Investors and others should note that we announce material financial information to our investors using our investor relations website (<https://investors.kaleido.com/>), SEC filings, press releases, public conference calls and webcasts. We use these channels as well as social media to communicate with the public about our company, our business, our product candidates, and other matters. It is possible that the information we post on social media could be deemed to be material information. Therefore, we encourage investors, the media, and others interested in our company to review the information we post on the social media channels listed on our investor relations website.*

### Overview

We are a clinical-stage healthcare company with a differentiated, chemistry-driven approach focused on targeting the microbiome to treat disease and improve human health. We have built a proprietary product platform for discovery and development that we believe will enable the rapid advancement of a broad portfolio of novel product candidates into human clinical studies under regulations supporting research with food. Our product candidates are Microbiome Metabolic Therapies (“MMT” or “MMTs”), which are designed to modulate the metabolic output and profile of the microbiome by driving the function and distribution of the gut’s existing microbes. We have an industrialized approach to the discovery and development of MMTs, and our initial MMTs are targeted glycans. Each targeted glycan is an ensemble of complex carbohydrates that is intended to modulate microbial metabolism and community composition to drive a specific biological response. We believe our MMTs have the potential to be novel treatments across a variety of diseases and conditions.

The human microbiome is generally a community of more than 30 trillion microbes, organisms that include bacteria, viruses, archaea and fungi, which reside on and inside the human body. By evolving together over thousands of years, microbes and humans have developed an intricate and mutually beneficial relationship. Given the profound impact that microbes have on human health, this highly complex microbial ecosystem has been referred to as a “newly discovered organ.” There is a growing body of research that links a healthy microbiome with overall human health, while dysbiosis, or imbalance, in the microbiome has been correlated with numerous human conditions, including those that can cause significant morbidity and mortality. Some of these conditions include irritable bowel syndrome, Parkinson’s disease, diabetes, metabolic syndrome, cancer, allergies and ulcerative colitis. The gut microbiome remains a largely untapped frontier in healthcare, and we believe that we are uniquely positioned to succeed in translating its promise into solutions for human health.

To date, therapeutic approaches to the microbiome have focused primarily on adding or subtracting bacteria, either through fecal microbiota transplant, the introduction of a consortia of bacteria, single strain approaches or antibiotics. We believe our approach is novel in that we seek to deliver MMTs that drive the function and distribution of the gut microbiome’s existing microbes, enabling an industrialized approach to treat disease and improve human health.

We have developed proprietary synthetic chemistry technologies that allow us to create MMT candidates. We believe the key characteristics of our MMT candidates include that they are orally administered, have limited systemic exposure and are selectively metabolized, structurally diverse, readily scalable, novel and proprietary. We believe that each of our MMT candidates works through one or more mechanisms of action, including decreasing production of metabolites, such as ammonia and trimethylamine generated by bacteria in the microbiome; increasing production of metabolites, such as short chain fatty acids generated by bacteria in the microbiome; and advantaging or disadvantaging certain existing species in the microbiome community (such as decreasing pathogenic bacteria).

Utilizing our proprietary product platform, we have created a library of more than 1,500 MMT candidates to probe the structure-activity relationships of our MMTs. Our MMT library is continuously growing as we continue to invest in techniques and technologies for chemical synthesis. Our MMT candidates and aspects of the proprietary product platform are supported by our expanding intellectual property portfolio, that includes twelve U.S. patents, two European Patent Office, or EPO, patents and more than 125 non-provisional applications pending worldwide.

Through the use of our proprietary product platform, the effect of MMTs is first tested *ex vivo* using a highly multiplexed advanced screening platform with microbiome communities from both healthy and patient populations. To establish how MMTs impact therapeutically relevant pathways, a broad range of bioanalytical technologies are used to analyze metabolites, effector molecules and host responses, while sequencing determines key microbial community changes. A candidate MMT may then either undergo further testing in animal models or go straight into clinical evaluation in humans.

Abbreviated development may be possible because in some cases MMTs are synthesized from naturally occurring carbohydrate monomers, are orally administered with limited systemic exposure and can be designated as Generally Recognized as Safe (GRAS).

This enables us to gain valuable insights into our MMT candidates' effects on the microbiome and human health before choosing to allocate additional time and capital to proceed to develop a drug product candidate under an IND or regulatory equivalent outside the United States.

