

**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 No. 001-35890

**Millendo Therapeutics, Inc.**

(Exact Name of Registrant as Specified in its Charter)

**Delaware**  
(State or Other Jurisdiction of  
Incorporation or Organization)  
**110 Miller Avenue, Suite 100**  
**Ann Arbor, Michigan**  
(Address of Principal Executive Offices)

**45-1472564**  
(I.R.S. Employer  
Identification No.)

**48104**  
(Zip Code)

**Registrant's telephone number, including area code: (734) 845-9000**

(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	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value	MLND	The Nasdaq Global 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 the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

The number of shares of Registrant's Common Stock, \$0.001 par value per share, outstanding as of May 5, 2021 was 19,043,034.

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## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Unless the context suggests otherwise, references in this Quarterly Report on Form 10-Q to “Millendo,” “the Company,” “we,” “us,” and “our” refer to Millendo Therapeutics, Inc. and, where appropriate, its subsidiaries.

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, that involve substantial risks and uncertainties. The forward-looking statements are contained principally in Part I, Item 1. “Business,” Part I, Item 1A. “Risk Factors,” and Part II, Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” but are also contained elsewhere in this Quarterly Report. In some cases, you can identify forward-looking statements by the words “may,” “might,” “will,” “could,” “would,” “should,” “expect,” “intend,” “plan,” “objective,” “anticipate,” “believe,” “estimate,” “predict,” “project,” “potential,” “continue” and “ongoing,” or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Quarterly Report on Form 10-Q, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain. Forward-looking statements include statements about:

- the impact of our discontinuation of the development of livoletide as a potential treatment of patients with Prader-Willi syndrome (“PWS”);
- the impact of our discontinuation of the development of nevanimibe as a potential treatment for classic congenital adrenal hyperplasia (“CAH”);
- the impact of our discontinuation of the development of MLE-301 as a potential treatment of vasomotor symptoms (“VMS”);
- our consideration of strategic alternatives, including our proposed merger with Tempest Therapeutics, Inc.;
- our ability to identify, recruit and retain key personnel;
- the impact of laws and regulations;
- the impact of the COVID-19 pandemic on our business, our financial condition and results of operations, future expenses, the funding of our operations as well as our future capital requirements and needs for additional financing.

You should refer to Part II, Item 1A. “Risk Factors” in this Quarterly Report on Form 10-Q as well as Part I, Item 1A. “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2020 for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Quarterly Report on Form 10-Q will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. The forward-looking statements in this Quarterly Report on Form 10-Q represent our views as of the date of this Quarterly Report on Form 10-Q. We anticipate that subsequent events and developments may cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report on Form 10-Q.

**PART I – FINANCIAL INFORMATION**  
**Item 1 – Financial Statements**

**MILLENDO THERAPEUTICS, INC.**  
**Consolidated Balance Sheets**  
(in thousands except share and per share amounts)

	(Unaudited) March 31, 2021	December 31, 2020
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 26,802	\$ 38,174
Short-term restricted cash	45	484
Marketable securities	439	—
Prepaid expenses and other current assets	1,808	1,929
Refundable tax credit	300	314
Total current assets	29,394	40,901
Operating lease right-of-use assets	2,014	2,157
Other assets	299	351
Total assets	<u>\$ 31,707</u>	<u>\$ 43,409</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Current portion of debt	\$ 235	\$ 239
Accounts payable	811	1,486
Accrued expenses	2,809	5,525
Operating lease liabilities — current	742	737
Total current liabilities	4,597	7,987
Debt, net of current portion	—	61
Operating lease liabilities	1,482	1,635
Total liabilities	<u>6,079</u>	<u>9,683</u>
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized; 19,043,034 and 18,999,701 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	19	19
Additional paid-in capital	278,113	277,647
Accumulated deficit	(253,449)	(245,060)
Accumulated other comprehensive income	277	452
Total stockholders' equity attributable to Millendo Therapeutics, Inc.	24,960	33,058
Equity attributable to noncontrolling interests	668	668
Total stockholders' equity	<u>25,628</u>	<u>33,726</u>
Total liabilities and stockholders' equity	<u>\$ 31,707</u>	<u>\$ 43,409</u>

See accompanying Notes to unaudited Interim Consolidated Financial Statements

**MILLENDO THERAPEUTICS, INC.**  
**Consolidated Statements of Operations and Comprehensive Loss**  
**(Unaudited)**  
**(in thousands except share and per share amounts)**

	Three Months Ended March 31,	
	2021	2020
<b>Operating expenses:</b>		
Research and development	\$ 2,152	\$ 7,540
General and administrative	6,410	4,595
Loss from operations	8,562	12,135
<b>Other expenses (income):</b>		
Interest expense (income), net	\$ 1	\$ (162)
Other (gain) / loss	(174)	25
Net loss	\$ (8,389)	\$ (11,998)
Net loss per share of common stock, basic and diluted	\$ (0.44)	\$ (0.65)
Weighted-average shares of common stock outstanding, basic and diluted	19,023,293	18,448,507
<b>Other comprehensive income (loss):</b>		
Foreign currency translation adjustment	\$ (175)	\$ (42)
Comprehensive loss	\$ (8,564)	\$ (12,040)

See accompanying Notes to unaudited Interim Consolidated Financial Statements

**MILLENDO THERAPEUTICS, INC.**  
**Consolidated Statements of Stockholders' Equity (Deficit)**  
**(Unaudited)**  
**(in thousands except share amounts)**

Three Months Ended March 31, 2021

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity (Deficit) attributable to Millendo Therapeutics, Inc.	Total Equity Attributable to Noncontrolling Interests	Total Stockholders' Equity (Deficit)
	Shares	Amount						
Balance at January 1, 2021	18,999,701	\$ 19	\$ 277,647	\$ (245,060)	\$ 452	\$ 33,058	\$ 668	\$ 33,726
Exercise of stock options	43,333	—	86	—	—	86	—	86
Stock-based compensation expense	—	—	380	—	—	380	—	380
Foreign currency translation adjustment	—	—	—	—	(175)	(175)	—	(175)
Net loss	—	—	—	(8,389)	—	(8,389)	—	(8,389)
Balance at March 31, 2021	19,043,034	\$ 19	\$ 278,113	\$ (253,449)	\$ 277	\$ 24,960	\$ 668	\$ 25,628

Three Months Ended March 31, 2020

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity (Deficit) attributable to Millendo Therapeutics, Inc.	Total Equity Attributable to Noncontrolling Interests	Total Stockholders' Equity (Deficit)
	Shares	Amount						
Balance at January 1, 2020	18,266,545	\$ 18	\$ 267,018	\$ (208,654)	\$ 165	\$ 58,547	\$ 1,324	\$ 59,871
Issuance of common stock, net of issuance costs	719,400	1	5,649	—	—	5,650	—	5,650
Exercise/forfeiture of BSPCE warrants	12,307	—	593	—	—	593	(515)	78
Stock-based compensation expense	—	—	1,080	—	—	1,080	—	1,080
Foreign currency translation adjustment	—	—	—	—	(42)	(42)	—	(42)
Net loss	—	—	—	(11,998)	—	(11,998)	—	(11,998)
Balance at March 31, 2020	18,998,252	\$ 19	\$ 274,340	\$ (220,652)	\$ 123	\$ 53,830	\$ 809	\$ 54,639

See accompanying Notes to unaudited Interim Consolidated Financial Statements

**MILLENDO THERAPEUTICS, INC.**  
**Consolidated Statements of Cash Flows**  
(Unaudited)  
(in thousands)

	Three Months Ended March 31,	
	2021	2020
<b>Operating activities:</b>		
Net loss	\$ (8,389)	\$ (11,998)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	33	37
Stock-based compensation expense	380	1,080
Foreign currency remeasurement gain	(174)	—
Amortization of right-of-use asset	143	243
Loss on disposal of equipment	9	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(319)	1,807
Other assets	—	(1)
Accounts payable	(669)	1,329
Accrued expenses and other liabilities	(2,700)	(2,255)
Operating lease liabilities	(149)	(403)
Cash used in operating activities	<u>(11,835)</u>	<u>(10,161)</u>
<b>Investing activities:</b>		
Proceeds (purchases) from property and equipment	8	(26)
Cash provided by (used) in investing activities	<u>8</u>	<u>(26)</u>
<b>Financing activities:</b>		
Repayment of debt	(54)	—
Proceeds from the issuance of common stock, net of issuance costs	—	5,521
Proceeds from option and BSPCE warrant exercises	86	78
Repayment of principal on finance lease	(10)	(10)
Cash provided by financing activities	<u>22</u>	<u>5,589</u>
Effect of foreign currency exchange rate changes on cash	(6)	(37)
Net decrease in cash, cash equivalents and restricted cash	(11,811)	(4,635)
Cash, cash equivalents and restricted cash at beginning of period	38,658	63,512
Cash, cash equivalents and restricted cash at end of period	<u>\$ 26,847</u>	<u>\$ 58,877</u>
<b>Supplemental schedule of non-cash investing and financing activities:</b>		
Financing costs in accounts payable and accrued expenses	<u>\$ —</u>	<u>\$ 68</u>

See accompanying Notes to unaudited Interim Consolidated Financial Statements

**MILLENDO THERAPEUTICS, INC.**  
**Notes to Unaudited Interim Consolidated Financial Statements**

**1. Organization and Description of Business**

***Description of Business***

Millendo Therapeutics, Inc. (the “Company”), a Delaware corporation, together with its subsidiaries, is a biopharmaceutical company that was previously primarily focused on developing novel treatments for orphan endocrine diseases where current therapies do not exist or are insufficient.

The Company had been developing livoletide (AZP-531), as a potential treatment for Prader-Willi syndrome, (“PWS”), a rare and complex genetic endocrine disease characterized by hyperphagia, or insatiable hunger. The Company discontinued the development of livoletide as a potential treatment for PWS in April 2020 based upon results from its Phase 2b trial. All costs, including estimated closeout costs associated with the livoletide program were recognized during 2020. The Company does not expect to incur future material expenses related to this program.

In an effort to streamline costs after discontinuing the PWS program, the Company eliminated employee positions representing approximately 30% of its prior headcount, which were completed in the second quarter of 2020. The Company recorded one-time costs of \$1.1 million in the form of termination benefits related to this plan in the second quarter of 2020.

