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**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, DC 20549**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**FORM 10-K**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**(Mark One)**

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|  |  |  |  |  |  |
| ☒ | | | **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934** | | |

**For the fiscal year ended December 31, 2020**

**OR**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |
| ☐ | | | **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934** | | |

**Commission File Number: 001-35890**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Millendo Therapeutics, Inc.**

**(Exact Name of Registrant as Specified in its Charter)**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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|  |  |  |  |  |  |
| **Delaware** | | | **45-1472564** | | |
| **(State or other jurisdiction of incorporation or organization)** | | | **(I.R.S. Employer Identification No.)** | | |
| **110 Miller Avenue, Suite 100**  **Ann Arbor, Michigan** | | | **48104** | | |
| **(Address of principal executive offices)** | | | **(Zip Code)** | | |

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

**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 Stock Market, LLC | | |

**Securities registered pursuant to Section 12(g) of the Act: None**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  ¨   No   x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act.   Yes  ☐   No  x

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  x   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).    Yes  x    No  ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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.

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Large accelerated filer | | | ☐ | | |  | | | Accelerated filer | | | ☐ | | |
| Non-accelerated filer | | | x | | |  | | | Smaller reporting company | | | ☒ | | |
|  | | | ☐ | | |  | | | Emerging growth company | | | ☐ | | |

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

Indicated by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C 7262(b)) by the registered public accounting firm that prepared or issued its audit report.     Yes  ¨    No  x

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

The aggregate market value of the voting and non-voting common equity of the registrant held by non-affiliates as of June 30, 2020 (the last business day of the registrant’s most recently completed second fiscal quarter), based on a closing price of $1.76 per share of the registrant’s common stock as reported on The Nasdaq Capital Market on June 30, 2020, was approximately $33.3 million. For purposes of this computation, all officers, directors, and 10% beneficial owners of the registrant are deemed to be affiliates. Such determination should not be deemed to be an admission that such officers, directors or 10% beneficial owners are, in fact, affiliates of the registrant.

As of March 15, 2021, the registrant had 19,043,034 shares of common stock, $0.001 par value per share, outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant’s definitive Proxy Statement for its 2021 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K are incorporated by reference in Part III, Items 10-14 of this Annual Report on Form 10-K.

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**EXPLANATORY NOTE**

On December 7, 2018, OvaScience, Inc., or the Company, completed a reverse merger with what was then known as “Millendo Therapeutics, Inc.”, or Private Millendo, in accordance with the terms of the Agreement and Plan of Merger and Reorganization dated as of August 8, 2018, as amended on September 25, 2018 and November 1, 2018, or the OvaScience Merger Agreement, by and among the Company, Private Millendo and Orion Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of the Company, or Orion Merger Sub, pursuant to which, among other matters, Orion Merger Sub merged with and into Private Millendo, with Private Millendo continuing as a wholly owned subsidiary of the Company. We refer to the foregoing transactions in this Annual Report on Form 10-K as “the OvaScience Merger”. On December 6, 2018, in connection with, and prior to the completion of, the OvaScience Merger, the Company effected a 1-for-15 reverse stock split of its common stock, or the Reverse Stock Split, and immediately following the OvaScience Merger, the Company changed its name to “Millendo Therapeutics, Inc.” Following the completion of the OvaScience Merger, the business conducted by the Company became the business conducted by Private Millendo, which was a late-stage biopharmaceutical company primarily focused on developing novel treatments for orphan endocrine diseases. All references to common stock share and per share amounts in this Annual Report have been retroactively adjusted to reflect, where applicable, the Reverse Stock Split, as indicated. As used herein, the words “Millendo,” “we,” “us,” and “our” refer to Millendo Therapeutics, Inc. and its direct and indirect subsidiaries, as applicable. In addition, the word “OvaScience” refers to the Company prior to the completion of the OvaScience Merger.

**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This Annual Report on Form 10-K, or this Annual Report, 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 Annual 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 Annual Report, 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 competitive position and the development of and projections relating to our competitors or our industry;

•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 Item 1A. “Risk Factors” in this Annual Report 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 Annual Report 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 Annual Report represent our views as of the date of this Annual Report. 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 Annual Report.

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**SUMMARY OF SELECTED RISKS ASSOCIATED WITH OUR BUSINESS**

Our business is subject to numerous risks and uncertainties, including those discussed at length in the section titled "Risk Factors." These risks include, among others, the following:

•Our merger with Tempest may not be consummated or may not deliver the anticipated benefits we expect.

•Certain provisions of the Merger Agreement may discourage third-parties from submitting alternative acquisition proposals, including proposals that may be superior to the arrangements contemplated by the Merger Agreement.

•The announcement and pendency of the Merger, whether or not consummated, may adversely affect the trading price of our common stock and our business prospects.

•Failure to consummate the Merger may result in us paying a termination fee to Tempest and could harm our common stock price and our future business and operations.

•If we do not successfully consummate the transaction with Tempest, our board of directors may dissolve or liquidate our assets to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such transaction or liquidation.

•We have incurred significant operating losses since inception and anticipate that we will continue to incur operating losses for the foreseeable future and may never achieve or maintain profitability.

•We have a limited operating history and have never generated any revenue from product sales, which may make it difficult to assess our future viability.

•We will require additional capital to finance our operations, which may not be available on acceptable terms, if at all.

•Raising additional capital by issuing equity or debt securities may cause dilution to our existing stockholders, and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.

•Our business could be materially and adversely affected by the current COVID-19 pandemic.

•We are highly dependent on the services of our key executives and personnel, including Louis Arcudi III, our chief executive officer and Jennifer Minai-Azary, our chief financial officer and if we are not able to retain these members of our management team or recruit and retain additional management or personnel, our business will be harmed.

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**PART I**

**ITEM 1. BUSINESS**

**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. In April 2020, our Board of Directors (“Board”) decided to discontinue the development of livoletide, an unacylated ghrelin analogue, as a potential treatment for Prader-Willi syndrome (“PWS”) based upon results from its Phase 2b trial. In addition, in June 2020, our Board decided to cease investing in the development of nevanimibe as a potential treatment for classic congenital adrenal hyperplasia, (“CAH”) based on an interim review of data from its Phase 2b trial. Finally, in January 2021, our Board also decided to discontinue our investment in MLE-301, a neurokinin 3 receptor (“NK3R”) antagonist we were developing for the treatment of menopausal vasomotor symptoms (“VMS”), based on an analysis of the pharmacokinetic and pharmacodynamic data from the ongoing single ascending dose portion of the Phase 1 study conducted in healthy male volunteers. 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 an effort to streamline costs after discontinuing the PWS program, we eliminated employee positions representing approximately 30% of our prior headcount, which was 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.

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, the Board determined to reduce our workforce by up to 85%, with the majority of the reduction in personnel expected to be completed by April 15, 2021. We initiated this reduction in force in January 2021 and expect to 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, substantially all of which 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 and identifying and reviewing potential candidates for a strategic acquisition or other transaction, on March 29, 2021, we entered into a 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 organization.

We expect to devote significant time and resources to completion of this Merger. However, there can be no assurance 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. In this case, we consider one of the following courses of action to be the most likely alternatives:

•*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, which may include seeking protection from creditors in a bankruptcy proceeding. 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.

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•*Operate our business.* Although less likely than the alternatives above, our Board may elect to seek new product candidates for development.

**Historical Business and Programs**

In 2020, we advanced three product candidates. Livoletide (AZP-531), was a potential treatment for PWS, a rare and complex genetic endocrine disease usually characterized by hyperphagia, or insatiable hunger, that contributes to serious complications, a significant burden on patients and caregivers, and early mortality. In a randomized, double-blind, placebo-controlled Phase 2a clinical trial in 47 patients with PWS, we observed that administration of livoletide once daily was associated with a clinically meaningful improvement in hyperphagia, as well as a reduction in appetite. In a pre-specified analysis of 38 home-resident patients with PWS from the Phase 2a trial, we observed a larger and statistically significant decrease in hyperphagia following administration of livoletide as compared to placebo. In March 2019, we initiated a Phase 2b/3 clinical trial of livoletide in patients with PWS. In April 2020, we discontinued the PWS program based on topline data 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 were developing nevanimibe (ATR-101) as a potential treatment for patients with CAH, a rare, monogenic adrenal disease that requires lifelong treatment with exogenous cortisol, often at high doses. These chronic high doses of cortisol can result in side effects that include diabetes, obesity, hypertension and psychological problems. When on suboptimal doses of cortisol, female patients with CAH can experience hirsutism, infertility and menstrual irregularity, and male patients with CAH can experience testicular atrophy, infertility and testicular tumors. It is often difficult for physicians to appropriately treat CAH without causing adverse consequences. We reported results from our Phase 2a clinical trial of nevanimibe in patients with CAH in March 2018 and initiated a Phase 2b trial in the third quarter of 2018. In June 2020, we elected to cease investing in the development of nevanimibe as a potential treatment for CAH. 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 are no longer developing nevanimibe for the treatment of CAH.

We were also developing a NK3R antagonist (MLE-301) as a potential treatment of vasomotor symptoms (“VMS”), commonly known as hot flashes and night sweats, in menopausal women. The sensations of heat and/or perspiration associated with VMS can occur frequently, generally lasting several minutes, and are often preceded or followed by sensations of cold and/or shivering. VMS interfere with the lives of affected women in a number of ways, including disrupting patients' ability to sleep and concentrate and causing anxiety and depression. VMS is experienced by up to 70% of women as they advance through menopause. We believe that over 20 million women in the United States experience VMS at any given time and that these patients are motivated to seek medical treatment for relief. In September 2020, we initiated our Phase 1 clinical trial of MLE-301. The Phase 1 clinical trial was supported by preclinical studies in which we observed potency and selectivity for the NK3R, the potential for once-daily dosing, and testosterone lowering consistent with the expected activity of an NK3R antagonist. In January 2021, we discontinued further investment in the development of 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 and the competitive NK3R antagonist market.

We had also been investigating nevanimibe (ATR-101) as a potential treatment for patients with endogenous Cushing’s syndrome (“CS”), a rare endocrine disease characterized by excessive cortisol production from the adrenal glands. As a result of slower than anticipated enrollment in our CS Phase 2 clinical trial, we elected to discontinue the trial in August 2019 and are no longer developing nevanimibe for the treatment of CS.

**Sales and Marketing**

We are not currently conducting sales and marketing efforts with respect to any of our previous programs and are in the process of terminating the license agreements pursuant to which we had development and commercialization rights with respect to livoletide, nevanimibe and MLE-301.

**Research and Development**

We are not currently conducting research and development of any of our previous programs and our plans for future research and development are dependent on the results of our ongoing strategic evaluation.

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**Assignment Agreement with Erasmus University Medical Center and the University of Turin**

We have an assignment agreement (the “Assignment Agreement”) with Erasmus University Medical Center, the University of Turin and certain individuals, which we refer to collectively as the assignors, for certain patents and patent applications relating to livoletide.