In our human clinical studies, we are able to measure safety, tolerability and potential markers of effect, which allows us to assess the potential use of our MMT candidates in humans. Furthermore, we initiated our first Phase 2 clinical trial under an IND approximately two years after conducting our first ex vivo screening. We believe that this provides support for our belief that our approach is more expeditious and cost efficient than traditional drug development.

Since our inception in 2015, we have devoted substantially all of our resources to building our proprietary product platform, developing our pipeline of MMT candidates, building our intellectual property portfolio and process development and manufacturing function, business planning, raising capital and providing general and administrative support for these operations. To date, we have primarily financed our operations through public offering of our equity securities, private placement of our convertible preferred stock and borrowings of long-term debt.

We have incurred significant net losses since inception and expect to continue to incur net operating losses for the foreseeable future. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We expect that our expenses and capital requirements will increase substantially in connection with our ongoing activities, particularly if and as we:

- conduct preclinical studies, clinical studies and clinical trials for our product candidates;
- advance the development of our product candidate pipeline;
- continue to discover and develop additional product candidates;
- continue to build out our proprietary product platform and to increase its throughput for the discovery and nomination of product candidates;
- develop, acquire or in-license other product candidates and technologies;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, scientific and commercial personnel;
- expand manufacturing capabilities, including in-house and third-party commercial manufacturing, through the purchase, renovation, customization and operation of a manufacturing facility and securing supply chain capacity sufficient to provide clinical study and clinical trial materials and commercial quantities of any product candidates which we may commercialize;
- seek regulatory approvals for any product candidates for therapeutic indications that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain regulatory approval or identify alternate commercial pathways for such products; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts, as well as to support our transition to a public reporting company.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for or identify alternate non-drug pathways for our product candidates. If we obtain regulatory approval for or otherwise commercialize any of our product candidates, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing and distribution.

As of March 31, 2021, we had \$92.4 million in cash and cash equivalents and an accumulated deficit of \$297.2 million. Based on our current operating plans and net proceeds from the 2021 Offering, we have sufficient cash and cash equivalents to fund our operating expenses and capital expenditures into the first quarter of 2022. We will require substantial additional capital to sustain our operations and pursue our growth strategy, including the development of our MMT candidates. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through equity or debt financings or other capital sources, which may include collaborations with other companies or other strategic transactions. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, reduce or eliminate the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions. See "Liquidity and capital resources."

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales,



we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

## **Financial Overview**

### *Revenue*

We have recently begun to generate collaboration revenue but have not generated and do not expect to generate any revenue from the sale of products in the near future, if at all. If our development efforts for our current product candidates or additional product candidates that we may develop in the future are successful and can be commercialized, or if we enter into future collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from such collaboration or license agreements.

The collaboration revenue recognized in 2021 relates to a research collaboration with Janssen's World Without Disease Accelerator, part of the Janssen Pharmaceutical Companies of Johnson & Johnson. The collaboration explores the potential for Kaleido's Microbiome Metabolic Therapies (MMT™) to prevent the onset of childhood allergy and other atopic, immune and metabolic conditions by driving specific microbiome features which support an appropriate maturation of the infant immune system. We do not expect the total revenue under this arrangement to be material in the aggregate.

### *Research and Development Expenses*

Research and development expenses consist primarily of costs incurred in connection with the discovery and development of our product candidates. These expenses include:

- development and operation of our proprietary product platform;
- employee-related expenses, including salaries, related benefits and stock-based compensation expense, for employees engaged in research and development functions;
- expenses incurred in connection with the preclinical and clinical development of our product candidates, including under agreements with third parties, such as consultants and contract research organizations, or CROs;
- the cost of laboratory supplies and acquiring, developing and manufacturing products for use in our preclinical studies, clinical studies and clinical trials, including under agreements with third parties, such as consultants and contract manufacturing organizations, or CMOs;
- facilities, depreciation and other expenses, which include direct or allocated expenses for rent and maintenance of facilities and insurance; and
- costs related to compliance with regulatory requirements.