The Company had also been developing nevanimibe (ATR-101) as a potential treatment for patients with classic congenital adrenal hyperplasia, (“CAH”), a rare, monogenic adrenal disease that requires lifelong treatment with exogenous cortisol, often at high doses. The Company elected to cease investing in the development of nevanimibe as a potential treatment for CAH in June 2020 based on an interim review of data from its Phase 2b trial. All costs, including estimated closeout costs associated with the nevanimibe program for the treatment of CAH were recognized during 2020. The Company does not expect to incur future material expenses related to its nevanimibe program for the treatment of CAH.

The Company had also been developing a selective neurokinin 3-receptor (NK3R) antagonist (MLE-301) as a potential treatment of vasomotor symptoms (“VMS”), commonly known as hot flashes and night sweats, in menopausal women. In January 2021, the Company discontinued further investment in MLE-301 for the treatment of VMS based on an analysis of the pharmacokinetic and pharmacodynamic data from the single ascending dose portion of the Phase 1 study. All costs, including estimated closeout costs associated with the MLE-301 program were recognized during the first quarter of 2021 and the Company does not expect to incur future material expenses related to this program.

In January 2021, as a result of its decision to discontinue its investment in MLE-301, the Company's Board of Directors (the “Board”) also approved a corporate restructuring plan (the “Plan”) furthering the Company's ongoing efforts to align its resources with its current strategy and operations. In connection with the Plan, the Company plans to reduce its workforce by up to 85%, and the majority of the reduction in personnel was completed by April 15, 2021. The Company initiated this reduction in force in January 2021 and has provided or will provide severance payments and continuation of group health insurance coverage for a specified period to the affected employees. The Company has also entered into retention arrangements with employees who are expected to remain with the Company. The Company estimates that it will incur costs of approximately \$5.5 million for termination benefits and retention arrangements related to the Plan, of which approximately \$4.2 million has been recorded in the first quarter of 2021. Substantially all termination benefits will be cash expenditures.

In 2020, the Company undertook a strategic review process, which was intended to result in an actionable plan that leverages its assets, capital and capabilities to maximize stockholder value. Following an extensive process of evaluating strategic alternatives, including identifying and reviewing potential candidates for a strategic acquisition or other transaction, on March 29, 2021, the Company entered into an Agreement and Plan of Merger (the “Merger Agreement”) with Tempest Therapeutics, Inc. (“Tempest”) under which the privately held Tempest will merge with a wholly owned subsidiary of Millendo (the “Merger”). The Merger is subject to certain closing conditions, including, among other things, approval by the Company's stockholders. If the Merger is completed, the business of Tempest will continue as the business of the combined company.

***Liquidity***

The Company has incurred net losses since inception and it expects to generate losses from operations for the foreseeable future primarily due to the ongoing review of corporate strategic alternatives that include, but are not limited to, the potential sale or merger of the Company or its assets. As of March 31, 2021, the Company had cash, cash equivalents, marketable securities and restricted cash of \$27.3 million and an accumulated deficit of \$253.4 million.

In April 2019, the Company entered into an “at-the-market” (“ATM”) equity distribution agreement with Citigroup Global Markets Inc. acting as sole agent with an aggregate offering value of up to \$50.0 million, which allows the Company to sell its common stock through the facilities of the Nasdaq Capital Market. Subject to the terms of the ATM equity distribution agreement, the Company is able to determine, at its sole discretion, the timing and number of shares to be sold under this ATM facility. In March 2020, the Company amended and restated the equity distribution agreement to include SVB Leerink LLC as an additional sales agent for the ATM. In March 2020, the Company sold 719,400 shares of its common stock under its ATM equity distribution agreement for net proceeds of approximately \$5.5 million. The Company does not expect to sell additional shares of common stock under the equity distribution agreement.

Given its limited expected financing options, the Company is currently exploring an expanded range of strategic alternatives that include, but are not limited to, the potential sale or merger of the Company or its assets. In the event that the Company does not complete the Merger with Tempest, the Company (i) may elect to pursue a dissolution and liquidation of the Company, (ii) may pursue another strategic transaction or (iii) may resume research and development activities.

The Company believes its cash, cash equivalents and restricted cash at March 31, 2021 are sufficient to fund its current operations for at least 12 months following the issuance of these financial statements.

## **2. Basis of Presentation and Summary of Significant Accounting Policies**

### ***Basis of presentation and consolidation principles***

The accompanying unaudited Interim Consolidated Financial Statements include the accounts of Millendo Therapeutics, Inc. and its subsidiaries, and all intercompany amounts have been eliminated. The unaudited Interim Consolidated Financial Statements have been prepared in conformity with U.S. generally accepted accounting principles (“GAAP”). Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification (“ASC”) and Accounting Standards Updates (“ASU”) of the Financial Accounting Standards Board (“FASB”). The unaudited Interim Consolidated Financial Statements include the accounts of the Company’s subsidiaries in which the Company holds a controlling financial interest as of the financial statement date.

### ***Unaudited Interim Consolidated Financial Statements***

The Company has prepared the accompanying unaudited Interim Consolidated Financial Statements based on Securities and Exchange Commission (“SEC”) rules that permit reduced disclosure for interim periods. These unaudited Interim Consolidated Financial Statements include, in the Company’s opinion, all adjustments, consisting only of normal recurring adjustments that the Company considers necessary for a fair presentation of its consolidated financial position and results of operations for these periods. The Company’s historical results are not necessarily indicative of the results to be expected in the future and the Company’s operating results for the three months ended March 31, 2021 are not necessarily indicative of the results that may be expected for the year ending December 31, 2021.

The accompanying unaudited Interim Consolidated Financial Statements should be read in conjunction with the Consolidated Financial Statements and notes thereto included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2020 as filed with the SEC on March 29, 2021. Since the date of such financial statements, there have been no changes to the Company’s significant accounting policies except as noted below:

### ***Use of estimates***

The preparation of the Consolidated Financial Statements in conformity 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 financial statements and reported amounts of expenses during the reporting period. Due to the uncertainty of factors surrounding the estimates or judgments used in the preparation of the Consolidated Financial Statements, actual results may materially vary from these estimates. Estimates and assumptions are periodically reviewed and the effects of revisions are reflected in the financial statements in the period they are determined to be necessary.

### ***Significant Risks and Uncertainties***

With the global impacts of the ongoing COVID-19 pandemic continuing in the first quarter of 2021, the Company is maintaining business continuity plans designed to address and mitigate the impact of the COVID-19 pandemic on its business. The Company anticipates that the COVID-19 pandemic will continue to have an impact on business activities. The extent to which the COVID-19 pandemic impacts the Company’s business, its strategic planning and the value of and market for its

common stock, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the U.S., Europe and other countries, and the effectiveness of actions taken globally to contain and treat the disease. The global economic slowdown, the overall disruption of global healthcare systems and the other risks and uncertainties associated with the pandemic could have a material adverse effect on the Company's business, financial condition, results of operations and growth prospects.

#### **Restricted Cash and Marketable Securities**

Restricted cash relates to amounts used to secure the Company's credit card facility balances held on deposit with major financial institutions and to collateralize a letter of credit in the name of the Company's landlord pursuant to a certain operating lease agreement as of December 31, 2020. In the first quarter of 2021, the letter of credit in the amount of \$0.4 million expired and remained invested in a certificate of deposit. This amount is reflected in marketable securities on the Company's consolidated balance sheet as the original maturity of the certificate of deposit was greater than three months when acquired.

#### **Net loss per share**

Basic loss per share of common stock is computed by dividing net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during each period. Diluted loss per share of common stock includes the effect, if any, from the potential exercise or conversion of securities, such as restricted stock and stock options, which would result in the issuance of incremental shares of common stock. In computing the basic and diluted net loss per share, the weighted-average number of shares of common stock remains the same for both calculations due to the fact that when a net loss exists, dilutive shares are not included in the calculation as the impact is anti-dilutive.

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares of common stock outstanding, as they would be anti-dilutive (amounts shown as common stock equivalents):

	March 31,	
	2021	2020
Stock options	3,520,358	3,340,732
Common stock warrants	17,125	17,125
BSA and BSPCE warrants	48,265	58,415
	<u>3,585,748</u>	<u>3,416,272</u>

#### **Recent accounting pronouncements**

In January 2020, the FASB issued ASU 2020-01, *Investments-Equity Securities (Topic 321), Investments-Equity Method and Joint Ventures (Topic 323), and Derivatives and Hedging (Topic 815)*. ASU 2020-01 states any equity security transitioning from the alternative method of accounting under Topic 321 to the equity method, or vice versa, due to an observable transaction will be remeasured immediately before the transition. In addition, the ASU clarifies the accounting for certain non-derivative forward contracts or purchased call options to acquire equity securities stating such instruments will be measured using the fair value principles of Topic 321 before settlement or exercise. The ASU is effective for fiscal years beginning after December 15, 2020, and will be applied on a prospective basis. The Company adopted ASU 2020-01 on January 1, 2021, which did not have a material effect on the consolidated financial statements.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740) - Simplifying the Accounting for Income Taxes*. ASU 2019-12 simplifies the accounting for income taxes by removing exceptions within the general principles of Topic 740 regarding the calculation of deferred tax liabilities, the incremental approach for intra-period tax allocation, and calculating income taxes in an interim period. In addition, the ASU adds clarifications to the accounting for franchise tax (or similar tax), which is partially based on income, evaluating tax basis of goodwill recognized from a business combination, and reflecting the effect of any enacted changes in tax laws or rates in the annual effective tax rate computation in the interim period that includes the enactment date. The ASU is effective for fiscal years beginning after December 15, 2020, and will be applied either retrospectively or prospectively based upon the applicable amendments. The Company adopted ASU 2019-01 on January 1, 2021, which did not have a material effect on the consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820) Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement*. ASU 2018-13 resulted in certain modifications to fair value

measurement disclosures, primarily related to level 3 fair value measurements. This standard was effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, and early adoption was permitted. The adoption of this ASU did not have a material impact on the consolidated financial statements and related disclosures.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses (Topic 326) Measurement of Credit Losses on Financial Instruments*, which replaces the incurred loss impairment methodology in current GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. Additionally, ASU 2016-13 requires a financial asset measured at amortized cost basis to be presented at the net amount expected to be collected through the use of an allowance of expected credit losses. In May 2019, the FASB issued ASU 2019-05, *Financial Instruments - Credit Losses (Topic 326) Targeted Transition Relief*, which amends ASU 2016-13 by providing entities with an option to irrevocably elect the fair value option to be applied on an instrument-by-instrument basis for eligible financial instruments that are within the scope of Topic 326. The fair value option election does not apply to held-to-maturity debt securities. In November 2019, the FASB issued ASU 2019-10, *Financial Instruments - Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842)*, which finalized effective date delays for private companies, not-for-profit organizations, and certain smaller reporting companies applying the credit losses, leases, and hedging standards. Also, in November 2019, the FASB issued ASU 2019-11, *Codification Improvements to Topic 326, Financial Instruments - Credit Losses*, which provides clarity about certain aspects of the amendments in ASU 2016-13. ASU 2016-13, as amended, is effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years, and requires a modified retrospective approach. The Company is in the process of evaluating the impact of this new guidance on its consolidated financial statements and related disclosures.