In connection with the Assignment Agreement, we agreed to pay the assignors a flat, low single digit royalty on net commercial sales of products containing livoletide that are covered by the claims of the assigned intellectual property. Further, upon approval of livoletide by the FDA or EMA, we are required to pay the assignors CDN$100,000, which amount will be deducted from any future royalty payments due to the assignors. We also agreed to pay the assignors a low single digit percentage of any amounts received in connection with our license of the assigned intellectual property or products containing livoletide that are covered by the claims of the assigned intellectual property.

The assignors have a right to repurchase the assigned intellectual property at a certain price in the event we do not, upon receiving notice, use reasonable efforts to develop, introduce for sale and promote products derived from the assigned intellectual property. Such reasonable efforts involve spending an annual amount of at least CDN$100,000 in research and development related to livoletide, actively pursuing the registration, licenses and permits necessary to market livoletide, and the actual commercialization of livoletide, if approved. In addition, pursuant to the assignment agreement, certain individuals at the Erasmus University Medical Center and the University of Turin were granted non-exclusive rights to use the assigned intellectual property for non-commercial research with our prior written consent. In March 2021, we notified the assignors that we had discontinued the PWS program.

**License Agreement with the University of Michigan**

In June 2013, we entered into a license agreement with the University of Michigan, or the UM License Agreement, for a worldwide, exclusive, sublicensable license to the University of Michigan’s interest in certain patent rights jointly owned with us, covering, among other things, the use of nevanimibe to treat CAH. Such license rights allowed us to make, have made, import, export, use, market, offer for sale and sell products containing nevanimibe for such use in the United States. Due to our decision to cease investing in the nevanimibe program, effective on March 5, 2021, we notified the University of Michigan of our decision to terminate the UM License Agreement, which termination shall be effective April 30, 2021, as agreed to by the University of Michigan.

**License Agreement with Roche**

On October 16, 2018, we entered into a license agreement with F. Hoffmann-La Roche Ltd and Hoffman-La Roche Inc. (collectively, “Roche”), for a worldwide, exclusive license to Roche's interest in certain patent rights and know-how covering, among other things, the use of a neurokinin 3 receptor antagonist (the "Roche License Agreement"). Such license rights have allowed us to research, have researched, develop, have developed, register, have registered, use, have used, make, have made, import, have imported, export, have exported, market, have marketed, distribute, have distributed, sell and have sold an NK3R antagonist for use in all countries in the world and for all other uses other than diagnostic use. Due to our decision to discontinue investing in the MLE-301 program, in March 2021, we notified Roche that we were terminating the Roche License Agreement effective three months from the date of such notice.

**Intellectual Property**

When applicable to our development programs, we seek to obtain and maintain patent and other intellectual property and proprietary protection for our drug candidates in the United States and internationally, including composition-of-matter, dosage and formulation patents, as well as patent and other intellectual property and proprietary protection for our novel biological discoveries and other important technology inventions and know-how. In addition to patents, we rely upon unpatented trade secrets, know-how, and continuing technological innovation to develop and maintain our intellectual property rights. We protect our proprietary information, in part, using confidentiality agreements with our commercial partners, collaborators, employees and consultants and invention assignment agreements with our employees as well as selected commercial partners and consultants. Despite these measures, any of our intellectual property and proprietary rights could be challenged, invalidated, circumvented, infringed or misappropriated, or such intellectual property and proprietary rights may not be sufficient to permit us to take advantage of current market trends or otherwise to provide competitive advantages. In addition, such confidentiality agreements and invention assignment agreements can be breached and we may not have adequate remedies for any such breach. For more information, please see “*Risk Factors—Risks Related to Our Intellectual Property*.”

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We seek patent protection in significant markets and/or countries for each drug in development. We also seek to maximize patent term. The patent exclusivity period for a drug will prevent generic drugs from entering the market. Patent exclusivity depends on a number of factors including the strength of the claims, the initial patent term, patent term adjustments and available patent term extensions based upon delays caused by the regulatory approval process.

The patent positions of biotechnology companies like ours are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Consequently, we may not obtain or maintain adequate patent protection for any of our product candidates. As of December 31, 2020, with respect to livoletide patent rights, we owned four issued U.S. patents, one pending U.S. patent application, and a number of patents and pending patent applications in other jurisdictions. As of December 31, 2020, with respect to nevanimibe patent rights, we owned two issued U.S. patents, two pending U.S. patent applications, and a number of pending patent applications in other jurisdictions, and we jointly owned, with University of Michigan, three issued U.S. patents, one pending U.S. patent application, and a number of patent applications in other jurisdictions. As of December 31, 2020, with respect to MLE-301 patent rights, we owned one pending U.S. patent application, and we exclusively licensed from Roche one issued U.S. patent and a number of patents and pending patent applications in other jurisdictions.

We cannot predict whether the patent applications we pursue will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide any proprietary protection from competitors. The patent portfolios for our leading product candidates as of December 31, 2020 are summarized below.

***Livoletide***

With respect to livoletide patent rights, as of December 31, 2020 we owned four issued U.S. patents, which are not due to expire before 2028, 2028, 2029, and 2033, respectively, excluding any additional term for patent term extension pursuant to the Hatch-Waxman Act; one pending U.S. patent application, which is not due to expire before 2034, excluding any additional term for patent term adjustment or extension; and a number of patent applications in other jurisdictions. The foregoing patents and patent applications cover a form of and methods of making and using livoletide or its analogs. Related international patent applications have issued in Australia, Canada, China, Europe, Japan, and Mexico and are pending in a number of other countries, including Canada, Europe, and India. In March 2021, in connection with the discontinuation of our livoletide program, we notified the assignors of our decision to discontinue development of livoletide. We do not expect our livoletide patents to enable development of livoletide apart from the intellectual property licensed.

***Nevanimibe***

With respect to nevanimibe patent rights, as of December 31, 2020, we owned two issued U.S. patents, which are not due to expire before 2035, excluding any additional term for patent term adjustment or extension; two pending U.S. patent applications, which, if issued, are not due to expire before 2035 and 2036, respectively, excluding any additional term for patent term adjustment or extension; and a number of patent applications in other jurisdictions. As of December 31, 2020, we jointly owned, with University of Michigan, three issued U.S. patents, which are each not due to expire before 2033, excluding any additional term for patent term adjustments or extensions; one pending U.S. patent application, which, if issued, is not due to expire before 2033, excluding any additional term for patent term adjustment or extension; and a number of patent applications in other jurisdictions. The foregoing patents and patent applications cover a form of and methods of making and using nevanimibe or its analogs. Related international patent applications have issued in Australia, China, Japan, Mexico, and New Zealand and are pending in a number of other countries, including Australia, Brazil, Canada, China, Europe, and Mexico. Due to our decision to discontinue the development of our nevanimibe program, in March 2021, we notified the University of Michigan of our decision to terminate the UM License Agreement, which termination shall be effective as of April 30, 2021, as agreed with the University of Michigan. We do not expect our nevanimibe patents to enable development of nevanimibe apart from the intellectual property licensed pursuant to the UM License Agreement.

***MLE-301***

With respect to MLE-301 patent rights, as of December 31, 2020, we owned one pending Patent Cooperation Treaty patent application, which, if issued, is not due to expire before 2040, excluding any additional term for patent term adjustment or extension. As of December 31, 2020, we exclusively licensed from Roche one issued U.S. patent, which is not due to expire before 2031, excluding any additional term for patent term adjustment or extension. The foregoing patents and patent applications cover a form of and methods of making and using MLE-301 or its analogs. Related international patent applications have issued in China, Europe, Japan, South Korea, and Mexico, and are pending in a number of other countries,

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including Brazil, Canada, India, and Russia. Due to our decision to discontinue developing the MLE-301 program in March 2021, we notified Roche that we were terminating the Roche License Agreement effective three months from the date of such notice. We do not expect our MLE-301 patents to enable development of MLE-301 apart from the intellectual property licensed pursuant to the Roche License Agreement.

**Manufacturing**

We relied on contract manufacturing organizations, or CMOs, to produce drug candidates in accordance with the FDA’s current Good Manufacturing Practices, or cGMP, regulations for use in our prior clinical trials. The manufacture of pharmaceuticals is subject to extensive cGMP regulations, which impose various procedural and documentation requirements and govern all areas of record keeping, production processes and controls, personnel and quality control.

**Government Regulation and Approval**

***United States-FDA process***

In the United States, the FDA regulates drugs. The Federal Food, Drug, and Cosmetic Act, or FDCA, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of drugs. To obtain regulatory approvals in the United States and in foreign countries, and subsequently comply with applicable statutes and regulations, we will need to spend substantial time and financial resources.

***Approval process***

The FDA must approve any new drug or a drug with certain changes to a previously approved drug before a manufacturer can market it in the United States. If a company does not comply with applicable United States requirements it may be subject to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending applications, warning or untitled letters, clinical holds, drug recalls, drug seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution. The steps we must complete before we can market a drug include:

•completion of preclinical laboratory tests, animal studies, and formulation studies, all performed in accordance with the FDA’s good laboratory practice, or GLP, regulations;

•submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical studies start. The sponsor must update the IND annually;

•approval of the study by an independent institutional review board, or IRB, or ethics committee representing each clinical site before each clinical study begins;

•performance of adequate and well-controlled human clinical studies to establish the safety and efficacy of the drug for each indication to the FDA’s satisfaction;

•submission to the FDA of an NDA;

•potential review of the drug application by an FDA advisory committee, where appropriate and if applicable;

•satisfactory completion of an FDA inspection of the manufacturing facility or facilities to assess compliance with current good manufacturing practices, cGMP, or regulations; and

•FDA review and approval of the NDA.

It generally takes companies many years to satisfy the FDA approval requirements, but this varies substantially based upon the type, complexity, and novelty of the drug or disease. Preclinical tests include laboratory evaluation of a drug’s chemistry, formulation, and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the drug. The conduct of the preclinical tests must comply with federal regulations and requirements, including GLP. The company submits the results of the preclinical testing to the FDA as part of an IND along with other information, including information about the product drug’s chemistry, manufacturing and controls, and a proposed clinical study protocol. Long term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, are generally conducted after submitting the initial IND.

The FDA requires a 30-day waiting period after the submission of each IND before the company can begin clinical testing in humans in the United States. The FDA may, within the 30-day time period, raise concerns or questions relating to one or more

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proposed clinical studies and place the study on a clinical hold. In such a case, the company and the FDA must resolve any outstanding concerns before the company begins the clinical study. Accordingly, the content of an IND submission may or may not be sufficient for the FDA to permit the sponsor to start a clinical study. The company must also make a separate submission to an existing IND for each successive clinical study conducted in the U.S. during drug development.

***Clinical studies***

Clinical studies involve administering the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. The company must conduct clinical studies:

•in compliance with federal regulations;

•in compliance with good clinical practice, or GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical study sponsors, administrators, and monitors; as well as

•under protocols detailing the objectives of the trial, the safety monitoring parameters, and the effectiveness criteria.