We expense research and development costs as incurred. Advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

Our direct external research and development expenses are tracked on a program-by-program basis and consist of costs that include fees, reimbursed materials and other costs paid to consultants, contractors, CMOs and CROs in connection with our preclinical and clinical development and manufacturing activities. We do not allocate employee costs, costs associated with our discovery efforts, laboratory supplies and facilities expenses, including depreciation or other indirect costs, to specific product development programs because these costs are deployed across multiple programs and our platform technology and, as such, are not separately classified.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. At this time, we cannot accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our product candidates. The successful development and commercialization of our product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with product development and commercialization, including the following:

- the timing and progress of preclinical and clinical development activities;
- the number and scope of programs we decide to pursue and their regulatory paths to market;
- raising additional funds necessary to complete preclinical and clinical development of and commercialize our product candidates;
- the progress of the development efforts of parties with whom we have entered into and may enter into collaboration arrangements;
- our ability to maintain our current research and development programs and to establish new ones;

- our ability to maintain existing and establish new licensing or collaboration arrangements;
- the successful initiation and completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to the U.S. Food and Drug Administration or any comparable foreign regulatory authority;
- the receipt and related terms of regulatory approvals from applicable regulatory authorities for any product candidates to begin studies under an Investigational New Drug (IND) application or Clinical Trial Application (CTA) or approval to commercialize for one or more therapeutic indications;
- the availability of specialty raw materials for use in production of our product candidates;
- establishing agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if any of our product candidates is approved or commercialized on an alternate regulatory pathway;
- meeting demand in a timely fashion with sufficient supply at appropriate quality levels;
- our ability to obtain and maintain patents, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- our ability to protect our rights in our intellectual property portfolio;
- the commercialization of our product candidates, if and when approved if approval to market is required;
- obtaining and maintaining third-party insurance coverage and adequate reimbursement;
- the acceptance of our product candidates, if commercialized, by patients, consumers, the medical community and third-party payors;
- competition with other products; and
- a continued acceptable safety profile of our therapies following commercialization.

A change in the outcome of any of these variables with respect to the development of our product candidates could significantly change the costs and timing associated with the development of that product candidate. We may never succeed in obtaining regulatory approval or commercialization for any of our product candidates.

#### *General and Administrative Expenses*

General and administrative expenses consist primarily of salaries and related costs, including stock-based compensation, for personnel in executive, finance, corporate and business development and administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters; professional fees for accounting, auditing, tax and administrative consulting services; insurance costs; administrative travel expenses; and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our product candidates.

## Results of Operations

### Comparison of Three Months Ended March 31, 2021 and 2020

The following table summarizes our results of operations for the three months ended March 30, 2021 and 2020:

	<b>Three Months Ended March 31,</b>		<b>Change</b>
	<b>2021</b>	<b>2020</b>	
	(in thousands)		
Revenue:	\$ 297	\$ —	\$ 297
Collaboration revenue			
Operating expenses:			
Research and development	17,185	13,137	4,048
General and administrative	5,460	5,917	(457)
Total operating expenses	22,645	19,054	3,591
Loss from operations	(22,348)	(19,054)	(3,294)
Other income (expense)			
Interest income	21	193	(172)
Interest expense	(709)	(688)	(21)
Other expense	(6)	(2)	(4)
Total other expense, net	(694)	(497)	(197)
Net loss	\$ (23,042)	\$ (19,551)	\$ (3,491)

### Research and Development Expenses

	<b>Three Months Ended March 31,</b>		<b>Change</b>
	<b>2021</b>	<b>2020</b>	
	(in thousands)		
Personnel-related	\$ 4,985	\$ 4,716	\$ 269
Stock-based compensation expense	2,511	940	1,571
External manufacturing and research	3,729	3,556	173
Laboratory supplies and research materials	576	372	204
Professional and consulting fees	2,644	1,123	1,521
Facility-related and other	2,740	2,430	310
Total research and development expenses	\$ 17,185	\$ 13,137	\$ 4,048

Research and development expenses increased by \$4.0 million for the three months ended March 31, 2021 as compared to the three months ended March 31, 2020. The increase in stock-based compensation expense of \$1.6 million was primarily due to the modification of the vesting provisions of stock options and restricted stock units related to the resignation of our former Chief Medical Officer. The increase in professional and consulting fees of \$1.5 million was primarily the result of increased spend relating to our two COVID-19 studies.