### 3. Fair Value Measurements

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

	March 31, 2021		
	(Level 1)	(Level 2)	(Level 3)
<b>Assets</b>			
Money market funds (included in cash and cash equivalents)	\$ 24,637	\$ —	\$ —
Certificate of deposit	\$ 439	\$ —	\$ —
	December 31, 2020		
	(Level 1)	(Level 2)	(Level 3)
<b>Assets</b>			
Money market funds (included in cash and cash equivalents)	\$ 33,636	\$ —	\$ —

### 4. Accrued Expenses

Accrued expenses consist of the following (amounts in thousands):

	March 31, 2021	December 31, 2020
Compensation and related benefits	\$ 781	\$ 1,978
Professional fees	1,009	719
Preclinical and clinical costs	131	1,002
Insurance premiums	775	1,476
Other	113	350
Total	\$ 2,809	\$ 5,525

### 5. Debt

#### *Bpifrance Reimbursable Advance*

In December, 2017, in connection with its acquisition of Alizé Pharma SAS (“Alizé”), the Company assumed €0.7 million of debt that Alizé had outstanding with Bpifrance Financing (“Bpifrance”). The original advance amount of €0.8 million (“the

Bpifrance Advance”) was provided to Alizé as an innovation aid that required Alizé to carry out certain activities related to its livoletide clinical development program and incur a certain level of program expenditures. No interest is charged or accrued under the advance.

The Company is required to make quarterly principal payments, which began in December 2016 and continue through September 2021. The quarterly principal payments escalate over the repayment period beginning with €17,500 per quarter and increasing to €50,000 through maturity. In addition to the quarterly payments, beginning January 1, 2016, Bpifrance may require the Company to pay, by no later than March 31 of each year, a reimbursement annuity equal to 20% of the proceeds generated by the Company from license, assignment or use of livoletide. Under no circumstance, however, would the Company be required to reimburse to Bpifrance principal amounts greater than the original advance it received.

The Company is permitted to repay the Bpifrance Advance at any time, at which point it would be released from all commitments and obligations under the Bpifrance Advance agreement. The Bpifrance Advance agreement does not contain any ongoing financial covenants.

During the three months ended March 31, 2021, the Company made \$54,000 in principal payments. During the three months ended March 31, 2020, the Company made no principal payments under the Bpifrance Advance agreement due to the fact that in April 2020, Bpifrance provided a six month deferral of principal payments to support businesses as a result of the COVID-19 pandemic. At March 31, 2021, the balance outstanding was \$0.2 million (or €0.2 million).

## **6. Commitments and Contingencies**

### ***Operating Leases***

The Company has noncancelable operating leases for office space which have remaining lease terms of approximately 3.2 years. The Company was a party to a sublease agreement for office and laboratory space located in Waltham, Massachusetts. The sublease commenced on January 15, 2019 and expired on November 30, 2020. The total minimum sublease rentals received under the Waltham, Massachusetts agreement was \$0.6 million. In February 2019 and October 2018, the Company entered into two additional noncancellable operating leases for office space in Ann Arbor, Michigan for the Company’s headquarters; one that the Company took possession of in April 2019, and the other that the Company took possession of in July 2019, respectively. One of its leases in Ann Arbor, Michigan expires in June 2024 and the other expires in March 2024. In April 2019, the Company entered into a lease agreement for office space in Lexington, Massachusetts. This lease was scheduled to expire on September 30, 2020; however, in June 2020 the Company exercised its right to terminate the lease early such that the lease terminated on August 11, 2020. Lease agreements generally do not require material variable lease payments, residual value guarantees or restrictive covenants. In January 2020, the Company terminated its office lease agreement in Lyon, France.

As of March 31, 2021, the operating lease ROU asset and the operating lease liabilities were \$2.0 million and \$2.2 million, respectively. The weighted average discount rate used to account for the Company’s operating leases under ASC 842 is the Company’s estimated incremental borrowing rate of 7.0%. The Company has options to extend certain of its leases for another five to ten years. These options to extend were not recognized as part of the Company’s measurement of the ROU assets and operating lease liabilities for the three months ended March 31, 2021. The weighted average remaining term of the Company’s noncancellable operating leases is 3.13 years.

Rent expense related to the Company’s operating leases was approximately \$0.2 million and \$0.2 million for the three months ended March 31, 2021 and 2020, respectively. The Company recognizes rent expense on a straight-lined basis over the lease period and has accrued for rent expense incurred but not yet paid.

Cash paid for amounts included in the measurement of the lease liabilities was approximately \$0.2 million and \$0.5 million during the three months ended March 31, 2021 and 2020, respectively. The Company received approximately \$87,000 in sublease payments related to its Waltham, Massachusetts lease during the three months ended March 31, 2020.

Future minimum rental payments under the Company's noncancellable operating leases at March 31, 2021 is as follows (amounts in thousands):

2021 (excluding the three months ended March 31, 2021)	\$	573
2022		783
2023		806
2024		302
2025		—
Thereafter		—
<b>Total</b>	<b>\$</b>	<b>2,464</b>
Present Value Adjustment		(240)
<b>Lease liability at March 31, 2021</b>	<b>\$</b>	<b>2,224</b>

### **Litigation**

Liabilities for loss contingencies arising from claims, assessments, litigation, fines, penalties, and other sources are recorded when it is probable that a liability has been incurred and the amount can be reasonably estimated.

On November 9, 2016, a purported shareholder derivative action was filed in the Business Litigation Session of the Suffolk County Superior Court in the Commonwealth of Massachusetts (Cima v. Dipp, No. 16-3443-BLS1 (Mass. Sup. Ct.)) against certain former officers and directors of the Company and one current director of the Company and the Company as a nominal defendant alleging breach of fiduciary duties, unjust enrichment, abuse of control, gross mismanagement and waste of corporate assets for purported actions related to the Company's January 2015 follow-on public offering. On February 22, 2017, the court approved the parties' joint stipulation to stay all proceedings in the action until further notice. Following a status conference in December 2017, the stay was lifted. On January 25, 2018, at the parties' request, the court entered a second order staying all proceedings in the action until further order of the court. On March 2, 2020, the parties submitted a status report requesting that the court continue the stay. On March 5, 2020, the court entered an order continuing the stay and requiring that the parties file a further status report on or before June 30, 2020. On June 30, 2020, the parties filed a further status report requesting that the court continue the stay. The court continued the stay until at least January 7, 2021. On January 7, 2021, the parties filed a further status report requesting that the court continue the stay until at least April 30, 2021. The court continued the stay until April 30, 2021. On April 30, 2021, the defendants filed a status report requesting that the court continue the stay. The court has not acted yet on the April 30, 2021 status report. The Company believes that the complaint is without merit and intends to defend against the litigation. There can be no assurance, however, that the Company will be successful. At present, the Company is unable to estimate potential losses, if any, related to the lawsuit.

On March 24, 2017, a purported shareholder class action lawsuit was filed in the U.S. District Court for the District of Massachusetts (Dahhan v. OvaScience, Inc., No. 1:17-cv-10511-IT (D. Mass.)) against the Company and certain former officers of the Company alleging violations of Sections 10(b) and 20(a) of the Exchange Act (the "Dahhan Action"). On July 5, 2017, the court entered an order approving the appointment of Freedman Family Investments LLC as lead plaintiff, the firm of Robins Geller Rudman & Dowd LLP as lead counsel and the Law Office of Alan L. Kovacs as local counsel. Plaintiff filed an amended complaint on August 25, 2017. The Company filed a motion to dismiss the amended complaint, which the court denied on July 31, 2018. On August 14, 2018, the Company answered the amended complaint. On December 9, 2019, the court granted leave for the lead plaintiff to file a second amended complaint under seal and permitted the defendants to file a motion to strike the second amended complaint. On December 30, 2019, the court granted the parties' joint motion to stay all proceedings in the case pending mediation. On March 3, 2020, the parties conducted a mediation session. The mediation was unsuccessful. The Company filed a motion to strike the second amended complaint on May 1, 2020.

On August 17, 2020, the court granted the parties' joint motion to again stay all proceedings in the case pending mediation. The parties agreed to participate in a second mediation session on November 10, 2020. The mediation was unsuccessful. The Company believes that the amended complaint and the second amended complaint are without merit. On October 16, 2020, the court granted the parties' joint request to extend the stay until November 16, 2020. On November 16, 2020, the parties filed a joint status report seeking to extend the stay for an additional thirty days. On November 17, 2020, the court ordered the parties to file a supplemental joint status report clarifying whether they sought a continuance of the stay of all proceedings or instead, a partial lifting of the stay. On November 19, 2020, the parties filed a joint status report seeking to continue a partial stay of the case while the parties engaged in additional settlement discussions, and a partial lifting of the stay to the extent required for the court to rule on the Company's pending motion to strike and motions to dismiss filed by other defendants. Those motions

remain pending. The Company believes that the amended complaint and the second amended complaint are without merit. A resolution of this lawsuit adverse to the Company or the other defendants could have a material effect on the Company's consolidated financial position and results of operations. At present, the Company is unable to estimate potential losses, if any, related to the lawsuit.