The company must submit each protocol involving testing on United States patients and subsequent protocol amendments to the FDA as part of the IND. The FDA may order the temporary, or permanent, discontinuation of a clinical study at any time, or impose other sanctions, if it believes that the sponsor is not conducting the clinical study in accordance with FDA requirements or presents an unacceptable risk to the clinical study patients. The sponsor must also submit the study protocol and informed consent information for patients in clinical studies to an institutional review board for approval. An IRB may halt the clinical study, either temporarily or permanently, for failure to comply with the IRB’s requirements, or may impose other conditions.

Companies generally divide the clinical investigation of a drug into three or four phases. While companies usually conduct these phases sequentially, they are sometimes overlapped or combined.

•*Phase 1.* The company evaluates the drug in healthy human subjects or patients with the target disease or condition. These studies typically evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the investigational new drug in humans, the side effects associated with increasing doses, and if possible, gain early evidence on effectiveness.

•*Phase 2.* The company administers the drug to a limited patient population to evaluate dosage tolerance and optimal dosage, identify possible adverse side effects and safety risks, and preliminarily evaluate efficacy.

•*Phase 3.* The company administers the drug to an expanded patient population, generally at geographically dispersed clinical study sites, to generate enough data to statistically evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational drug, and to provide an adequate basis for product approval.

•*Phase 4.* In some cases, the FDA may condition approval of an NDA for a drug on the company’s agreement to conduct additional clinical studies after approval. In other cases, a sponsor may voluntarily conduct additional clinical studies after approval to gain more information about the drug. We typically refer to such post-approval studies as Phase 4 clinical studies.

A pivotal study is a clinical study that adequately meets regulatory agency requirements to evaluate a drug’s efficacy and safety to justify the approval of the drug. Generally, pivotal studies are Phase 3 studies, but the FDA may accept results from Phase 2 studies if the study design provides a well controlled and reliable assessment of clinical benefit, particularly in situations in which there is an unmet medical need and the results are sufficiently robust.

The FDA, the IRB, or the clinical study sponsor may suspend or terminate a clinical study at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Additionally, an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board or committee, may oversee some clinical studies. This group provides authorization for whether or not a study may move forward at designated checkpoints based on access to certain data from the study. We may also suspend or terminate a clinical study based on evolving business objectives and the competitive climate.

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***Submission of an NDA***

After a company completes the required clinical testing, it can prepare and submit an NDA to the FDA, who must approve the NDA before it can start marketing the drug in the United States. An NDA must include all relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the drug’s chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies on a drug, or from a number of alternative sources, including studies initiated by investigators or studies not conducted under a U.S. IND. To support marketing authorization, the data we submit must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug to the FDA’s satisfaction.

The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, and the manufacturer and/or sponsor under an approved new drug application are also subject to annual program user fees. The FDA typically increases these fees annually. Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical study costs, tax advantages, and user-fee waivers.

The FDA has 60 days from its receipt of an NDA to determine whether it will accept the application for filing based on the agency’s threshold determination that the application is sufficiently complete to permit substantive review. Once the FDA accepts the filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs. Under the Prescription Drug User Fee Act, the FDA has a goal of responding to standard review NDAs within ten months after the 60-day filing review period, but this timeframe may be extended. The FDA reviews most applications for standard review drugs within ten to 12 months and most applications for priority review drugs within six to eight months. Priority review can be applied to drugs that the FDA determines offer major advances in treatment, or provide a treatment where no adequate therapy exists.

The FDA may also refer applications for novel drugs that present difficult questions of safety or efficacy, to an advisory committee. This is typically a panel that includes clinicians and other experts that will review, evaluate, and recommend whether the FDA should approve the application. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP, and will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the drug unless compliance with cGMP is satisfactory and the NDA contains data that provide evidence that the drug is safe and effective in the indication studied.

***The FDA’s decision on an NDA***

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter indicates that the FDA has completed its review of the application, and the agency has determined that it will not approve the application in its present form. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional clinical data and/or other significant, expensive, and time-consuming requirements related to clinical studies, preclinical studies and/or manufacturing. The FDA has committed to reviewing resubmissions of the NDA addressing such deficiencies in two or six months, depending on the type of information included. Even if we submit such data, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Also, the government may establish additional requirements, including those resulting from new legislation, or the FDA’s policies may change, which could delay or prevent regulatory approval of our drugs under development.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks. REMS can include communication plans for healthcare professionals, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for REMS can materially affect the potential market and profitability of the drug. Moreover, the FDA may condition approval on substantial post-approval testing and surveillance to monitor the drug’s safety or efficacy. Once granted, the FDA may withdraw drug approvals if the company fails to comply with regulatory standards or identifies problems following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before we can implement the change. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing new

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NDAs. As with new NDAs, the FDA often significantly extends the review process with requests for additional information or clarification.

***Post-approval requirements***

The FDA regulates drugs that are manufactured or distributed pursuant to FDA approvals and has specific requirements pertaining to recordkeeping, periodic reporting, drug sampling and distribution, advertising and promotion and reporting of adverse experiences with the drug. After approval, the FDA must provide review and approval for most changes to the approved drug, such as adding new indications or other labeling claims. There also are continuing, annual user fee requirements for any marketed drugs and the establishments who manufacture its drugs, as well as new application fees for supplemental applications with clinical data.

Drug manufacturers are subject to periodic unannounced inspections by the FDA and state agencies for compliance with cGMP requirements. There are strict regulations regarding changes to the manufacturing process, and, depending on the significance of the change, it may require prior FDA approval before we can implement it. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if a company does not comply with regulatory requirements and maintain standards or if problems occur after the drug reaches the market. If a company or the FDA discovers previously unknown problems with a drug, including adverse events of unanticipated severity or frequency, issues with manufacturing processes, or the company’s failure to comply with regulatory requirements, the FDA may revise the approved labeling to add new safety information; impose post-marketing studies or other clinical studies to assess new safety risks; or impose distribution or other restrictions under a REMS program. Other potential consequences may include:

•restrictions on the marketing or manufacturing of the drug, complete withdrawal of the drug from the market or drug recalls;

•fines, warning letters or holds on post-approval clinical studies;

•the FDA refusing to approve pending NDAs or supplements to approved NDAs, or suspending or revoking of drug license approvals;

•drug seizure or detention, or refusal to permit the import or export of drugs; or

•injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising, and promotion of drugs that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. However, companies may share truthful and not misleading information that is otherwise consistent with the product’s FDA approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. We could be subject to significant liability if we violated these laws and regulations.

***Marketing Exclusivity***

In addition to patent term (as extended by the Hatch-Waxman Act), the holder of the NDA for a listed drug may be entitled to a period of marketing exclusivity, during which the FDA cannot approve an abbreviated new drug application, or ANDA, or 505(b)(2) application that relies on the listed drug. For example, a pharmaceutical manufacturer may obtain five years of non-patent exclusivity upon NDA approval of a new chemical entity, or NCE, which is a drug that contains an active moiety that has not been approved by FDA in any other NDA. An "active moiety" is defined as the molecule or ion responsible for the drug substance's physiological or pharmacological action. During the five year exclusivity period, the FDA cannot accept for filing any ANDA seeking approval of a generic version of that drug or any 505(b)(2) NDA for the same active moiety and that relies on the FDA's findings regarding that drug, except that FDA may accept an application for filing after four years if the follow-on applicant makes a paragraph IV certification.

A drug, including one approved under Section 505(b)(2), may obtain a three-year period of exclusivity for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant. Should this occur, the FDA would be precluded from approving any ANDA or 505(b)(2)

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application for the protected modification until after that three-year exclusivity period has run. However, unlike NCE exclusivity, the FDA can accept an application and begin the review process during the exclusivity period.

***Orphan drug designation***

The FDA may grant orphan drug designation to sponsors of drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making the drug for this type of disease or condition will be recovered from sales in the United States.

Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical study costs, tax advantages, and user-fee waivers. In addition, if a drug receives FDA approval for the indication for which it has orphan designation, the drug may be entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the drug with orphan exclusivity.

***Pediatric information***

Under the Pediatric Research Equity Act, or PREA, NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which the FDA has granted an orphan designation.

***Healthcare reform***

In the United States and foreign jurisdictions, the legislative landscape continues to evolve. There have been a number of legislative and regulatory changes to the healthcare system that could affect the future results of our operations. In particular, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reform the way in which healthcare is funded and reduce healthcare costs. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively PPACA, was enacted, which included measures that have significantly changed health care financing by both governmental and private insurers. The provisions of PPACA of importance to the pharmaceutical and biotechnology industry are, among others, the following:

•an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs agents, apportioned among these entities according to their market share in certain government healthcare programs;

•an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively;

•a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts to negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D;

•extension of manufacturers’ Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, unless the drug is subject to discounts under the 340B drug discount program;

•expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers’ Medicaid rebate liability;

•expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;

•expansion of healthcare fraud and abuse laws, including the federal civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;

•new requirements under the federal Physician Payments Sunshine Act for drug manufacturers to report information related to payments and other transfers of value made to physicians, as defined by such law, and

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teaching hospitals as well as ownership or investment interests held by physicians and their immediate family members; and

•new requirement to annually report certain drug samples that manufacturers and distributors provide to licensed practitioners, or to pharmacies of hospitals or other healthcare entities.

There have been executive, judicial and Congressional challenges to certain aspects of the PPACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the PPACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act, included a provision that repealed, effective January 1, 2019, the tax based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the PPACA mandated “Cadillac” tax on high cost employer sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the PPACA, effective January 1, 2019, to increase from 50% to 70% the point of sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole.” On December 14, 2018, a Texas U.S. District Court Judge ruled that the PPACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the PPACA are invalid as well. The United States Supreme Court is currently reviewing this case, but it is unknown when a decision will be reached. Although the U.S. Supreme Court has not yet ruled on the constitutionality of the PPACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the PPACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the PPACA. It is unclear how the Supreme Court ruling, other such litigation and the healthcare reform measures of the Biden administration will impact the PPACA.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. In August 2011, the President signed into law the Budget Control Act of 2011, as amended, which, among other things, included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which began in 2013 and, following passage of subsequent legislation, including the BBA, will continue through 2030 with the exception of a temporary suspension from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic, unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was enacted and, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempted to implement several of the administration’s proposals. As a result, the FDA also released a final rule on September 24, 2020, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed pending review by the Biden administration until March 22, 2021. On November 20, 2020, CMS issued an interim final rule implementing the Trump administration’s Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in

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some cases, designed to encourage importation from other countries and bulk purchasing. It also possible that governmental action will be taken in response to the COVID-19 pandemic.

***European Union-EMA process***

In the European Union, our product candidates are also be subject to extensive regulatory requirements. As in the United States, medicinal products can only be marketed if a marketing authorization, or MA, from the competent regulatory agencies has been obtained.