### General and Administrative Expenses

	<b>Three Months Ended March 31,</b>		<b>Change</b>
	<b>2021</b>	<b>2020</b>	
	(in thousands)		
Personnel-related	\$ 1,534	\$ 1,758	\$ (224)
Stock-based compensation expense	1,718	1,785	(67)
Professional and consulting fees	756	956	(200)
Facility-related and other	1,452	1,418	34
Total general and administrative expenses	\$ 5,460	\$ 5,917	\$ (457)

General and administrative expenses decreased by \$0.5 million for the three months ended March 31, 2021 as compared to the period ended March 31, 2020. The decrease in personnel-related cost of \$0.2 million was primarily due to reduced headcount in our general and administrative functions. The decrease in professional and consulting fees of \$0.2 million was primarily due to lower utilization of outside contractors.

### Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. We have not yet commercialized any of our product candidates and we do not expect to generate revenue from sales of any product candidates for several years, if at all. To date, we have primarily financed our operations through the public offering of our equity securities, private placement of our convertible preferred stock and borrowings of long-term debt. As of March 31, 2021, \$22.5 million was outstanding under the debt facility and \$12.5 million was available for borrowing contingent upon successful completion of financing and operational milestones. On June 4, 2020, the Company completed a public offering (the "Offering"), pursuant to which it issued and sold 4,750,000 shares of the common stock. The aggregate net proceeds received by the Company from the Offering were \$34.5 million, including 185,000 shares exercised on July 1, 2020 for the Underwriters' option. On August 4, 2020, the Company entered into an Equity Distribution Agreement (the "Sales Agreement") with a sales agent for the sale of up to \$50.0 million of the Company's shares of common stock, from time to time in an at-the-market public offering (the "ATM"). The sales agent is entitled to compensation at a fixed commission rate of 3.0% of the gross proceeds from the sale of the Company's common stock pursuant to the Sales Agreement. During the year ended December 31, 2020, the Company sold 361,299 shares of its common stock under the ATM which resulted in aggregate net proceeds of \$3.4 million after payment of related commissions.

In January and February 2021, the Company sold 309,656 shares of its common stock under the ATM which resulted in aggregate net proceeds of \$4.9 million after payment of commissions. As of March 31, 2021, there was \$41.5 million available under the ATM. On February 8, 2021, the Company completed a public offering (the "2021 Offering"), pursuant to which it issued and sold 6,037,500 shares our common stock for aggregate net proceeds of \$65.3 million, which included the full exercise of the Underwriters' over allotment option. As of March 31, 2021, we had \$92.4 million in cash and cash equivalents and an accumulated deficit of \$297.2 million. Based on our current operating plans, we have sufficient cash and cash equivalents to fund our operating expenses and capital expenditures into the first quarter of 2022. We will require substantial additional capital to sustain our operations and pursue our growth strategy, including the development of our MMT candidates. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, reduce or eliminate the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions. These factors raise substantial doubt about our ability to continue as a going concern.

### Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented:

	Three Months Ended March 31,	
	2021	2020
	(in thousands)	
Net cash used in operating activities	\$ (23,974)	\$ (17,899)
Net cash used in investing activities	(30)	(1,075)
Net cash provided by financing activities	70,144	1,539
Net (decrease) increase in cash, cash equivalents and restricted cash	<u>\$ 46,140</u>	<u>\$ (17,435)</u>

#### Net Cash Used in Operating Activities

During the three months ended March 31, 2021, operating activities used \$24.0 million of cash, due to our net loss of \$23.0 million, and net cash used as a result of changes in our operating assets and liabilities of \$6.1 million, partially offset by non-cash charges of \$5.2 million. Net cash used as a result of changes in our operating assets and liabilities consisted of a \$6.0 million decrease in accounts payable, accrued expenses and other liabilities and a \$0.2 million increase in prepaid expenses and other assets.

During the three months ended March 31, 2020, operating activities used \$17.9 million of cash, due to our net loss of \$19.6 million and net cash used as a result of changes in our operating assets and liabilities of \$1.8 million, partially offset by non-cash charges of \$3.4 million. Net cash used as a result of changes in our operating assets and liabilities primarily consisted of a \$1.6 million increase in prepaid expenses and other assets arising from reimbursable tenant improvements and a \$0.8 million decrease in accounts payable, partially offset by a \$0.7 million increase accrued expenses and other liabilities.

Changes in prepaid expenses and other current assets, accounts payable and accrued expenses and other liabilities were generally due to the advancement of our research programs and the timing of vendor invoices and payments.

### *Net Cash Used in Investing Activities*

During the three months ended March 31, 2021 and 2020, net cash used in investing activities was \$0.3 million and \$1.1 million, respectively, due to purchases of property and equipment.