On July 27, 2017, a purported shareholder derivative complaint was filed in the U.S. District Court for the District of Massachusetts (Chiu v. Dipp, No. 1:17-cv-11382-IT (D. Mass.)) against OvaScience as a nominal defendant, certain former officers and directors of the Company and one current director of the Company alleging breach of fiduciary duties, unjust enrichment and violations of Section 14(a) of the Exchange Act alleging that compensation awarded to the director defendants was excessive and seeking redress for purported actions related to the Company's January 2015 follow-on public offering and other public statements concerning the Company's former products. On September 26, 2017, the plaintiff filed an amended complaint which eliminated all claims regarding allegedly excessive director pay and additionally alleged claims of abuse of control and waste of corporate assets. On October 27, 2017, the defendants filed a motion to dismiss the amended complaint. The court heard oral argument on the motion to dismiss on April 5, 2018. On April 13, 2018, the court granted the defendants' motion to dismiss the amended complaint for failure to state a claim for relief under Section 14(a). The court also dismissed the plaintiffs' pendent state law claims without prejudice, based on lack of subject matter jurisdiction. On April 25, 2018, the plaintiffs moved for leave to amend the complaint and to stay this case pending the outcome of the Dahhan Action. The Company does not believe that the proposed amended complaint cures the defects in the current complaint, but informed plaintiffs' counsel that, in the interest of judicial economy, the defendants would not oppose the proposed amendment if the court would consider staying the case pending the resolution of the Dahhan Action. On April 27, 2018, the court granted the plaintiffs' motion for leave to amend the complaint and for a stay. On April 30, 2018, the plaintiffs filed their second amended complaint. On May 23, 2018, the court entered an order staying this case pending the resolution of the Dahhan Action. The Company believes that the second amended complaint is without merit and intends to defend against the litigation. There can be no assurance, however, that the Company will be successful. At present, the Company is unable to estimate potential losses, if any, related to the lawsuit.

On April 23, 2021 a complaint was filed against the Company and each of its directors in the United States District Court for the Southern District of New York. The lawsuit, captioned Nakkhumpun v. Millendo Therapeutics, Inc., alleges violations of Sections 14(a) and 20(a) of the Securities Exchange Act of 1934 and Rule 14a-9 promulgated thereunder, as well as breach of fiduciary duty of candor, against the defendants for allegedly disseminating a materially incomplete and misleading registration statement with the SEC in connection with the proposed Merger. The plaintiff seeks to enjoin the defendants from proceeding with a shareholder vote on the proposed Merger until the Company discloses the material information. The plaintiff also seeks damages and an award of costs, expert fees and attorneys' fees.

On April 27, 2021, a second complaint was filed against the Company and each of its directors in the United States District Court for the Southern District of New York. The lawsuit, captioned Klaus v. Millendo Therapeutics Inc., alleges violations of Sections 14(a) and 20(a) of the Securities Exchange Act of 1934 and Rule 14a-9 promulgated thereunder against the defendants for allegedly disseminating a materially incomplete and misleading registration statement with the SEC in connection with the proposed Merger. The plaintiff seeks to enjoin the defendants from proceeding with or consummating the proposed merger, or, in the event the proposed Merger is consummated, the plaintiff seeks to rescind it or recover damages. The plaintiff also seeks an award of costs, expert fees and attorneys' fees. Finally, the plaintiff seeks to direct the Company to disseminate a registration statement that does not contain any alleged misstatements of material fact.

On April 29, 2021, a third complaint was filed against the Company and each of its directors in the United States District Court for the Eastern District of New York. The lawsuit, captioned Campbell v. Millendo Therapeutics Inc., alleges the same violations and demands the same relief as in Klaus v. Millendo Therapeutics Inc.

On April 30, 2021, a complaint was filed against the Company and each of its directors in the United States District Court for the Southern District of New York. The lawsuit, captioned Schmidt v. Millendo Therapeutics, Inc., alleges the same violations as Campbell v. Millendo Therapeutics, Inc. and Klaus v. Millendo Therapeutics, Inc. It also demands the same relief.

On May 4, 2021, a complaint was filed against the Company and each of its directors in the United States District Court for the Southern District of New York. The lawsuit, captioned Colthurst v. Millendo Therapeutics, Inc., alleges the same violations as Campbell v. Millendo Therapeutics, Inc., Klaus v. Millendo Therapeutics, Inc., and Schmidt v. Millendo Therapeutics, Inc. It also demands the same relief.

On May 7, 2021, a complaint was filed against the Company and each of its directors in the United States District Court for the Eastern District of Michigan. The lawsuit, captioned Wilhelm v. Millendo Therapeutics, Inc., alleges the same violations as

Colthurst v. Millendo Therapeutics, Inc., Campbell v. Millendo Therapeutics, Inc., Klaus v. Millendo Therapeutics, Inc., and Schmidt v. Millendo Therapeutics, Inc. It also demands the same relief.

On May 10, 2021, a complaint was filed against the Company and each of its directors in the United States District Court for the District of Delaware. The lawsuit, captioned Carlisle v. Millendo Therapeutics, Inc., alleges the same violations as Wilhelm v. Millendo Therapeutics, Inc., Colthurst v. Millendo Therapeutics, Inc., Campbell v. Millendo Therapeutics, Inc., Klaus v. Millendo Therapeutics, Inc., and Schmidt v. Millendo Therapeutics, Inc. It also demands the same relief.

On May 11, 2021, a complaint was filed against the Company and each of its directors in the United States District Court for the Eastern District of Pennsylvania. The lawsuit, captioned Cech v. Millendo Therapeutics, Inc., alleges the same violations as Carlisle v. Millendo Therapeutics, Inc., Wilhelm v. Millendo Therapeutics, Inc., Colthurst v. Millendo Therapeutics, Inc., Campbell v. Millendo Therapeutics, Inc., Klaus v. Millendo Therapeutics, Inc., and Schmidt v. Millendo Therapeutics, Inc. It also demands the same relief.

In addition to the matters described above, the Company may be a party to litigation and subject to claims incident to the ordinary course of business from time to time. Regardless of the outcome, litigation can have an adverse impact on the Company because of defense and settlement costs, and diversion of management resources.

## **7. Stock-Based Compensation**

On June 11, 2019, the Company held its 2019 Annual Meeting of Stockholders (the “Annual Meeting”). At the Annual Meeting, the Company’s stockholders approved the Company’s 2019 Equity Incentive Plan (the “2019 Plan”) and the Company’s 2019 Employee Stock Purchase Plan (the “2019 ESPP,” and together with the 2019 Plan, the “Equity Plans”). The 2019 Plan is the successor to the Private Millendo 2012 Stock Plan and the OvaScience 2012 Stock Incentive Plan (each, as amended, the “Prior Plans”) and allows the Company to grant stock options, restricted stock unit awards and other awards at levels determined appropriate by the Company’s Board of Directors (the “Board”) or the Compensation Committee of the Board. No additional awards will be granted under either of the Prior Plans. The 2019 ESPP enables employees to purchase shares of the Company’s common stock through offerings of rights to purchase the Company’s common stock to all eligible employees. The Equity Plans were adopted by the Board on April 29, 2019, subject to approval by the Company’s stockholders, and became effective with such stockholder approval on June 11, 2019. Outstanding awards under the Prior Plans continue to be subject to the terms and conditions of the Prior Plans.

The aggregate number of shares of the Company’s common stock initially reserved for issuance under the 2019 Plan was 2,919,872 shares, which is the sum of (i) 534,320 shares, (ii) the number of unallocated shares remaining available for grant under the Prior Plans as of the effective date of the 2019 Plan, and (iii) the Prior Plans’ Returning Shares (as defined below), as such shares become available from time to time. The number of shares of the Company’s common stock reserved for issuance under the 2019 Plan will automatically increase on January 1 of each year, for a period of ten years, from January 1, 2020 continuing through January 1, 2029, by 4% of the total number of shares of the Company’s common stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares as may be determined by the Board. Pursuant to the terms of the 2019 Plan, an additional 4% of the total number of shares of the Company’s common stock outstanding on December 31, 2020 were added to the number of available shares effective January 1, 2021.

The term “Prior Plan’s Returning Shares” refers to the following shares of the Company’s common stock subject to any outstanding stock award granted under either of the Prior Plans: shares of common stock subject to awards that (i) expire or terminate for any reason prior to exercise or settlement; (ii) are forfeited because of the failure to meet a contingency or condition required to vest such shares or otherwise return to the Company; (iii) are reacquired, withheld (or not issued) to satisfy a tax withholding obligation in connection with an award or to satisfy the purchase price or exercise price of a stock award. The foregoing includes shares subject to outstanding awards under the OvaScience 2011 Stock Incentive Plan that expire, terminate or are otherwise surrendered, canceled, forfeited or repurchased by the Company at their original issuance price pursuant to a contractual repurchase right.

The following shares of the Company’s common stock under the 2019 Plan (collectively, the “2019 Plan Returning Shares”) will also become available again for issuance under the 2019 Plan: (i) any shares subject to a stock award that are not issued because such stock award expires or otherwise terminates without all of the shares covered by such stock award having been issued, (ii) any shares subject to a stock award that are not issued because such stock award is settled in cash; (iii) any shares issued pursuant to a stock award that are forfeited back to or repurchased by the Company because of the failure to meet a contingency or condition required for the vesting of such shares; and (iv) any shares reacquired by the Company in satisfaction of tax withholding obligations on a stock award or as consideration for the exercise or purchase price of a stock award.

The aggregate number of shares of the Company's common stock that may be issued under the 2019 ESPP is 133,580 shares, plus the number of shares of the Company's common stock that are automatically added on January 1st of each year, for a period of up to ten years, from January 1, 2020 continuing through January 1, 2029, by the lesser of (i) 1% of the total number of shares of the Company's capital stock outstanding on December 31 of the preceding calendar year, or (ii) 133,580 shares of the Company's common stock, unless a lesser number of shares is determined by the Board. Pursuant to the terms of the 2019 Employee Stock Purchase Plan, an additional 133,580 shares were added to the number of available shares effective January 1, 2021.

The Company measures employee and nonemployee stock-based awards at grant date fair value and records compensation expense on a straight-line basis over the vesting period of the award.