Similar to the United States, the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls. Clinical trials of medicinal products in the European Union must be conducted in accordance with European Union and national regulations and the International Conference on Harmonization, or ICH, guidelines on Good Clinical Practices, or GCP. Although the EU Clinical Trials Directive 2001/20/EC has sought to harmonize the European Union clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the European Union, the EU Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the Member State regimes. To improve the current system, Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, which repealed Directive 2001/20/EC, was adopted on April 16, 2014 and published in the European Official Journal on May 27, 2014. The Regulation aims to harmonize and streamline the clinical trials authorization process, simplify adverse event reporting procedures, improve the supervision of clinical trials, and increase their transparency. Although the Regulation entered into force on June 16, 2014, it will not be applicable until six months after the full functionality of the IT portal and database envisaged in the Regulation is confirmed by an independent audit, and the European Commission publishes a notice of this confirmation. This is not expected to occur until before 2021 as an audit of the system is intended to commence in December 2020. Until then the Clinical Trials Directive 2001/20/EC will still apply.

In addition, the transitory provisions of the new Regulation offer the sponsors the possibility to choose between the requirements of the Directive and the Regulation for one year from the entry into application of the Regulation.

Under the current regime, before a clinical trial can be initiated it must be approved in each of the EU Member States where the trial is to be conducted by two distinct bodies: the National Competent Authority, or NCA, and one or more Ethics Committees, or ECs. Under the current regime all suspected unexpected serious adverse reactions, or SUSARs, to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the Member State where they occurred and would also be reported in all countries where the drug is being used in a clinical trial.

***Approval Process***

Under the centralized procedure, after the EMA issues an opinion, the European Commission issues a single marketing authorization valid across the European Union, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for human drugs that are: derived from biotechnology processes, such as genetic engineering; contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders diseases or autoimmune diseases and other immune dysfunctions; advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines; and officially designated orphan drugs. For drugs that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA, as long as the drug concerned contains a new active substance; is a significant therapeutic, scientific or technical innovation; or if its authorization would be in the interest of public health.

There are also three other possible routes to authorize medicinal products in the European Union, which are available for products that fall outside the scope of the centralized procedure:

•National procedure. National MAs, issued by the competent authorities of the Member States of the EEA, are available however these only cover their respective territory;

•Decentralized procedure. Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one European Union country of a medicinal product that has not yet been authorized in any European Union country; and

•Mutual recognition procedure. In the mutual recognition procedure, a medicine is first authorized in one European Union Member State, in accordance with the national procedures of that country. Thereafter, further marketing authorizations can be sought from other European Union countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

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Pursuant to Regulation (EC) No 1901/2006, all applications for marketing authorization for new medicines must include the results of all studies performed and details of all information collected in compliance with as described in a pediatric investigation plan, or PIP, agreed between regulatory authorities, the EMA’s Pediatric Committee, and the applicant, unless the medicine is exempt because of a deferral or waiver (e.g., because the relevant disease or condition occurs only in adults). Applicants are encouraged to submit pediatric investigation plans early during product development, in time for studies to be conducted in the pediatric population, where appropriate, before marketing authorization applications are submitted.  Before the EMA is able to begin its assessment of a centralized procedure MA application, it will validate that the applicant has complied with an agreed pediatric investigation plan, or an application for a waiver has been submitted. The applicant and the EMA may, where such a step is adequately justified, agree to modify a pediatric investigation plan to assist validation. Modifications are not always possible; may take longer to agree than the period of validation permits; and may still require the applicant to withdraw its marketing authorization application, or MA, and to conduct additional non-clinical and clinical studies.  Products that are granted a MA on the basis of the pediatric clinical trials conducted in accordance with the PIP are eligible for a six month extension of the protection under a supplementary protection certificate or a patent qualifying for a supplementary protection (if any is in effect at the time of approval) or certificate or, in the case of orphan medicinal products, a two year extension of the orphan market exclusivity. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

***Orphan drug designation***

In the European Union, Regulation (EC) No 141/2000, as amended, states that a drug will be designated as an orphan drug if its sponsor can establish:

•that it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the European Union when the application is made, or that it is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the drug in the European Union would generate sufficient return to justify the necessary investment; and

•that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Union or, if such method exists, that the drug will be of significant benefit to those affected by that condition.

Regulation (EC) No 847/2000 sets out further provisions for implementation of the criteria for designation of a drug as an orphan drug. An application for the designation of a drug as an orphan drug may be submitted at any stage of development of the drug before submission of a MA application.  However, an application for designation as an orphan drug may be submitted for a new therapeutic indication for an already authorized medicinal product.

If a centralized procedure MA in respect of an orphan drug is granted pursuant to Regulation (EC) No 726/2004, regulatory authorities will not, for a period of 10 years, accept another application for a MA, or grant a MA or accept an application to extend an existing MA, for the same therapeutic indication, in respect of a similar drug. This period may however be reduced to six years if, at the end of the fifth year, it is established, in respect of the drug concerned, that the criteria for orphan drug designation are no longer met, for example, when it is shown on the basis of available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity. The exclusivity period may increase to 12 years if, among other things, the MA includes the results of studies from an agreed pediatric investigation plan. Notwithstanding the foregoing, a MA may be granted for the same therapeutic indication to a similar drug if:

•the holder of the MA for the original orphan drug has given its consent to the second applicant;

•the holder of the MA for the original orphan drug is unable to supply sufficient quantities of the drug; or

•the second applicant can establish in the application that the second drug, although similar to the orphan drug already authorized, is safer, more effective or otherwise clinically superior.

Regulation (EC) No 847/2000 lays down definitions of the concepts ‘similar drug’ and ‘clinical superiority’. Other incentives available to orphan drugs in the European Union include financial incentives such as a reduction of fees or fee waivers and protocol assistance. Orphan drug designation does not shorten the duration of the regulatory review and approval process.

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***Good manufacturing practices***

Like the FDA, the EMA, the competent authorities of the European Union Member States and other regulatory agencies regulate and inspect equipment, facilities and processes used in the manufacturing of drugs intended for the EU market to ensure that certain minimum standards are met. These requirements apply, no matter where in the world the manufacturing process takes place and are designed to ensure that products intended for the EU market are of consistent high quality, are appropriate for their intended use and meet the requirements of the marketing authorization or clinical trial authorization.  If, after receiving clearance from regulatory agencies, a company makes a material change in manufacturing equipment, location, or process, additional regulatory review and approval may be required. A company and its partners will be required to continue to comply with cGMP, and drug-specific regulations enforced by, the European Commission, the EMA and the competent authorities of European Union Member States following drug approval. Also like the FDA, the EMA, the competent authorities of the European Union Member States and other regulatory agencies also conduct regular, periodic visits to reinspect equipment, facilities, and processes following the initial approval of a drug. If, as a result of these inspections, the regulatory agencies determine that a company or its partners’ equipment, facilities, or processes do not comply with applicable regulations and conditions of drug approval, they may seek civil, criminal or administrative sanctions and/or remedies against us, including the suspension of its manufacturing operations or the withdrawal of our drug from the market.

***Post-Approval Controls***

The holder of a European MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance, or QPPV, who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new MAs must include a risk management plan, or RMP, describing the risk management system that the company will put in place, recording the product’s safety profile and documenting the effectiveness of risk-minimization measures. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies. RMPs and PSURs are routinely available to third-parties requesting access, subject to limited redactions. All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the European Union. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each EU Member State and can differ from one country to another.

***Data and market exclusivity***

Similar to the United States, there is a process to authorize generic versions of innovative drugs in the European Union. Generic competitors can, where data exclusivity has expired, submit abridged applications to authorize generic versions of drugs authorized by the EMA through the centralized procedure referencing the innovator’s data and demonstrating bioequivalence to the reference drug, among other things. If a marketing authorization is granted for a medicinal product containing a new active substance, that product benefits from eight years of data exclusivity, during which generic marketing authorization applications referring to the data of that product may not be accepted by the regulatory authorities, and a further two years of market exclusivity, during which such generic products may not be placed on the market. The two-year period may be extended to three years if during the first eight years a new therapeutic indication with significant clinical benefit over existing therapies is approved. This system is usually referred to as “8+2”. There is also a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product, for example, because of differences in raw materials or manufacturing processes. For such products, the results of appropriate preclinical or clinical trials must be provided, and guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product.  In addition, there are certain circumstances, such as where the innovator company is granted a marketing authorization for a significant new indication for the relevant medicinal product, where an additional one year of marketing exclusivity may be granted.   As referenced above, orphan medicinal products are subject to separate marketing exclusivity arrangements.

***Other international markets-drug approval process***

In some international markets (such as China or Japan), although data generated in United States or European Union trials may be submitted in support of a marketing authorization application, regulators may require additional clinical studies conducted in the host territory, or studying people of the ethnicity of the host territory, prior to the filing or approval of marketing applications within the country.

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***Pricing and reimbursement***

Significant uncertainty exists as to the coverage and reimbursement status of any drugs for which companies may obtain regulatory approval. In the United States and markets in other countries, sales of any drugs for which companies receive regulatory approval for commercial sale will depend in part on the availability of coverage and reimbursement from third-party payors. Third-party payors include government authorities, managed care plans, private health insurers and other organizations. The process for determining whether a third-party payor will provide coverage for a drug may be separate from the process for setting the reimbursement rate that the payor will pay for the drug. Third-party payors may limit coverage to specific drugs on an approved list, or formulary, which might not include all of the FDA-approved drugs for a particular indication. Moreover, a third-party payor’s decision to provide coverage for a drug does not imply that an adequate reimbursement rate will be approved. Additionally, coverage and reimbursement for drugs can differ significantly from payor to payor. One third-party payor’s decision to cover a particular drug does not ensure that other payors will also provide coverage for the drug, or will provide coverage at an adequate reimbursement rate. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on its investment in drug development.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of drugs and services, in addition to their safety and efficacy. To obtain coverage and reimbursement for any drug that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies to demonstrate the medical necessity and cost-effectiveness of our drug. These studies will be in addition to the studies required to obtain regulatory approvals. If third-party payors do not consider a drug to be cost-effective compared to other available therapies, they may not cover the drug after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its drugs at a profit.

The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price controls, restrictions on reimbursement and requirements for substitution of generic drugs for branded prescription drugs. By way of example, PPACA contains provisions that may reduce the profitability of drugs, including, for example, increased rebates for drugs sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies’ share of sales to federal health care programs. Adoption of government controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for our drugs.

In the European Community, governments influence the price of drugs through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those drugs to consumers. Some jurisdictions operate positive and negative list systems under which drugs may only be marketed once a reimbursement price has been agreed to by the government. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical studies that compare the cost effectiveness of a particular drug candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new drugs. In addition, in some countries, cross border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any drugs for which companies receive regulatory approval for commercial sale may suffer if government and other third-party payors fail to provide coverage and adequate reimbursement. In addition, the focus on cost containment measures in the United States and other countries has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time.