### *Net Cash Provided by Financing Activities*

During the three months ended March 31, 2021, net cash provided by financing activities was \$70.1 million, consisting primarily of proceeds from the Offering in February 2021, ATM, and proceeds from the exercise of stock options.

During the three months ended March 31, 2020, net cash provided by financing activities was \$1.5 million, consisting primarily of proceeds from exercise of stock options.

### **Credit agreement**

In December 2019, we entered into a Credit Agreement (“the Credit Agreement”) with Hercules Capital, Inc. (the “Lender”). Under the Credit Agreement, and we borrowed \$22.5 million to us, with the option to drawn down an additional \$12.5 million if certain milestones and conditions are met.

The Credit Agreement contains customary representations and warranties, events of default and affirmative and negative covenants, including, among others, covenants that limit or restrict our ability to, amount other things, incur additional indebtedness, merge or consolidate, make acquisitions, pay dividends or other distributions or repurchase equity, make investment, dispose of assets and entered into certain transactions with affiliates, in each case subject to certain exceptions. As security under the Credit Agreement, we granted the Lender a first priority security interest on substantially all of our assets (other than intellectual property), subject to certain exceptions.

Following the entry into a Third Amendment to Loan and Security Agreement, the facility has a 48-month term with interest only payments has been extended to January 31, 2022. The Term Loan will mature in January 2024 and bears an interest rate of equal to the greater of (a) 9.35% and (b) 9.35% plus the Wall Street Journal prime rate minus 3.25%. The Term Loan is subject to mandatory prepayment provisions that require prepayment upon the occurrence of a Change in Control event (as defined in the Credit Agreement).

### **Funding Requirements**

Over the next several quarters, we are focusing our activities on key exploratory and clinical studies and clinical trials which we expect will reduce our overall expense rate. In the periods that follow, assuming the success of our clinical studies and clinical trials, we anticipate our expenses to increase as we progress towards larger and more pivotal clinical studies and clinical trials of our product candidates, with the potential for larger clinical studies, clinical trials and associated manufacturing. The timing and amount of our operating expenditures will depend largely on:

- the commencement, enrollment or results of the planned clinical studies or clinical trials of our product candidates or any future clinical studies or clinical trials we may conduct, or changes in the development status of our product candidates;
- the timing and outcome of regulatory review of our product candidates;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- changes in laws or regulations applicable to our product candidates, including but not limited to clinical trial requirements for approvals;
- developments concerning our CMOs;
- our ability to obtain materials and to produce adequate current good manufacturing practice compliant product supply for any approved or commercialized product or inability to do so at acceptable prices;
- our ability to establish and maintain collaborations, if needed;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we obtain marketing approval or identify an alternate regulatory pathway to market;
- the costs involved in prosecuting patent applications and enforcing patent claims and other intellectual property claims;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates; and
- the terms and timing of any collaboration, license or other arrangement, including the terms and timing of any milestone payments thereunder.

We believe that our existing cash and cash equivalents will enable us to fund our operating expenses, capital expenditure requirements and debt service into the first quarter of 2022. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, and marketing, distribution or licensing arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specified actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, reduce or eliminate our product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

***Contractual Obligations and Commitments***

During the three months ended March 31, 2021, there were no material changes to our contractual obligations and commitments.

***Off-Balance Sheet Arrangements***

As of March 31, 2021, we did not have any off-balance sheet arrangements as defined under applicable SEC rules.

***Critical Accounting Policies and Significant Judgments and Estimates***

Our condensed consolidated financial statements are prepared in accordance with generally accepted accounting principles. The preparation of our condensed consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

There have been no significant changes to our critical accounting policies from those described in our Annual Report on Form 10-K filed with the SEC on March 3, 2021.

***Recent Accounting Pronouncements***

Refer to Note 2, “Summary of Significant Accounting Policies,” in the accompanying notes to the consolidated financial statements for a discussion of recent accounting pronouncements.

***Emerging Growth Company and Smaller Reporting Company Status***

The Jumpstart Our Business Startups Act of 2012 permits an “emerging growth company” such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected to not “opt out” of this provision and, as a result, we will adopt new or revised accounting standards at the time private companies adopt the new or revised accounting standard and will do so until such time that we either (i) irrevocably elect to “opt out” of such extended transition period or (ii) no longer qualify as an emerging growth company.