The Company recorded stock-based compensation expense in the following expense categories of its accompanying consolidated statements of operations and comprehensive loss for the three months ended March 31, 2021 and 2020, respectively (amounts in thousands):

	Three Months Ended March 31,	
	2021	2020
Research and development	\$ (258)	\$ 300
General and administrative	638	780
Total	<u>\$ 380</u>	<u>\$ 1,080</u>

### Stock options

Options issued may have a contractual life of up to 10 years and may be exercisable in cash or as otherwise determined by the Board. Vesting generally occurs over a period of not greater than four years. In May 2020, the Company granted 840,450 stock options to its employees in connection with the PWS and CAH program changes that occurred during the second quarter of 2020 (see Note 1). The vesting is as follows: 1) 50 percent of the shares subject to this option grant will vest on the earlier of (i) December 31, 2020 or (ii) the Board's approval of the achievement of certain performance criteria; and 2) one twelfth (1/12th) of the remaining shares subject to this option grant will vest in equal monthly installments thereafter.

Stock-based compensation expense is negative for research and development employees and decreased for general and administrative employees for the three months ended March 31, 2021 as compared to the prior period due to forfeitures as a result of the reduction in force initiated in the first quarter of 2021.

The following table summarizes the activity related to stock option grants to employees and nonemployees for the three months ended March 31, 2021:

	Shares	Weighted average exercise price per share	Weighted-average remaining contractual life (years)
Outstanding at January 1, 2021	3,749,102	\$ 11.60	7.9
Granted	534,000	2.07	
Exercised	(43,333)	2.00	
Forfeited	(719,411)	6.69	
Outstanding at March 31, 2021	<u>3,520,358</u>	<u>\$ 11.28</u>	<u>6.7</u>
Vested and exercisable at March 31, 2021	<u>2,035,439</u>	<u>\$ 15.49</u>	<u>4.9</u>
Vested and expected to vest at March 31, 2021	<u>3,520,358</u>	<u>\$ 11.28</u>	<u>6.7</u>

As of March 31, 2021, the unrecognized compensation cost related to 1,484,919 unvested stock options expected to vest was \$5.2 million. This unrecognized compensation will be recognized over an estimated weighted-average amortization period of 2.2 years. There were 43,333 stock options exercised during the three months ended March 31, 2021. There were no options exercised during the three months ended March 31, 2020. The aggregate intrinsic value of options exercised during the three months ended March 31, 2021 was \$29,000. The aggregate intrinsic value of both options outstanding and options exercisable

as of March 31, 2021 was \$10,000. The options granted during the three months ended March 31, 2021 had an estimated weighted-average grant date fair value of \$1.36. The grant date fair value of each option grant was estimated during the three months ended March 31, 2021 and 2020 using the following assumptions within the Black-Scholes option-pricing model:

	<b>Three Months Ended March 31, 2021</b>	<b>Three Months Ended March 31, 2020</b>
Expected term (in years)	6.07	6.08
Expected volatility	75%	78%
Risk-free interest rate	0.95%	1.36%
Expected dividend yield	0%	0%

At the time of the Alizé acquisition, Alizé had 6,219 nonemployee (BSA) warrants and 5,360 employee (BSPCE) warrants outstanding, which have weighted-average exercise prices of €80.06 and €83.40, respectively. As of March 31, 2021, all BSA and BSPCE warrants were vested. During the three months ended March 31, 2021, no shares were exercised. As of March 31, 2021, there were an aggregate of 48,265 shares of common stock issuable upon the exercise of the BSA and BSPCE warrants with a weighted-average exercise price of \$7.50 per share. These instruments are included in the equity attributable to noncontrolling interests.

## **8. Subsequent Events**

Subsequent events were evaluated through the filing date of this Quarterly Report on Form 10-Q.

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

*You should read the following discussion of our financial condition and results of operations in conjunction with our unaudited Interim Consolidated Financial Statements and the notes thereto included elsewhere in this Quarterly Report on Form 10-Q and with our annual audited Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2020 as filed with the Securities and Exchange Commission ("SEC") on March 29, 2021. In addition to historical financial information, the following discussion contains forward-looking statements that reflect our plans, estimates, beliefs and expectations that involve risks and uncertainties. Our actual results and the timing of events could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K, particularly in Item 1A. "Risk Factors" and "Special Note Regarding Forward-Looking Statements."*

### **Overview**

We are a biopharmaceutical company that was previously primarily focused on developing novel treatments for endocrine diseases where current therapies do not exist or are insufficient. The endocrine system is a collection of glands that secrete hormones into the blood stream to regulate a number of functions, including appetite, metabolism, growth, development and reproduction. Diseases of the endocrine system can cause multiple and varied symptoms, including appetite dysregulation, metabolic dysfunction, obesity, cardiovascular disease, menstrual irregularity, hirsutism, and infertility.

We had been developing livoletide (AZP-531) as a potential treatment for Prader-Willi syndrome ("PWS"), a rare and complex genetic endocrine disease characterized by hyperphagia, or insatiable hunger. As previously announced, we discontinued the development of livoletide as a potential treatment for PWS in April 2020, including the 9-month extension study and the initiation of the Phase 3 ZEPHYR trial. The decision to discontinue the PWS program was based on results from the Phase 2b ZEPHYR study, which showed that treatment with livoletide did not result in a statistically significant improvement in hyperphagia and food-related behaviors as measured by the Hyperphagia Questionnaire for Clinical Trials (HQ-CT) compared to placebo. We do not expect to incur future material expenses related to our livoletide program for the treatment of PWS.

In an effort to streamline costs after discontinuing our PWS program, we eliminated employee positions representing approximately 30% of our prior headcount, which were completed in the second quarter of 2020. We also began evaluating corporate strategic plans to prioritize and allocate resources to our remaining product candidates at the time and any future pipeline assets.

We had also been developing nevanimibe (ATR-101) as a potential treatment for patients with classic congenital adrenal hyperplasia ("CAH"), a rare, monogenic adrenal disease that requires lifelong treatment with exogenous cortisol, often at high doses. As we previously announced, we elected to cease investing in the development of nevanimibe as a potential treatment for CAH in June 2020. The decision to cease investment in the CAH program was based on the interim review of results from the Phase 2b clinical study and the changing competitive environment. Results from 10 subjects, nine from cohort 1 and one from cohort 2, with at least 12 weeks of treatment with nevanimibe in this open-label, continuous dose escalation study showed that one patient (10%) met the primary endpoint of achieving 17-hydroxyprogesterone (17-OHP) levels less than or equal to 2-times the upper limit of normal. Treatment under the amended protocol with dose titration starting at 500 mg BID improved tolerability of nevanimibe. We do not expect to incur future material expenses related to our nevanimibe program for the treatment of CAH as we are no longer developing this program.

We had also been developing a selective neurokinin 3-receptor (NK3R) antagonist (MLE-301) as a potential treatment of vasomotor symptoms ("VMS"), commonly known as hot flashes and night sweats, in menopausal women. As we previously announced, in January 2021, we discontinued further investment in MLE-301 for the treatment of VMS based on an analysis of the pharmacokinetic and pharmacodynamic data from the single ascending dose portion of the Phase 1 study. Given our limited expected financing options, we began exploring an expanded range of strategic alternatives that included, but was not limited to, the potential sale or merger of the Company or our assets.

In January 2021, as a result of our decision to discontinue our investment in MLE-301, our Board also approved a corporate restructuring plan (the "Plan") furthering our ongoing efforts to align our resources with our current strategy and operations. In connection with the Plan, we plan to reduce our workforce by up to 85%, and the majority of the reduction in personnel completed was by April 15, 2021. We initiated this reduction in force in January 2021 and we have provided or will provide severance payments and continuation of group health insurance coverage for a specified period to the affected employees. We have also entered into retention arrangements with employees who are expected to remain with the Company. We estimate that we will incur costs of approximately \$5.5 million for termination benefits and retention arrangements related to the Plan, of

which approximately \$4.2 million has been recorded in the first quarter of 2021. Substantially all termination benefits will be cash expenditures. In 2020, we undertook a strategic review process, which was intended to result in an actionable plan that leverages our assets, capital and capabilities to maximize stockholder value. Following an extensive process of evaluating strategic alternatives, including identifying and reviewing potential candidates for a strategic acquisition or other transaction, on March 29, 2021, we entered into an Agreement and Plan of Merger (the “Merger Agreement”), with Tempest Therapeutics, Inc. (“Tempest”) under which the privately held Tempest will merge with a wholly owned subsidiary of Millendo (the “Merger”). If the Merger is completed, the business of Tempest will continue as the business of the combined company.

We expect to devote significant time and resources to the completion of the Merger. However, there can be no assurances that such activities will result in the completion of the Merger. Further, the completion of the Merger may ultimately not deliver the anticipated benefits or enhance shareholder value. If the Merger is not completed, we will reconsider our strategic alternatives. We consider one of the following courses of action to be the most likely alternatives if the Merger is not completed:

- *Dissolve and liquidate our assets.* If, for any reason, the Merger does not close, our Board may conclude that it is in the best interest of stockholders to dissolve the Company and liquidate our assets. In that event, we would be required to pay all of our debts and contractual obligations, and to set aside certain reserves for potential future claims. There would be no assurances as to the amount or timing of available cash remaining to distribute to stockholders after paying our obligations and setting aside funds for reserves.
- *Pursue another strategic transaction.* We may resume the process of evaluating a potential strategic transaction in order to attempt another strategic transaction like the Merger.
- *Operate our business.* Although less likely than the alternatives above, our Board may elect to seek new product candidates for development.

Since inception, we have incurred significant operating losses and negative operating cash flows and there is no assurance that we will ever achieve or sustain profitability. Our net losses were \$8.4 million and \$12.0 million for the three months ended March 31, 2021 and 2020, respectively. As of March 31, 2021, we had an accumulated deficit of \$253.4 million. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future.

### **Merger Agreement**

After conducting a diligent and extensive process of evaluating strategic alternatives for the Company and identifying and reviewing potential candidates for a strategic acquisition or other transaction, which included the careful evaluation and consideration of proposals from interested parties, and following extensive negotiation with Tempest, on March 29, 2021, we, Mars Merger Corp. (“Merger Sub”), a wholly owned subsidiary of the Company, and Tempest entered into the Merger Agreement. Pursuant to the Merger Agreement, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Tempest, with Tempest continuing as a wholly owned subsidiary of the Company and the surviving corporation of the Merger.