***Other healthcare laws impacting sales, marketing, and other company activities***

Numerous regulatory authorities in addition to the FDA, including, in the United States, CMS, other divisions of the U.S. Department of Health and Human Services, or HHS, the U.S. Department of Justice, and similar foreign, state, and local government authorities, regulate and enforce laws and regulations applicable to sales, promotion and other activities of pharmaceutical manufacturers. These laws and regulations may impact, among other things, our clinical research programs, proposed sales and marketing and education activities, and financial and business relationships with future prescribers of our product candidates, once approved. These laws and regulations include U.S. federal, U.S. state and foreign anti-kickback, false claims, and data privacy and security laws, which are described below, among other legal requirements that may affect our current and future operations.

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The FDA regulates all advertising and promotion activities for drugs under its jurisdiction both prior to and after approval. Only those claims relating to safety and efficacy that the FDA has approved may be used in labeling once the drug is approved. Physicians may prescribe legally available drugs for uses that are not described in the drug’s labeling and that differ from those we tested and the FDA approved. Such off-label uses are common across medical specialties, and often reflect a physician’s belief that the off-label use is the best treatment for the patients. The FDA does not regulate the behavior of physicians in their choice of treatments, but FDA regulations do impose stringent restrictions on manufacturers’ communications regarding off-label uses. If we do not comply with applicable FDA requirements we may face adverse publicity, enforcement action by the FDA, corrective advertising, consent decrees and the full range of civil and criminal penalties available to the FDA. Promotion of off-label uses of drugs can also implicate the false claims laws described below.

Anti-kickback laws including, without limitation, the federal Anti-Kickback Statute that applies to items and services reimbursable under governmental healthcare programs such as Medicare and Medicaid, make it illegal for a person or entity to, among other things, knowingly and willfully solicit, receive, offer or pay remuneration, directly or indirectly, to induce, or in return for, purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any good, facility, item, or service reimbursable, in whole or in part, under a federal healthcare program. Due to the breadth of the statutory provisions and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that our practices might be challenged under anti-kickback or similar laws. Moreover, recent healthcare reform legislation has strengthened these laws. For example, PPACA among other things, amends the intent requirement of the federal Anti-Kickback Statute and certain other criminal healthcare fraud statutes to clarify that a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a crime. In addition, PPACA clarifies that the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

False claims laws, including, without limitation, the federal civil False Claims Act, and civil monetary penalty laws prohibit, among other things, anyone from knowingly and willingly presenting, or causing to be presented for payment, to the federal government (including Medicare and Medicaid) claims for reimbursement for, among other things, drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Our activities relating to the sales and marketing of its drugs may be subject to scrutiny under these laws, as well as civil monetary penalties laws and the criminal healthcare fraud provisions enacted as part of the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA.

HIPAA imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations governs the conduct of certain electronic healthcare transactions and imposes requirements with respect to safeguarding the security and privacy of protected health information on HIPAA covered entities and their business associates who provide services involving HIPAA protected health information to such covered entities.

The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives provided during the previous year.

In addition, companies may be subject to state law equivalents of each of the above federal laws, such as anti-kickback, self-referral, and false claims laws which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical manufacturers to comply with the industry’s voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers; state laws that require pharmaceutical manufacturers to file reports with states regarding marketing information, such as the tracking and reporting of gifts, compensation and other remuneration

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and items of value provided to healthcare professionals and entities; state laws that require the reporting of information related to drug pricing; state and local laws requiring the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of personal data and protected health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

Violations of these laws may result in significant criminal, civil and administrative sanctions, including fines and civil monetary penalties, the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid), disgorgement, contractual damages, reputational harm and the imposition of corporate integrity agreements or other similar agreements with governmental entities, which may impose, among other things, rigorous operational and monitoring requirements on companies. Similar sanctions and penalties, as well as imprisonment, also can be imposed upon executive officers and employees, including criminal sanctions against executive officers under the so-called “responsible corporate officer” doctrine, even in situations where the executive officer did not intend to violate the law and was unaware of any wrongdoing. Given the significant penalties and fines that can be imposed on companies and individuals if convicted, allegations of such violations often result in settlements even if the company or individual being investigated admits no wrongdoing. Settlements often include significant civil sanctions and additional corporate integrity obligations.

Similar rigorous restrictions are imposed on the promotion and marketing of drugs in the European Union and other countries.

**Employees**

As of March 15, 2021, we had 13 employees, 12 of whom were full-time employees and one of whom was a part-time employee. As of March 15, 2021, one of our employees was engaged in research and development activities and 12 of our employees were engaged in business development, finance, information systems, facilities, human resources or administrative support. As of March 15, 2021, we had 12 employees located in the United States and one employee located in France. None of our U.S. employees are represented by any collective bargaining agreements. Our French employee is represented by a collective bargaining agreement.

In connection with the Plan, our Board determined to reduce our workforce by up to 85%, with the majority of the reduction in personnel expected to be completed by April 15, 2021.

**OvaScience Merger**

On December 7, 2018, OvaScience, Inc., or OvaScience, now known as Millendo Therapeutics, Inc., completed its reverse merger or, the OvaScience Merger, with what was then known as “Millendo Therapeutics, Inc.,” or Private Millendo, in accordance with the terms of the Agreement and Plan of Merger and Reorganization dated as of August 8, 2018, as amended on September 25, 2018 and November 1, 2018. OvaScience’s shares of common stock listed on The Nasdaq Capital Market, previously trading through the close of business on Friday, December 7, 2018 under the ticker symbol “OVAS,” commenced trading on The Nasdaq Capital Market, under the ticker symbol “MLND,” on Monday, December 10, 2018.

Immediately following the OvaScience Merger, Private Millendo became a wholly-owned subsidiary of OvaScience. Upon consummation of the OvaScience Merger, OvaScience adopted the business plan of Private Millendo and discontinued the pursuit of OvaScience’s business plan pre-Closing.

**Available Information**

Our internet website address is www.millendo.com. In addition to the information about us and our subsidiaries contained in this Annual Report, information about us can be found on our website. Our website and information included in or linked to our website are not part of this Annual Report.

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge through our website as soon as reasonably practicable after they are electronically filed with or furnished to the Securities and Exchange Commission, or SEC. Additionally the SEC maintains an internet site that contains reports, proxy and information statements and other information. The address of the SEC’s website is www.sec.gov.

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**ITEM 1A. RISK FACTORS**

*You should carefully consider the risks described below, as well as general economic and business risks and the other information in this Annual Report on Form 10-K. The occurrence of any of the following risks 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**

***Our merger with Tempest may not be consummated or may not deliver the anticipated benefits we expect.***

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 and identifying and reviewing potential candidates for a strategic acquisition or other transaction, on March 29, 2021, we entered into a merger agreement with Tempest Therapeutics, Inc. (“Tempest”), under which the privately held Tempest will merge with a wholly owned subsidiary of Millendo (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 in the Merger Agreement results in gross proceeds of approximately $30 million). We are devoting substantially all of our time and resources to consummating this transaction, however, there can be no assurance that such activities will result in the consummation of this transaction or that such transaction will deliver the anticipated benefits or enhance stockholder value.

***Certain provisions of the Merger Agreement may discourage third-parties from submitting alternative acquisition proposals, including proposals that may be superior to the arrangements contemplated by the Merger Agreement.***

The terms of the Merger Agreement prohibit each party from soliciting or engaging in discussions with third parties regarding alternative acquisition proposals, except in limited circumstances when such party’s board of directors determines in good faith that an unsolicited acquisition proposal constitutes or could reasonably be expected to lead to a superior proposal and that failure to take such action would reasonably be expected to be inconsistent with its fiduciary duties under applicable law. In addition, if the Merger Agreement is terminated by us or Tempest under certain circumstances, including because of a decision of our board of directors to accept a superior proposal, we would 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. This termination fee may discourage third parties from submitting alternative takeover proposals to us or our stockholders, and may cause our board of directors to be less inclined to recommend an alternative proposal.

***The announcement and pendency of the Merger, whether or not consummated, may adversely affect the trading price of our common stock and our business prospects.***

The announcement and pendency of the Merger, whether or not consummated, may adversely affect the trading price of our common stock and our business prospects. In the event that the Merger is not completed, the announcement of the termination of the Merger Agreement may also adversely affect the trading price of our common stock and our business prospects.

***Failure to consummate the Merger may result in us paying a termination fee to Tempest and could harm our common stock price and our future business and operations.***

The Merger will not be consummated if the conditions precedent to the consummation of the transaction are not satisfied or waived, or if the Merger Agreement is terminated in accordance with its terms. If the Merger is not consummated, we are subject to the following risks:

•if the Merger Agreement is terminated under certain circumstances, we will 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

•the price of our common stock may decline and remain volatile.

If the Merger does not close for any reason, our board of directors may elect to, among other things, attempt to complete another strategic transaction, attempt to sell or otherwise dispose of our various assets, dissolve or liquidate our assets or seek to continue to operate our business. If we seek another strategic transaction or attempt to sell or otherwise dispose of our various assets, there is no assurance that we will be able to do so, that the terms would be equal to or superior to the terms of the Merger or as to the timing of such transaction. If we decide to dissolve and liquidate our assets, we would be required to pay all of our

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debts and contractual obligations, and to set aside certain reserves for potential future claims, and there can be no assurance as to the amount or timing of available cash left to distribute to stockholders after paying our debts and other obligations and setting aside funds for reserves.

If we were to seek to continue our business, we would need to determine whether to acquire one or more other product candidates. We would also need to raise funds to support continued operations and re-assess our workforce requirements in consideration of our reduced workforce.

If the Merger is not consummated, we may be unable to retain the services of key remaining members of our management team and, as a result, may be unable to seek or consummate another strategic transaction, properly dissolve and liquidate our assets or continue our business.

***If we do not successfully consummate the transaction with Tempest, our board of directors may dissolve or liquidate our assets to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such transaction or liquidation.***

If the Merger does not close for any reason, our board of directors may elect to, among other things, dissolve or liquidate our assets, which may include seeking protection from creditors in a bankruptcy proceeding. If we decide to dissolve and liquidate our assets, we would be required to pay all of our debts and contractual obligations, and to set aside certain reserves for potential future claims, and there can be no assurances as to the amount or timing of available cash left to distribute to stockholders after paying our debts and other obligations and setting aside funds for reserves.

In the event of a dissolution and liquidation, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, ultimately, such liquidation, since the amount of cash available for distribution continues to decrease as we fund our operations in preparation for the consummation of the Merger. Further, the Merger Agreement contains certain termination rights for each party, and provides that, upon termination under specified circumstances, we 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, which would further decrease our available cash resources. If our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. Our commitments and contingent liabilities may include (i) regulatory and clinical obligations remaining under our clinical trials; (ii) obligations under our employment, separation and retention agreements with certain employees that provide for severance and other payments following a termination of employment occurring for various reasons, including a change in control of us; and (iii) potential litigation against us, and other various claims and legal actions arising in the ordinary course of business. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation of us. If a dissolution and liquidation were pursued, our board of directors, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of our liquidation, dissolution or winding up.