We are also a “smaller reporting company” meaning that the market value of our stock held by non-affiliates is less than \$700 million and our annual revenue was less than \$100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than \$250 million or (ii) our annual revenue was less than \$100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than \$700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

**Item 3. Qualitative and Quantitative Disclosures about Market Risk**

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information under this item.

**Item 4. Controls and Procedures.**

***Evaluation of Disclosure Controls and Procedures***

We have established disclosure controls and procedures designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, (the "Exchange Act"), is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and is accumulated and communicated to management, including the principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

Our management, with the participation of our Principal Executive Officer and Principal Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2021. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2021, our Principal Executive Officer and Principal Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

***Changes in Internal Control over Financial Reporting***

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15(d)-15(f) under the Exchange Act) that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II—OTHER INFORMATION

### **Item 1. Legal Proceedings.**

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We are not currently a party to any material legal proceedings.

### **Item 1A. Risk Factors.**

We operate in a changing environment that involves numerous known and unknown risks and uncertainties that could materially adversely affect our operations. You should carefully consider the following discussion of risk factors, in its entirety, in addition to the other information contained in this Quarterly Report on Form 10-Q, our Annual Report on Form 10-K for the year ended December 31, 2020 and the other filings we make with the SEC. Factors that have affected our Company are described in Part I, Item 1A of our Annual Report on Form 10-K filed with the SEC for the year ended December 31, 2020 as filed with the SEC on March 3, 2021, and are incorporated by reference herein.

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

None.

### **Item 3. Defaults Upon Senior Securities.**

None.

### **Item 4. Mine Safety Disclosures.**

None.

### **Item 5. Other Information.**

None.



**Item 6. Exhibits**

<u>Exhibit No.</u>	<u>Exhibit Index</u>
10.1	<a href="#">Separation Agreement, dated January 25, 2021, by and between Kaleido Biosciences, Inc. and Katharine Knobil (Incorporated by reference to Exhibit 10.1. to the Registrant’s Current Report on Form 8-K (File No. 001-38822) filed on January 25, 2021.</a>
31.1*	<a href="#">Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>
31.2*	<a href="#">Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>
32.1†	<a href="#">Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>
101.INS	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

\* Filed herewith.

† This certification will not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into such filing.

**SIGNATURES**

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

Date: May 4, 2021

**KALEIDO BIOSCIENCES, INC.**

By: /s/ Daniel L. Menichella

Daniel L. Menichella  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: May 4, 2021

By: /s/ William Duke, Jr.

William Duke, Jr.  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

**CERTIFICATION PURSUANT TO RULE 13a-14(a) OR 15d-14(a)  
OF THE SECURITIES EXCHANGE ACT OF 1934,  
AS ADOPTED PURSUANT TO SECTION 302 OF  
THE SARBANES-OXLEY ACT OF 2002**

I, Daniel L. Menichella, certify that:

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

Date: May 4, 2021

By: /s/ Daniel L. Menichella  
Daniel L. Menichella  
President and Chief Executive Officer  
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO RULE 13a-14(a) OR 15d-14(a)  
OF THE SECURITIES EXCHANGE ACT OF 1934,  
AS ADOPTED PURSUANT TO SECTION 302 OF  
THE SARBANES-OXLEY ACT OF 2002**

I, William Duke, Jr., certify that:

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

Date: May 4, 2021

By: /s/ William Duke, Jr.  
William Duke, Jr.  
Chief Financial Officer  
(Principal Financial Officer)

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

In connection with the Quarterly Report on Form 10-Q of Kaleido Biosciences, Inc. for the quarterly period ended March 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Daniel Menichella, as President and Chief Executive Officer of Kaleido Biosciences, Inc., hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge, the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Kaleido Biosciences, Inc.

Date: May 4, 2021

By: /s/ Daniel L. Menichella  
Daniel L Menichella  
President and Chief Executive Officer  
(Principal Executive Officer)

In connection with the Quarterly Report on Form 10-Q of Kaleido Biosciences, Inc. for the quarterly period ended March 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), William Duke, Jr., as Chief Financial Officer of Kaleido Biosciences, Inc., hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge, the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Kaleido Biosciences, Inc.

Date: May 4, 2021

By: /s/ William Duke, Jr.  
William Duke, Jr.  
Chief Financial Officer  
(Principal Financial Officer)