Subject to the terms and conditions of the Merger Agreement, at the closing of the Merger, (a) each outstanding share of Tempest common stock (including shares of Tempest common stock issued upon conversion of Tempest preferred stock and shares of Tempest common stock issued in the financing transaction described below) will be converted into the right to receive a number of shares of Millendo common stock (subject to the payment of cash in lieu of fractional shares and after giving effect to a reverse stock split of Millendo common stock described below) calculated in accordance with the Merger Agreement (the “Exchange Ratio”) and (b) each then outstanding Tempest stock option and warrant to purchase Tempest common stock will be assumed by Millendo, subject to adjustment as set forth in the Merger Agreement. Under the terms of the Merger Agreement, the Millendo board of directors may accelerate the vesting of any Millendo stock options that are outstanding as of immediately prior to the closing of the Merger.

Under the Exchange Ratio formula in the Merger Agreement, upon the closing of the Merger, on a pro forma basis and based upon the number of shares of Millendo common stock expected to be issued in the Merger, pre-Merger Millendo shareholders will own approximately 18.5% of the combined company and pre-Merger Tempest stockholders will own approximately 81.5% of the combined company (assuming the financing transaction described below results in gross proceeds of approximately \$30 million). For purposes of calculating the Exchange Ratio, shares of Millendo common stock underlying Millendo stock options outstanding as of the immediately prior to the closing of the Merger with an exercise price per share of less than or equal to \$5.00 (as adjusted for the reverse stock split described below) will be deemed to be outstanding and all shares of Tempest

common stock underlying outstanding Tempest stock options, warrants and other derivative securities will be deemed to be outstanding. The Exchange Ratio will be adjusted to the extent that Millendo's net cash at closing is less than \$15.3 million or greater than \$18.7 million and based on the amount of the financing transaction described below, as further described in the Merger Agreement.

In connection with the Merger, Millendo will seek the approval of its stockholders to (a) issue the shares of Millendo common stock issuable in connection with the Merger under the rules of The Nasdaq Stock Market LLC ("Nasdaq") and (b) amend its certificate of incorporation to effect a reverse split of Millendo common stock at a ratio of between 1:10 and 1:15, as determined by a committee of the Millendo board of directors prior to the closing of the Merger (the "Millendo Voting Proposals").

Each of Millendo and Tempest has agreed to customary representations, warranties and covenants in the Merger Agreement, including, among others, covenants relating to (1) using reasonable best efforts to obtain the requisite approval of its stockholders, (2) non-solicitation of alternative acquisition proposals, (3) the conduct of their respective businesses during the period between the date of signing the Merger Agreement and the closing of the Merger, (4) Millendo using reasonable best efforts to maintain the existing listing of the Millendo common stock on Nasdaq and Millendo causing the shares of Millendo common stock to be issued in connection with the Merger to be approved for listing on Nasdaq prior to the closing of the Merger, and (5) Millendo filing with the U.S. Securities and Exchange Commission (the "SEC") and causing to become effective a registration statement to register the shares of Millendo common stock to be issued in connection with the Merger (the "Registration Statement").

Consummation of the Merger is subject to certain closing conditions, including, among other things, the (1) approval by Millendo stockholders of the Millendo Voting Proposals, (2) approval by the Tempest stockholders of the adoption of the Merger Agreement, (3) Nasdaq's approval of the listing of the shares of Millendo common stock to be issued in connection with the Merger, (4) the effectiveness of the Registration Statement, and (5) the determination of Millendo's net cash in accordance with the Merger Agreement. Each party's obligation to consummate the Merger is also subject to other specified customary conditions, including the representations and warranties of the other party being true and correct as of the date of the Merger Agreement and as of the closing date of the Merger, generally subject to an overall material adverse effect qualification, and the performance in all material respects by the other party of its obligations under the Merger Agreement required to be performed on or prior to the date of the closing of the Merger. Millendo's obligation to consummate the Merger also is subject to the completion of at least \$25.0 million of the financing transaction described below.

The Merger Agreement contains certain termination rights of each of Millendo and Tempest, including, subject to compliance with the applicable terms of the Merger Agreement, the right of each party to terminate the Merger Agreement to enter into a definitive agreement for a superior proposal. Upon termination of the Merger Agreement under specified circumstances, Millendo may be required to pay Tempest a termination fee of \$1.4 million or reimburse Tempest's expenses up to a maximum of \$1.0 million and Tempest may be required to pay Millendo a termination fee of \$2.8 million or reimburse Millendo's expenses up to a maximum of \$1.0 million.

Concurrently with the execution of the Merger Agreement, (i) certain executive officers, directors and stockholders of Tempest (solely in their respective capacities as Tempest stockholders) holding approximately 87% of the outstanding shares of Tempest capital stock have entered into support agreements with Millendo and Tempest to vote all of their shares of Tempest capital stock in favor of adoption of the Merger Agreement and against any alternative acquisition proposals (the "Tempest Support Agreements") and (ii) certain executive officers, directors and stockholders of Millendo (solely in their respective capacities as Millendo stockholders) holding approximately 16% of the outstanding shares of Millendo common stock have entered into support agreements with Millendo and Tempest to vote all of their shares of Millendo common stock in favor of the Millendo Voting Proposals and against any alternative acquisition proposals (the "Millendo Support Agreements", and together with the Tempest Support Agreements, the "Support Agreements").

Concurrently with the execution of the Merger Agreement, certain executive officers, directors and stockholders of Tempest have entered into lock-up agreements (the "Lock-Up Agreements") pursuant to which, subject to specified exceptions, they agreed not to transfer their shares of Millendo common stock for the 180-day period following the closing of the Merger. In addition, each of Millendo and Tempest is obligated under the Merger Agreement to use reasonable best efforts prior to the closing of the Merger to obtain a Lock-Up Agreement from any person who will serve as a director or officer of Millendo following completion of the Merger.

At the effective time of the Merger, the Board of Directors of Millendo is expected to consist of seven members, six of whom will be designated by Tempest and one of whom will be designated by Millendo.

Concurrently with the execution and delivery of the Merger Agreement, certain parties have entered into agreements with Tempest pursuant to which they have agreed, subject to the terms and conditions of such agreements, to purchase prior to the consummation of the Merger shares of Tempest common stock for an aggregate purchase price of approximately \$30 million. The consummation of the transactions contemplated by such agreements is conditioned on the satisfaction or waiver of the conditions set forth in the Merger Agreement. Shares of Tempest common stock issued pursuant to this financing transaction will be converted into shares of Millendo common stock in the Merger in accordance with the Exchange Ratio.

#### ***At-the-Market Equity Distribution Agreement***

In April 2019, we entered into an "at-the-market" ("ATM") equity distribution agreement with Citigroup Global Markets Inc. acting as sole agent with an aggregate offering value of up to \$50.0 million. Subject to the terms of the ATM equity distribution agreement, we are able to determine, at our sole discretion, the timing and number of shares to be sold under this ATM facility. In March 2020, we amended and restated the equity distribution agreement to include SVB Leerink LLC as an additional sales agent for the ATM. In March 2020, we sold 719,400 shares of our common stock under our ATM equity distribution agreement for net proceeds of approximately \$5.5 million. We do not expect to sell additional shares under this ATM facility.

Sales of our common stock pursuant to the ATM have been made pursuant to our registration statement on Form S-3 (Registration Statement No. 333-230749), which was declared effective by the Securities and Exchange Commission on April 18, 2019.

#### **COVID-19 Business Update**

With the global impacts of the ongoing COVID-19 pandemic continuing in the first quarter of 2021, we are maintaining the business continuity plans we established and implemented in the first quarter of 2020, which are designed to address and mitigate the impact of the COVID-19 pandemic on our employees, operations and our business. While we are experiencing limited financial impacts from the pandemic at this time, given the global economic slowdown, the overall disruption of global healthcare systems and the other risks and uncertainties associated with the pandemic, our business, financial condition, and results of operations, could be materially adversely affected. We continue to closely monitor the COVID-19 situation as we evolve our business continuity plans and response strategy. In March 2020, our global workforce transitioned to working remotely. Throughout the first quarter of 2021, we continued our plan to allow some employees to return to the office voluntarily, which was based on a phased approach that is principles-based, flexible and local in design, with a focus on employee safety and optimal work environment. Our current plans remain fluid as federal, state and local guidelines, rules and regulations continue to evolve.

#### **Components of Our Results of Operations**

##### ***Research and development expense***

Research and development expense consists primarily of costs incurred in connection with the development of our product candidates. We expense research and development costs as incurred. These expenses include:

- personnel expenses, including salaries, benefits and stock-based compensation expense;
- costs of funding research performed by third-parties, including pursuant to agreements with contract research organizations, ("CROs"), as well as investigative sites and consultants that conduct our preclinical studies and clinical trials;
- expenses incurred under agreements with contract manufacturing organizations ("CMOs"), including manufacturing scale-up expenses and the cost of acquiring and manufacturing preclinical study and clinical trial materials;
- payments made under our third-party licensing agreements;
- consultant fees and expenses associated with outsourced professional scientific development services;
- expenses for regulatory activities, including filing fees paid to regulatory agencies; and
- allocated expenses for facility costs, including rent, utilities, depreciation and maintenance.

Milestone payment obligations incurred prior to regulatory approval of a product candidate, which are accrued when the event requiring payment of the milestone occurs are included in research and development expense.

We typically use our employee, consultant and infrastructure resources across our development programs. We track certain outsourced development costs by product candidate, but do not allocate all personnel costs or other internal costs to specific product candidates.