***As a result of our decision to discontinue further investment in MLE-301 and the reductions in our workforce, we have only 12 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 current headcount has been reduced to 12 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 Financial Position and Need for Additional Capital**

***We have incurred significant operating losses since inception and anticipate that we will continue to incur operating losses for the foreseeable future and may never achieve or maintain profitability.***

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 loss was $36.4 million and $44.6 million and for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had an accumulated deficit of $245.1 million. We

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expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We have devoted substantially all of our efforts to the acquisition of and preclinical and clinical development of MLE-301, in which we decided to discontinue our investment in January 2021, nevanimibe, in which we ceased investing in June 2020, and livoletide, of which we discontinued development in April 2020, as well as to building our management team and infrastructure. The net losses we incur may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses may increase if we resume drug development activities. Our failure to become and remain profitable would decrease our value and could impair our ability to raise capital, continue our operations. A decline in our value also could cause you to lose all or part of your investment.

***We have a limited operating history and have never generated any revenue from product sales, which may make it difficult to assess our future viability.***

We are a biopharmaceutical company with a limited operating history. Our operations to date, with respect to the development of our product candidates, have been limited to organizing and staffing the business, business planning, raising capital, acquiring our product candidates and other assets and conducting preclinical and clinical development of our product candidates. We have not demonstrated an ability to successfully complete clinical development of a product candidate, obtain marketing approval, manufacture a commercial-scale drug (or arrange for a third-party to do so on our behalf), or conduct sales and marketing activities necessary for successful commercialization. Consequently, our predictions about our future success or viability may not be as accurate as they could be if we had more experience developing product candidates.

***If the Merger is not completed, we would need to raise substantial additional funding to the extent we resume our drug development efforts, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our drug development efforts or other operations.***

If the Merger is not completed, we may require substantial additional capital to fund any research and development and expenses related to our business. We had cash, cash equivalents and restricted cash of $38.7 million at December 31, 2020. In the event that the Merger is not completed, we may pursue a liquidation, dissolution or winding-up of the company, or may seek to complete an alternate strategic transaction or may elect to resume investment in other product candidates. Based on our current operating plan, we believe that our existing cash, cash equivalents and restricted cash will be sufficient to allow us to fund our current operating plan for at least the next 12 months.

We cannot predict to what extent we will resume drug development activities for any other drug product candidates. If we resume drug development activities, only a small minority of all research and development programs ultimately result in commercially successful drugs. Clinical failure can occur at any stage of clinical development and clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical or preclinical trials. In addition, data obtained from trials are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a drug candidate. Further, even if we complete the development for a drug product candidate and gain marketing approvals from the FDA, and comparable foreign regulatory authorities in a timely manner, we cannot be sure that such drug product candidate will be commercially successful in the pharmaceutical market. If the results of clinical trials, the anticipated or actual timing of marketing approvals, or the market acceptance of any drug product candidate, if approved, do not meet the expectations of investors or public market analysts, the market price of our common stock would likely decline. Further, if we resume drug development activities, we will need substantial additional financing to complete the development of any other drug product candidates we may develop.

We expect to incur losses for the foreseeable future. Our ability to achieve profitability in the future is dependent upon achieving a level of revenues adequate to support our cost structure. We may never achieve profitability, and unless and until we do, we will continue to need to raise additional capital. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of those securities could result in substantial dilution for our current stockholders and the terms may include liquidation or other preferences that adversely affect the rights of our current stockholders, further diminishing current stockholders' ability to realize any value for their stock holdings. Furthermore, the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our common stock to decline further and existing stockholders may not agree with our financing plans or the terms of such financings. There can be no assurances, however, that additional funding will be available on terms acceptable to us, or at all.

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***We will require additional capital to finance our operations, which may not be available on acceptable terms, if at all. Failure to obtain capital when needed may force us to delay, limit or terminate certain of our development programs, future commercialization efforts or other operations.***

We expect our expenses to increase in connection with our ongoing activities and expect to continue to incur additional costs associated with operating as a public company. As of December 31, 2020, our cash, cash equivalents and restricted cash were $38.7 million. Our existing cash, cash equivalents and restricted cash are currently expected to be sufficient to fund our current operating plans through at least the next 12 months. This cash runway guidance is based on our current operational plans and excludes any additional funding that may be received and business development activities that may be undertaken. In addition, our operating plans may change as a result of many factors currently unknown to us, including the short- and long-term effects of the COVID-19 pandemic, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, third-party funding, and marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or a combination of these approaches. In any event, we will require additional capital to pursue preclinical and clinical activities, regulatory approval and the commercialization of our current and future product candidates. Even if we believe we have sufficient capital for our current operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. If we elect to do so, additional capital may not be available to us on acceptable terms, if at all. Our ability to access additional capital, and as a result our operating results and liquidity needs, could be negatively affected by market fluctuations and economic downturn. The COVID-19 pandemic 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 negatively affect our business. Any additional capital raising efforts may divert our management from its day-to-day activities, which may adversely affect our ability to develop and commercialize our current and future product candidates.

***Raising additional capital by issuing equity or debt securities may cause dilution to our existing stockholders, and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.***

Until such time as we can generate substantial revenue from product sales, if ever, we expect to finance our cash needs through a combination of equity and debt financings, strategic alliances and license and development agreements in connection with any future collaborations. To the extent that we raise additional capital by issuing equity securities, our existing stockholders’ ownership may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Equity and debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as redeeming our shares, making investments, incurring additional debt, making capital expenditures or declaring dividends.

The incurrence of indebtedness could result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants therein, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely affect our ability to conduct our business.

If we raise additional capital through collaborations, strategic alliances or third-party licensing arrangements, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional capital 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 develop and market ourselves.

**Risks Related to Development and Commercialization**

***We have never obtained marketing approval for a product candidate and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any future product candidates that we may develop.***

We have never obtained marketing approval for a product candidate. It is possible that the FDA may refuse to accept for substantive review any NDAs that we submit for any future candidates we may choose to develop or may conclude after review of our data that our application is insufficient to obtain marketing approval of our product candidates. If the FDA does not accept or approve our NDAs for any of our future product candidates, it may require that we conduct additional clinical trials, preclinical studies or manufacturing validation studies and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA-required trials or studies, approval of any NDA or application that we submit may be delayed by several years or may require us to expend more resources than we have available. It is also possible that additional trials or studies, if performed and completed, may not be considered sufficient by the FDA to approve our NDAs.

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Any delay in obtaining, or an inability to obtain, marketing approvals would prevent us from commercializing our product candidates, generating revenues and achieving and sustaining profitability. If any of these outcomes occurs, we may be forced to abandon our development efforts for our product candidates, which could significantly harm our business, prospects, operating results and financial condition.

***We are exposed to a variety of risks associated with our international operations.***

Since the closing date of the merger we completed with OvaScience in 2018 (“the OvaScience Merger”), we have been engaged in the process of winding up various subsidiaries of OvaScience, some or all of which are in foreign jurisdictions. We are also in the process of closing all other international subsidiaries. We expect to incur additional costs to complete these processes. Moreover, even if we successfully wind up these entities, we may be exposed to liability in these foreign jurisdictions as a result of their historical operations.

In addition, in December 2017, we acquired Alizé Pharma SAS (“Alizé”), a biopharmaceutical company based in Lyon, France. As of March 15, 2021, we had 12 employees located in the United States and one employee located in France. Our past and current global operations expose us to numerous and sometimes conflicting legal, tax and regulatory requirements, and violations or unfavorable interpretation by the respective authorities of these regulations could harm our business. Risks associated with international operations include the following, and these risks may be more pronounced if we seek to commercialize any future product candidates outside of the United States:

•reduced protection for intellectual property rights;

•unexpected changes in tariffs, trade barriers and regulatory requirements;

•economic weakness, including inflation, or political instability in particular foreign economies and markets;

•compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;

•foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;

•foreign reimbursement, pricing and insurance regimes;

•workforce uncertainty in countries where labor unrest is more common than in the United States;

•changes in diplomatic and trade relationships;

•anti-corruption laws, including the FCPA, and its equivalent in foreign jurisdictions, such as the UK Bribery Act;

•production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and

•business interruptions resulting from pandemics and public health emergencies, including those related to the COVID-19 pandemic, geopolitical actions, including war and terrorism or natural disasters including earthquakes, typhoons, floods and fires.

In addition, there are complex regulatory, tax, labor, and other legal requirements imposed by both the European Union and many of the individual countries in and outside of Europe, with which we may need to comply.

***Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any future product candidate that we may develop.***

We face an inherent risk of product liability exposure related to our historical testing of product candidates. If we cannot successfully defend ourselves against claims that any such product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

•decreased demand for any product candidate that we may develop;

•loss of revenue;

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•substantial monetary awards to trial participants or patients;

•significant time and costs to defend the related litigation;

•withdrawal of clinical trial participants;

•the inability to commercialize any product candidate that it may develop;

•injury to our reputation and significant negative media attention; and

•increased marketing costs to attempt to overcome any injury to our reputation or negative media attention.

In addition, we face an inherent risk of product liability exposure related to OvaScience’s prior use of fertility treatments in humans. Product liability claims involving OvaScience’s activities may be brought for significant amounts because OvaScience’s potential fertility treatments involved mothers and children. For example, it is possible that we will be subject to product liability claims that assert that OvaScience’s potential fertility treatments have caused birth defects in children or that such defects are inheritable. These claims could be made many years into the future based on effects that were not observed or observable at the time of birth. If we cannot successfully defend against claims that OvaScience’s potential fertility treatments caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in, among other things, significant costs to defend the related litigation; substantial monetary awards or payments to trial participants or patients; loss of revenue; and the diversion of management’s resources.

Although we maintain product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

***If OvaScience failed to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.***

OvaScience was subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. OvaScience’s prior operations involved the use of hazardous and flammable materials, including chemicals and biological materials. OvaScience’s prior operations also produced hazardous waste products. OvaScience generally contracted with third-parties for the disposal of these materials and wastes. In the event of contamination or injury resulting from OvaScience’s use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with OvaScience’s storage or disposal of biological, hazardous or radioactive materials.

**Risks Related to Regulatory Compliance**

***Regulatory, legislative or self-regulatory/standard developments regarding privacy and data security matters could adversely affect our ability to conduct our business.***

We are subject to and affected by laws, rules, regulations and industry standards related to data privacy and security, and restrictions or technological requirements regarding the collection, use, storage, security, retention or transfer of data. In the United States, the rules and regulations to which we may be subject include federal laws and regulations enforced by the Federal Trade Commission, HHS, and state privacy, data security, and breach notification laws, as well as regulator enforcement positions and expectations. Internationally, governments and agencies have adopted and could in the future adopt, modify, apply or enforce additional laws, policies, regulations, and standards covering privacy and data security that may apply to our business. New regulation or legislative actions regarding data privacy and security (together with applicable industry standards) may increase our costs of doing business. In addition to privacy and data security regulations currently in force in the jurisdictions where we operate, the European Union General Data Protection Regulation (“GDPR”), went into effect in May 2018. The GDPR contains numerous requirements and changes from existing European Union (“EU”), law, including more robust obligations on data processors and data controllers and heavier documentation requirements for data protection compliance programs. Specifically, the GDPR will introduce numerous privacy-related changes for companies operating in the EU, including greater control over personal data-by-data subjects (e.g., the “right to be forgotten”), increased data portability

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for EU consumers, data breach notification requirements, and increased fines. The GDPR requirements apply not only to third-party transactions, but also to transfers of information between us and our subsidiaries, including employee information. However, despite our ongoing efforts to bring our practices into compliance before the effective date of the GDPR, we may not be successful either due to various factors within our control, such as limited financial or human resources, or other factors outside our control. It is also possible that local data protection authorities may have different interpretations of the GDPR, leading to potential inconsistencies amongst various EU member states. Any failure or alleged failure (including as a result of deficiencies in our policies, procedures, or measures relating to privacy, data security, marketing, or communications) by us to comply with laws, regulations, policies, legal or contractual obligations, industry standards, or regulatory guidance relating to privacy or data security, may result in governmental investigations and enforcement actions, litigation, fines and penalties, additional regulatory oversight and reporting obligations or adverse publicity. Further, because of the work-from-home policies we implemented due to COVID-19, information that is normally protected, including company confidential information, may be less secure.

We expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the European Union, and in other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business. Future laws, regulations, standards and other obligations or any changed interpretation of existing laws or regulations could impair our ability to operate our business and negatively impact our results of operations.

**Risks Related to Our Intellectual Property**

***If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.***

To the extent we resume drug development activities, we will rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Further, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically published 18 months after filing, or in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and drugs. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act (the “Leahy-Smith Act”), was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The United States Patent and Trademark Office (“USPTO”), recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition. Any further changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents and patent applications or narrow the scope of our potential patent protection.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the

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scope of, or invalidate, our patent rights, allow third-parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and product candidates, or limit the duration of the patent protection of our technology and product candidates. Moreover, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years from the earliest filing date of a non-provisional patent application. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our current or future product candidates, we may be open to competition from generic versions of such drugs. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, we owned and licensed patent portfolio may not provide it with sufficient rights to exclude others from commercializing drugs similar or identical to that of us.

***We jointly own patents and patent applications with third-parties. Our ability to exploit or enforce these patent rights, or to prevent the third-party from granting licenses to others with respect to these patent rights, may be limited in some circumstances.***

We jointly own certain patents and patent applications with third-parties. In the absence of an agreement with each co-owner of jointly owned patent rights, we will be subject to default rules pertaining to joint ownership. Some countries require the consent of all joint owners to exploit, license or assign jointly owned patents, and if we are unable to obtain that consent from the joint owners, we may be unable to exploit the invention or to license or assign our rights under these patents and patent applications in those countries. For example, we secured exclusive rights from the University of Michigan for certain patents and patent applications that they jointly own with us related to nevanimibe. Additionally, in the United States, each co-owner may be required to be joined as a party to any claim or action we may wish to bring to enforce these patent rights, which may limit our ability to pursue third-party infringement claims.

***We have in-licensed patents and patent applications from third-parties. Our ability to exploit or enforce these patent rights, or to prevent the third-party from granting licenses to others with respect to these patent rights, may be limited in some circumstances.***

We have in-licensed certain patents and patent applications from third-parties. In the absence of an agreement with each patent rights owner, we will be subject to default rules pertaining to ownership. Some countries require the consent of all owners to exploit, license or assign owned patents, and if we are unable to obtain that consent from the owners, we may be unable to exploit the invention or to license or assign our rights under these patents and patent applications in those countries. For example, we secured exclusive rights from Roche for certain patents and patent applications that they own related to MLE-301. Additionally, in the United States, each owner may be required to be joined as a party to any claim or action we may wish to bring to enforce these patent rights, which may limit our ability to pursue third-party infringement claims.

***Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States in several stages over the lifetime of our owned and licensed patents and/or applications and any patent rights it may own or license in the future. We rely on our outside counsel or our licensing partners to pay these fees due to non-U.S. patent agencies. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules.

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There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction.

In such an event, potential competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

***Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.***

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. We have in the past sought, and in the future may seek, extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits extension of the term of one U.S. patent that includes at least one claim covering the composition of matter of an FDA-approved drug, an FDA-approved method of treatment using the drug. The extended patent term cannot exceed the shorter of five years beyond the non-extended expiration of the patent or 14 years from the date of the FDA approval of the drug. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. Further, we may not elect to extend the most beneficial patent to us or the claims underlying the patent that we choose to extend could be invalidated. If any of the foregoing occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing its clinical and preclinical data and launch their drug earlier than might otherwise be the case.

***Intellectual property rights do not necessarily address all potential threats to our business.***

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business. The following examples are illustrative:

•others may be able to make compounds or formulations that are similar to our formulation but that are not covered by the claims of the patents that we own or control;

•we or any strategic partners might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or control;

•we might not have been the first to file patent applications covering certain of our inventions;

•others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;

•it is possible that our pending patent applications will not lead to issued patents;

•issued patents that we own or control may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;

•our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights and then use the information learned from such activities to develop competitive drugs for sale in our major commercial markets;

•we may not develop additional proprietary technologies that are patentable; and

•the patents of others may have an adverse effect on our business.

***Third-parties may initiate legal proceedings, which are expensive and time consuming, alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse impact on the success of our business.***

The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. We may in the future become party to, or be threatened with, adversarial proceedings or

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litigation regarding intellectual property rights with respect to any future product candidates and technology, including interference proceedings, post grant review and inter partes review before the USPTO. Third-parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third-parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could have a material adverse effect on our ability to commercialize any future product candidates. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If we are found to infringe a third-party’s valid and enforceable intellectual property rights, we could be required to obtain a license from such third-party to continue developing, manufacturing and marketing our product candidate and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third-parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product candidate. In addition, we could be found liable for monetary damages, including treble damages and attorneys’ fees, if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us from manufacturing and commercializing any future product candidates or force us to cease some or all of our business operations, which would have a material adverse effect on our business. Claims that we have misappropriated the confidential information or trade secrets of third-parties could have a similar material adverse effect on our business. Even if we prevail in such infringement claims, patent litigation can be expensive and time consuming, which would harm our business, financial condition and results of operations.

***We may become involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time consuming and unsuccessful.***

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of ours patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third-party may also cause the third-party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third-parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, inter partes review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third-party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could have material adverse effect on our business.

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees. Even if we prevail in such infringement claims, patent litigation can be expensive and time consuming, which would harm our business, financial condition and results of operations.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common stock.

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***Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.***

The United States has recently enacted and implemented wide-ranging patent reform legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, federal courts, USPTO, and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future.

***We may not be able to protect our intellectual property rights throughout the world, which could have a material adverse effect on our business.***

Filing, prosecuting and defending patents covering any future product candidates throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop our own drugs and, further, may export otherwise infringing drugs to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These drugs may compete with our drugs in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

***We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third-parties.***

Certain of our employees, consultants or advisors are currently, or were previously, employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual’s current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while it is our approach to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third-parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property.

**Risks Related to Our Dependence on Third-Parties**

***We may in the future enter into collaborations with third-parties to develop our product candidates. If these collaborations are not successful, our business could be harmed.***

We may enter into collaborations with third-parties in the future. We may in the future determine to collaborate with other pharmaceutical and biotechnology companies for development and potential commercialization of our product candidates. These relationships, or those like them, may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we could face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. Our ability to reach a definitive collaboration agreement will depend, among other things, upon our assessment of the collaborator’s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator’s evaluation of several factors. If we license rights to our product candidates, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture.

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If any such potential future collaborations do not result in the successful development and commercialization of product candidates, or if one of our future collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, the development of our product candidates could be delayed and we may need additional resources to develop our product candidates. In addition, if one of our future collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and the perception of us in the business and financial communities could be adversely affected. All of the risks relating to product development, regulatory approval and commercialization apply to the activities of our potential future collaborators.

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

***Our business, preclinical studies and clinical development programs and timelines, our financial condition and results of operations could be materially and adversely affected by the current COVID-19 pandemic.***

A novel strain of coronavirus, SARS-CoV-2, causing COVID-19, has been declared a pandemic by the World Health Organization. The COVID-19 pandemic has resulted in travel and other restrictions in order to reduce the spread of the disease, including state and local orders across the country, which, among other things, direct individuals to shelter at their places of residence, direct businesses and governmental agencies to cease non-essential operations at physical locations, prohibit certain non-essential gatherings, and order cessation of non-essential travel. In response to these public health directives and orders, we have implemented work-from-home policies for certain employees. The effects of the executive orders, the shelter-in-place orders and our work-from-home policies may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

Quarantines, shelter-in-place and similar government orders related to COVID-19 may adversely impact our business operations and the business operations of our contract research organizations conducting our clinical trials and our third-party manufacturing facilities in the United States and other countries. In particular, some of our third-party manufacturers which we use for the supply of materials for product candidates or other materials necessary to manufacture product to conduct preclinical studies and clinical trials are located in countries affected by COVID-19, and should they experience disruptions, such as temporary closures or suspension of services, we would likely experience delays in advancing these tests and trials.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

The global pandemic of COVID-19 continues to rapidly evolve. The extent to which the COVID-19 pandemic impacts our business, our clinical development and regulatory efforts will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, travel restrictions, quarantines, social distancing requirements and business closures in the United States and other countries, and business disruptions, and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. Accordingly, we do not yet know the full extent of potential delays or impacts on our business, our clinical and regulatory activities, healthcare systems or the global economy as a whole. However, these impacts could adversely affect our business, financial condition, results of operations and growth prospects.

In addition, to the extent the ongoing COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this ‘‘Risk Factors’’ section.

***We are highly dependent*** ***on the services of our key executives and personnel, including Louis Arcudi III, our chief executive officer and Jennifer Minai-Azary, our chief financial officer and if we are not able to retain these members of our management team or recruit and retain additional management or personnel, our business will be harmed.***

We are highly dependent on Mr. Arcudi and Ms. Minai-Azary. The employment agreements we have with these officers do not prevent such persons from terminating their employment with us at any time. Further, these officers may be unable to perform their duties or have limited availability due to COVID-19 or other health emergencies. The temporary or permanent loss of the services of any of these persons could impede the achievement of our corporate objectives.

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To the extent we resume drug development activities, we will also be dependent on our continued ability to attract, retain and motivate highly qualified additional management and personnel. If we are not able to retain our management and to attract, on acceptable terms, additional qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or grow.

We may not be able to attract or retain qualified personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. Many of the other pharmaceutical companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles, are located in geographies with a larger biotechnology industry presence and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates and consultants than what we have to offer. If we are unable to continue to attract, retain and motivate high-quality personnel and consultants to accomplish our business objectives, the rate and success at which we can discover and develop product candidates and our business will be limited and we may experience constraints on our development objectives.