The following table summarizes our research and development expenses by product candidate, personnel expense and other expenses for the three months ended March 31, 2021 and 2020, respectively:

	Three Months Ended March 31,	
	2021	2020
	(dollars in thousands)	
Livote tide expenses	\$ (45)	\$ 4,846
Nevanimibe expenses	—	252
MLE-301 expenses	384	430
Personnel expenses	1,805	1,774
Other expenses	8	238
Total	<u>\$ 2,152</u>	<u>\$ 7,540</u>

Our research and development costs related to livote tide and nevanimibe have decreased significantly due to our decision to discontinue the livote tide and nevanimibe programs based on results from the Phase 2b ZEPHYR study in PWS and the Phase 2b clinical study in CAH, respectively. All costs, including estimated program closeout costs associated with these programs, were primarily recognized during the second quarter of 2020. Any revisions to estimated program closeout costs have been recognized as of March 31, 2021. Future expenses may be recorded as a result of changes to these estimated costs as closeout activities continue. Our research and development costs related to MLE-301 have decreased due to our decision in January 2021 to discontinue the MLE-301 program based on the data from the single ascending dose portion of the Phase 1 study. We do not expect to incur material costs in the future related to the MLE-301 program.

If we decide to resume product candidate development, the successful development of any future product candidates would be highly uncertain. We are also unable to predict when, if ever, material net cash inflows would commence from sales of any future product candidates that we may develop due to the numerous risks and uncertainties associated with clinical development, including risks and uncertainties related to:

- the ongoing COVID-19 pandemic, including the potential impact on various aspects and stages of the clinical development process;
- the number of clinical sites included in the trials;
- the length of time required to enroll suitable patients;
- the number of patients that ultimately participate in the trials;
- the number of doses patients receive;
- the duration of patient follow-up and number of patient visits;
- the results of our clinical trials;
- the establishment of commercial manufacturing capabilities;
- the receipt of marketing approvals; and
- the commercialization of product candidates.

We may never succeed in obtaining regulatory approval for any future product candidates we may develop.

### General and administrative expense

General and administrative expense consists primarily of personnel expenses, including salaries, benefits and stock-based compensation expense, for employees in executive, finance, accounting, business development, legal and human resource functions. General and administrative expense also includes corporate facility costs, including rent, utilities, depreciation and maintenance, not otherwise included in research and development expense, as well as legal fees related to intellectual property and corporate matters and fees for accounting, recruiting and consulting services. Our general and administrative expenses increased during the three months ended March 31, 2021 mainly due to termination benefits incurred related to our corporate restructuring plan and increased professional fees incurred due to the proposed Merger.

### Interest expense (income), net

Interest expense (income) represents amounts earned on our cash, cash equivalents, marketable securities and restricted cash balances.

### Results of operations

#### Comparison of the three months ended March 31, 2021 and 2020

The following table summarizes our operating results for the periods indicated:

	Three Months Ended March 31,		Change
	2021	2020	
	(dollars in thousands)		
Operating expenses:			
Research and development	\$ 2,152	\$ 7,540	\$ (5,388) (71.5)%
General and administrative	6,410	4,595	1,815 39.5
Loss from operations	8,562	12,135	(3,573) (29.4)
Other expenses (income):			
Interest expense (income), net	1	(162)	163 (100.6)
Other (gain) / loss	(174)	25	(199) (796.0)
Net loss	<u>\$ (8,389)</u>	<u>\$ (11,998)</u>	<u>\$ 3,609</u> (30.1)%

### Research and development expense

Research and development expense decreased by \$5.4 million to \$2.2 million for the three months ended March 31, 2021 from \$7.5 million for the three months ended March 31, 2020. The following table summarizes our research and development expenses for the three months ended March 31, 2021 and 2020:

	Three Months Ended March 31,		Change
	2021	2020	
	(dollars in thousands)		
Preclinical and clinical development expense	\$ 339	\$ 5,528	\$ (5,189) (93.9)%
Compensation expense, other than stock-based compensation	2,063	1,474	589 40.0
Stock-based compensation expense	(258)	300	(558) (186.0)
Other expenses	8	238	(230) (96.6)
Total research and development expense	<u>\$ 2,152</u>	<u>\$ 7,540</u>	<u>\$ (5,388)</u> (71.5)%

The decrease in total research and development expense is attributable to:

- a \$5.2 million decrease in preclinical and clinical development expense primarily related to decreased spend due to discontinuing our development of the livoletide, nevanimibe and MLE-301 programs;

- a \$0.6 million increase in compensation expense, other than stock-based compensation, primarily due to termination benefits incurred related to the reduction in force initiated in the first quarter of 2021; and
- a \$0.6 million decrease in stock-based compensation expenses primarily related to the reduction in force initiated in the first quarter of 2021.

**General and administrative expense**

General and administrative expense increased by \$1.8 million to \$6.4 million for the three months ended March 31, 2021 from \$4.6 million for the three months ended March 31, 2020. The increase was primarily due to higher compensation and professional fees offset by a decrease in stock-based compensation. The increase in compensation of \$1.6 million was a result of termination benefits incurred related to the reduction in force initiated in the first quarter of 2021, as a result of the discontinuance of our MLE-301 program. The increase in professional fees of \$0.4 million was a result of the proposed merger in the first quarter of 2021. These increases were offset by a decrease of \$0.1 million in stock-based compensation as a result of the reduction in force completed in the first quarter of 2021.

**Interest expense (income), net**

Interest expense (income), net decreased by \$0.2 million to \$1,000 interest expense, net for the three months ended March 31, 2021 from interest income, net of \$0.2 million for the three months ended March 31, 2020. The change was primarily due to lower interest income received as a result of lower cash and cash equivalent and marketable securities balances and lower interest rates.

**Other (gain) / loss**

Other (gain) / loss increased by \$0.2 million to a gain of \$0.2 million for the three months ended March 31, 2021 from a loss of \$25,000 for the three months ended March 31, 2020 due to lower foreign currency losses as a result of exchange rate fluctuations on transactions denominated in a currency other than our functional currency.

**Liquidity and Capital Resources**

**Cash flows**

The following table sets forth the primary uses of cash and cash equivalents for the three months ended March 31, 2021 and 2020:

	Three Months Ended March 31,	
	2021	2020
	(in thousands)	
Net cash used in operating activities	\$ (11,835)	\$ (10,161)
Net cash provided by (used in) investing activities	8	(26)
Net cash provided by financing activities	22	5,589
Effect of foreign currency exchange rate changes on cash	(6)	(37)
Net decrease in cash, cash equivalents and restricted cash	<u>\$ (11,811)</u>	<u>\$ (4,635)</u>

**Operating activities**

During the three months ended March 31, 2021, we used \$11.8 million of cash to fund operating activities. During the three months ended March 31, 2021, cash used in operating activities reflected our net loss of \$8.4 million and a net change in operating assets and liabilities of \$3.8 million, offset by non-cash charges of \$0.4 million, principally related to stock-based compensation.

During the three months ended March 31, 2020, we used \$10.2 million of cash to fund operating activities. During the three months ended March 31, 2020, cash used in operating activities reflected our net loss of \$12.0 million and a net change in operating assets and liabilities of \$0.5 million, offset by non-cash charges of \$1.4 million, principally related to stock-based compensation and the amortization of our right-of-use assets.

### *Investing activities*

During the three months ended March 31, 2021, we received proceeds of \$8,000 related to the sale of equipment. During the three months ended March 31, 2020, we paid \$26,000 in purchases of property and equipment.

### *Financing activities*

During the three months ended March 31, 2021, we received \$86,000 in proceeds from option exercises offset by the repayment of debt and principal on a finance lease. During the three months ended March 31, 2020, we received proceeds of \$5.7 million received from the issuance of common stock, net of issuance costs paid. These proceeds were offset by \$0.2 million in the payment of financing costs.

### *Funding requirements*

We expect our expenses to decrease as a result of our discontinuing the development of livoletide, nevanimibe and MLE-301 as compared to previous operations. However, we expect to continue to incur costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we may be forced to liquidate our assets. The COVID-19 pandemic continues to rapidly evolve and has already resulted in a significant disruption of global financial markets. If the disruption persists and deepens, we could experience an inability to access additional capital, which could in the future negatively affect our operations.

In April 2019, we entered into an “at-the-market” (“ATM”), equity distribution agreement with Citigroup Global Markets Inc. acting as sole agent with an aggregate offering value of up to \$50.0 million. Subject to the terms of the ATM equity distribution agreement, we are able to determine, at our sole discretion, the timing and number of shares to be sold under this ATM facility. In March 2020, we amended and restated the equity distribution agreement to include SVB Leerink LLC as an additional sales agent for the ATM. In March 2020, we sold 719,400 shares of common stock under our ATM equity distribution agreement for net proceeds of approximately \$5.5 million. We do not expect to sell additional shares under this ATM facility.

As of March 31, 2021, we had cash, cash equivalents, marketable securities and restricted cash of \$27.3 million, which we believe are sufficient to fund our planned operations through at least the next 12 months.

Our future capital requirements will depend on the results of our ongoing strategic evaluation, including whether we complete the Merger with Tempest. If the Merger is not completed, we will reconsider our strategic alternatives which may include a dissolution of the company, pursuit of another strategic transaction or the continued operation of product development. In the event we resume product candidate development, our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of preclinical studies and clinical trials;
- the scope, prioritization and number of our research and development programs;
- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under collaboration agreements, if any;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of securing manufacturing arrangements for commercial production; and
- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory approvals to market our product candidates.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes many years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, any future product candidates, if approved, may not achieve commercial success.

If we elect to resume product candidate development, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends

If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third-parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

### **Contractual Obligations and Commitments**

During the three months ended March 31, 2021, there were no material changes to our contractual obligations and commitments described under “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K.

### **Off-Balance Sheet Arrangements**

We did not have any off-balance sheet arrangements as of March 31, 2021, as defined in Item 303(a)(4)(ii) of Regulation S-K.

### **Critical Accounting Policies and Estimates**

Other than as described under Note 2 to our Unaudited Interim Consolidated Financial Statements, the Critical Accounting Policies included in our Annual Report on Form 10-K for the year ended December 31, 2020, as filed with the SEC on March 29, 2021, have not materially changed.

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

Not required for smaller reporting companies.

### **Item 4. *Controls and Procedures***

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

Our management, with the participation of our Chief Executive Officer (principal executive officer) and Chief Financial Officer (principal financial officer), evaluated the effectiveness of our disclosure controls and procedures (as defined in the Securities Exchange Act of 1934 Rules 13a-15(e) or 15d-15(e)) as required by paragraph (b) of Exchange Act Rules 13a-15 or 15d-15, as of March 31, 2021. Based on the evaluation of our disclosure controls and procedures as of March 31, 2021, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable assurance level.

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

There were no changes in internal control over financial reporting during the quarter ended March 31, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. We have not experienced any material impact to our internal controls over financial reporting despite the fact that our employees are working remotely due to the COVID-19 pandemic. We are continually monitoring and assessing the COVID-19 situation on our internal controls to minimize the impact on their design and operating effectiveness.

#### **Inherent Limitations on Effectiveness of Controls**

Our management, including our Chief Executive Officer and our Chief Financial Officer, believes that our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. However, our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

## **PART II**

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

Other than as described under Note 6 to our Unaudited Interim Consolidated Financial Statements, the Legal Proceedings included in our Annual Report on Form 10-K for the year ended December 31, 2020, as filed with the SEC on March 29, 2021, have not materially changed.

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

*Except as set forth below, during the three months ended March 31, 2021, there have been no material changes in our risk factors from those disclosed in Part I-Item 1A under the heading “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2020, as filed with the SEC on March 29, 2021. You should carefully consider the risks described below, as well as general economic and business risks and the other information in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2020. The occurrence of any of the following risks, or any of the risks set forth in our Annual Report on Form 10-K, could have a material adverse effect on our business, financial condition, results of operations and future growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment. We cannot assure you that any of the events discussed below will not occur. Such risks may be amplified by the COVID-19 pandemic and its potential impact on our business and the global economy.*

#### **Risks Related to Our Proposed Merger and Retention of Key Employees**

*As a result of our decision to discontinue further investment in MLE-301 and the reductions in our workforce, we have only seven employees remaining as of the date of this filing. If we are unable to retain certain of our remaining employees, our ability to consummate the planned Merger transaction may be delayed or seriously jeopardized.*

On January 28, 2021, we announced workforce reductions, and our current headcount has been reduced to seven employees as of the date of this filing. Our cash conservation activities may yield unintended consequences, such as attrition beyond the planned workforce reductions and reduced employee morale, which may cause the remaining employees to seek alternate employment. Competition among biotechnology companies for qualified employees is intense, and the ability to retain the remaining employees is critical to our ability to effectively manage our business and to consummate the planned Merger transaction. Additional attrition could have a material adverse effect on our business and ability to consummate the Merger. In addition, as a result of the reduction in our workforce, we face an increased risk of employment litigation.

#### **Risks Related to Our Business Operations and Employee Matters**

*We have recently reduced the size of our organization, and we may encounter difficulties in managing our business as a result of this reduction, or the attrition that may occur following this reduction, which could disrupt our operations. In addition, we may not achieve anticipated benefits and savings from the reduction.*

In January 2021, we began the implementation of a reduction in force that will reduce the number of our employees by up to 85 percent. As of the date of this filing, our current headcount has been reduced to seven employees. The reduction in force, and the attrition thereafter, resulted in the loss of longer-term employees, the loss of institutional knowledge and expertise and the reallocation and combination of certain of roles and responsibilities across the organization, all of which could adversely affect our operations. Given the complexity and nature of our business, we must continue to implement and improve our managerial, operational and financial systems, manage our facilities and continue to recruit and retain qualified personnel. This will be made more challenging given the reduction in force described above and additional measures we may take to reduce costs. As a result, our management may need to divert a disproportionate amount of its attention away from our day-to-day strategic and operational activities, and devote a substantial amount of time to managing these organizational changes. Further, the restructuring and possible additional cost containment measures may yield unintended consequences, such as attrition beyond our intended reduction in force and reduced employee morale. In addition, employees who were not affected by the reduction in force may seek alternate employment which would result in us seeking contract support at unplanned additional expense. In addition, we may not achieve anticipated benefits from the reduction in force. Due to our limited resources, we may not be able to effectively manage our operations or recruit and retain qualified personnel, which may result in weaknesses in our infrastructure and operations, risks that we may not be able to comply with legal and regulatory requirements, loss of business opportunities, loss of employees and reduced productivity among remaining employees. If our management is unable to effectively manage this transition and reduction in force and additional cost containment measures, our expenses may be more than expected, and we may not be able to implement our business strategy.

## **Risks Related to Ownership of Our Common Stock and Our Status as a Public Company**

### ***We are at risk of securities class action and similar litigation.***

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. We remain the subject of various securities class action lawsuits and shareholder derivative lawsuits that were filed against OvaScience and certain of its officer and directors, as described in more detail in Part II-Item 1 under the heading “Legal Proceedings”. These lawsuits, as well as any similar lawsuits initiated in the future, could result in substantial cost and a diversion of management’s attention and resources, which could harm our business.

As described above in Part II-Item 1 under the heading “Legal Proceedings”, eight complaints have been filed against us and each of our directors in connection with the Merger transaction. These lawsuits, as well as any similar lawsuits initiated in the future, could result in substantial cost and a diversion of management’s attention and resources, which could harm our business.

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

### **Recent Sales of Unregistered Securities**

We did not sell any unregistered securities during the three months ended March 31, 2021.

### **Issuer Purchases of Equity Securities**

We did not repurchase any securities during the three months ended March 31, 2021.

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

Not applicable.

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

Not applicable.

## **Item 5. Other Information**

### **Preliminary Unaudited Cash and Cash Equivalents as of March 31, 2021 and Net Loss for the Three Month Period Ended March 31, 2021.**

On May 10, 2021, we announced that although we had not finalized our full financial results for the fiscal quarter ended March 31, 2021, we expected to report that we had (a) cash, cash equivalents, restricted cash and marketable securities of approximately \$27.3 million as of March 31, 2021 and (b) a net loss of approximately \$8.4 million for the three-month period ended March 31, 2021. The estimated cash, cash equivalents, restricted cash and marketable securities and net loss figures were preliminary and unaudited, and represented our management’s estimates as of May 10, 2021. The financial information was subject to the completion of our financial closing procedures with respect to the interim consolidated financial statements, as of and for the three-month period ended March 31, 2021, which are included elsewhere in this Quarterly Report on Form 10-Q.

## Item 6. Exhibits

The following exhibits are incorporated by reference or filed as part of this report.

Exhibit Number	Description
2.1	<a href="#">Agreement and Plan of Merger, dated as of March 29, 2021, by and among Millendo Therapeutics, Inc., Mars Merger Corp. and Tempest Therapeutics, Inc. (incorporated by reference from Exhibit 2.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on March 29, 2021, File No. 001-35890)</a>
3.1	<a href="#">Restated Certificate of Incorporation of the Registrant, as amended (incorporated by reference from Exhibit 3.1 to the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 15, 2019 File No. 001-35890)</a>
3.2	<a href="#">Third Amended and Restated Bylaws, as Amended, of the Registrant (incorporated by reference from Exhibit 3.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on August 9, 2018 File No. 001-35890)</a>
10.1^	<a href="#">Executive Chair Agreement, by and between Millendo Therapeutics US, Inc. and Julia C. Owens, Ph.D., dated January 27, 2021 (incorporated by reference from Exhibit 10.29 to the Annual Report on Form 10-K, filed on March 29, 2021, File No. 001-35890).</a>
10.2^	<a href="#">Separation from Employment, by and between Millendo Therapeutics US, Inc. and Julia C. Owens, Ph.D., dated January 27, 2021 (incorporated by reference from Exhibit 10.30 to the Annual Report on Form 10-K, filed on March 29, 2021, File No. 001-35890).</a>
10.3^	<a href="#">Amended and Restated Employment Agreement between Louis Arcudi III and Millendo Therapeutics US, Inc., dated as of January 27, 2021 (incorporated by reference from Exhibit 10.31 to the Annual Report on Form 10-K, filed on March 29, 2021, File No. 001-35890).</a>
10.4^	<a href="#">Amended and Restated Employment Agreement between Jennifer Minai-Azary and Millendo Therapeutics US, Inc., dated of January 27, 2021 (incorporated by reference from Exhibit 10.32 to the Annual Report on Form 10-K, filed on March 29, 2021, File No. 001-35890).</a>
31.1*	<a href="#">Certification of Chief Executive Officer (Principal Executive Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002</a>
31.2*	<a href="#">Certification of Chief Financial Officer (Principal Financial Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002</a>
32.1^	<a href="#">Certification of Chief Executive Officer (Principal Executive Officer) and Chief Financial Officer (Principal Financial Officer) pursuant to Section 906 of Sarbanes-Oxley Act of 2002</a>
101.INS	Inline 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 Extension 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 - the cover page interactive data is embedded within the Inline XBRL document or included within the Exhibit 101 attachments.

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\* Filed herewith.

^ Indicates management contract or compensatory plan.

+ This certification is being furnished solely to accompany this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing of the registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof, regardless of any general incorporation language in 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.

MILLENDO THERAPEUTICS, INC.

By: /s/ Louis Arcudi III  
Louis Arcudi III  
President and Chief Executive Officer (Principal Executive Officer)

By: /s/ Jennifer Minai-Azary  
Jennifer Minai-Azary  
Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

Date: May 13, 2021

## CERTIFICATION

I, Louis Arcudi III, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Millendo Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. 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 controls over financial reporting, or caused such internal controls 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; and
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 13, 2021

/s/ Louis Arcudi III

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Louis Arcudi III  
President and Chief Executive Officer  
(Principal Executive Officer)

## CERTIFICATION

I, Jennifer Minai-Azary, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Millendo Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. 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; and
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 13, 2021

/s/ Jennifer Minai-Azary

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Jennifer Minai-Azary  
Chief Financial Officer  
(Principal Financial Officer)

## STATEMENT PURSUANT TO 18 U.S.C. § 1350

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Louis Arcudi III, President and Chief Executive Officer (Principal Executive Officer) of Millendo Therapeutics, Inc. (the “Company”) and Jennifer Minai-Azary, Chief Financial Officer (Principal Financial Officer) of the Company, each hereby certifies that, to the best of his or her knowledge:

- (1) The Company’s Quarterly Report on Form 10-Q for the period ended March 31, 2021, to which this Certification is attached as Exhibit 32.1 (the “Quarterly Report”) fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and
- (2) The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 13, 2021

/s/ Louis Arcudi III

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Louis Arcudi III

Date: May 13, 2021

/s/ Jennifer Minai-Azary

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Jennifer Minai-Azary

“This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Millendo Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.”