***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. 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.

***Our employees, independent contractors, principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in misconduct or other improper activities, including historical noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.***

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in other jurisdictions, provide accurate information to the FDA and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending itself or asserting our rights, those actions could have a negative impact on our business, financial condition and results of operations, including the imposition of significant fines or other sanctions.

***We may be delayed in our receipt of certain tax benefits that Alizé historically received as a French technology company.***

As a French technology company, Alizé historically benefited from certain tax advantages, including the French research tax

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credit (*credit d’impot recherche*) (“CIR”). The CIR is a French tax credit aimed at stimulating research and development and can offset French corporate income tax due. Alizé has historically received CIR reimbursements promptly following filing for such reimbursements with applicable French taxing authorities. For the year ended December 31, 2018, claims were made totaling $1.3 million, which we received in the third quarter of 2019. For the year ended December 31, 2019, claims were made totaling $1.3 million, which we received in the second quarter of 2020. In the future, we may no longer qualify as a French small or medium size enterprise, and, accordingly, we may be subject to a three-year waiting period for reimbursement of CIRs, which could adversely affect the combined business’s results of operations and cash flows. In addition, the amount of CIR received is, among other factors, dependent upon incurring qualified research and development expenses and maintaining a certain level of employee salaries and other personnel costs in France. The number of our research and development employees in France decreased during the year ended December 31, 2020 and we experienced a decrease in qualified research and development expenses for the year ended December 31, 2020 due to the discontinuation of our livoletide program. We plan to dissolve our subsidiary in France.

***Our internal computer systems, or those of our collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.***

Our internal computer systems and those of our current and any future collaborators and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we are not aware of any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed.

***We may be exposed to significant foreign exchange risk.***

We incur portions of our expenses, and may in the future derive revenue, in currencies other than the U.S. dollar, in particular, the euro. As a result, we are exposed to foreign currency exchange risk as our results of operations and cash flows are subject to fluctuations in foreign currency exchange rates. Any fluctuation in the exchange rate of these foreign currencies may negatively impact our business, financial condition and operating results. Global economic events, such as the COVID-19 pandemic, have and may continue to significantly impact local economies and the foreign exchange markets, which may increase the risks associated with sales denominated in foreign currencies. We currently do not engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the euro. Therefore, for example, an increase in the value of the euro against the U.S. dollar could be expected to have a negative impact on our operating expenses as euro denominated expenses, if any, would be translated into U.S. dollars at an increased value. We cannot predict the impact of foreign currency fluctuations, and foreign currency fluctuations in the future may adversely affect our financial condition, results of operations and cash flows.

***The risks arising with respect to the historic OvaScience business and operations may be different from what we anticipate, which could lead to significant, unexpected costs and liabilities and could materially and adversely affect our business going forward.***

It is possible that we may not have fully anticipated the extent of the risks associated with the OvaScience Merger we completed with OvaScience in 2018. After the OvaScience Merger, OvaScience’s historic business was discontinued, but prior to the transaction OvaScience had a significant operating history. As a consequence, we may be subject to claims, demands for payment, regulatory issues, costs and liabilities that were not and are not currently expected or anticipated. Notwithstanding our exercise of due diligence pre-transaction and winding down of the OvaScience business post-transaction, the risks involved with taking over a business with a significant operating history and the costs and liabilities associated with these risks may be greater than we anticipate. We may not be able to contain or control the costs or liabilities associated with OvaScience’s historic business, which could materially and adversely affect our business, liquidity, capital resources or results of operation.

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

***The trading price of the shares of our common stock has been and is likely to continue to be volatile, and purchasers of our common stock could incur substantial losses.***

The market price of our common stock has been and is likely to continue to be highly volatile and could be subject to wide fluctuations in price in response to various factors. A number of factors could influence the volatility in the trading price of our common stock, including changes in the economy or in the financial markets, including recently in connection with the ongoing COVID-19 pandemic, industry-related developments, and the impact of material events and changes in our operations, including as a result of our recent announcements that we have discontinued our livoletide program in PWS and ceased investing in our nevanimibe program and our MLE-301 program. Worsening economic conditions and other adverse effects or developments relating to our business or the ongoing COVID-19 pandemic may negatively affect the market price of our common stock. The market price for our common stock is likely to continue to be volatile, particularly due to the ongoing COVID-19 pandemic, and subject to significant price and volume fluctuations in response to market, industry and other factors, including the risk factors described in this “Risk Factors” section. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including:

•announcements and market perceptions related to the Merger;

•changes in financial estimates by us or by any securities analysts who might cover our stock;

•conditions or trends in our industry;

•changes in the market valuations of similar companies;

•stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;

•publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;

•announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;

•announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;

•investors’ general perception of our company and our business;

•recruitment or departure of key personnel;

•overall performance of the equity markets;

•trading volume of our common stock;

•disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;

•significant lawsuits, including patent or stockholder litigation;

•general political and economic conditions; and

•other events or factors, many of which are beyond our control.

In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies’ stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management’s attention and resources from our business.

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***Future sales of our common stock in the public market could cause our share price to decline.***

Sales of a substantial number of shares of our common stock in the public market could occur at any time, subject to the restrictions and limitations described below. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales, particularly sales by our directors, executive officers, and significant stockholders, may have on the prevailing market price of our common stock. As of December 31, 2020, we had 18,999,701 shares of common stock outstanding. All of our outstanding shares of common stock are available for sale in the public market, subject only to the restrictions of Rule 144 under the Securities Act. In addition, the shares of common stock subject to outstanding options under our equity incentive plans and the shares reserved for future issuance under our equity incentive plans will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. In addition, certain holders of our common stock have the right, subject to various conditions and limitations, to request we include their shares of our common stock in registration statements we may file relating to our securities.

***Provisions in our certificate of incorporation and by-laws and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.***

Provisions in our certificate of incorporation and by-laws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which our common stockholders might otherwise receive a premium price for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

•establish a classified board of directors such that not all members of the board are elected at one time;

•allow the authorized number of our directors to be changed only by resolution of our board of directors;

•limit the manner in which stockholders can remove directors from the board;

•establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and for nominations to our board of directors;

•limit who may call stockholder meetings;

•prohibit actions by our stockholders by written consent;

•require that stockholder actions be effected at a duly called stockholders meeting;

•authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a “poison pill” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and

•require the approval of the holders of at least 75 percent of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our certificate of incorporation or by-laws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns 15 percent or more of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired 15 percent or more of our outstanding voting stock, unless the merger or combination is approved in a manner prescribed by the statute.

***Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent our other stockholders from influencing significant corporate decisions.***

As of March 1, 2021, our executive officers, directors and current beneficial owners of 5% or more of our common stock and their respective affiliates, in the aggregate, beneficially own approximately 34.5% of our outstanding common stock. As a

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result, these persons, acting together, can significantly influence all matters requiring stockholder approval, including the election and removal of directors, any merger, consolidation, sale of all or substantially all of our assets, or other significant corporate transactions.

Some of these persons or entities may have interests different than yours. For example, because many of these stockholders purchased their shares at prices substantially below the current market price of our common stock and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders.

***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 our 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 Item 3, 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.

***If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.***

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, and the rules and regulations of the stock market on which our common stock is listed. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting and that we furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting. However, due to recent changes in SEC rules related to smaller reporting companies, we are not required to have our auditors formally attest to the effectiveness of our internal control over financial reporting in connection with this Annual Report on Form 10-K for the year ended December 31, 2020. For the year ended December 31, 2018, we were unable to conduct the required assessment primarily due to the OvaScience Merger occurring in the fourth quarter of 2018 and the substantial change in operational focus, management and the internal control environment following the OvaScience Merger. As a result, we provided our first internal control assessment with our Annual Report on Form 10-K for the year ended December 31, 2019.

We may identify weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system’s objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the Securities and Exchange Commission (“SEC”), or other regulatory authorities.

***We expect to continue to incur increased costs as a result of operating as a public company, and our management is required to devote substantial time to compliance with our public company responsibilities and corporate governance practices.***

As a relatively new public company, we continue to incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Capital Market and other applicable securities rules and regulations impose various requirements on public companies. Our management and other personnel need to devote a substantial amount of time to compliance with these requirements. Moreover, these rules and regulations increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain directors’ and officers’ liability insurance, compared to when we were a private company, which could make it more difficult for us to attract and retain qualified members of our board of directors. We cannot predict or

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estimate the amount of additional costs we will continue to incur as a public company or the timing of such costs.

***Changes in tax laws or regulations could materially adversely affect our company.***

New tax laws or regulations could be enacted at any time, and existing tax laws or regulations could be interpreted, modified or applied in a manner that is adverse to us, which could adversely affect our business and financial condition. For example, legislation enacted in 2017, informally titled the Tax Act, enacted many significant changes to the U.S. tax laws, including changes in corporate tax rates, the utilization of our NOLs and other deferred tax assets, the deductibility of expenses, and the taxation of foreign earnings. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. For example, the CARES Act modified certain provisions of the Tax Act. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the CARES Act, or any newly enacted federal tax legislation. The impact of changes under the Tax Act, the CARES Act, or future reform legislation could increase our future U.S. tax expense and could have a material adverse impact on our business and financial condition.

***Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of accrued amounts.***

We are subject to taxation in more than one tax jurisdiction. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such places. Nevertheless, our effective tax rate may be different than experienced in the past due to numerous factors, including passage of the newly enacted federal income tax law, changes in the mix of our profitability from jurisdiction to jurisdiction, the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes, cash repatriation restrictions and possible withholding taxes and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements.

***Our ability to use net operating losses and certain other tax attributes to offset future taxable income may be subject to limitation.***

As of December 31, 2020, we had federal and state net operating loss carryforwards (“NOLs”) of $330.8 million and $280.9 million, respectively. Our NOLs could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. Our NOLs generated in tax years ending on or prior to December 31, 2017 are permitted to be carried forward for only 20 years under applicable U.S. tax law. Our federal NOLs generated in tax years ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of federal NOLs generated in tax years beginning after December 31, 2020 is subject to certain limitations. It is uncertain if and to what extent various states will conform to the Tax Act. Our federal and state net operating loss carryforwards will begin to expire, if not utilized, by 2031.

In addition, under Section 382 and Section 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an “ownership change,” its ability to use its pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. A Section 382 “ownership change” generally occurs if one or more stockholders or groups of stockholders who own at least 5% of our stock increase their ownership by more than 50 percentage points (by value) over their lowest ownership percentage over a rolling three-year period. We may have experienced ownership changes in the past and may experience ownership changes in the future as a result of shifts in our stock ownership, such as the Merger with Tempest, or other changes (some of which are outside our control). As a result, if we earn net taxable income, our ability to use our pre-change NOLs to offset such taxable income may be subject to limitations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Consequently, even if we achieve profitability, we may not be able to utilize a material portion of our net operating loss carryforwards and certain other tax attributes, which could have a material adverse effect on cash flow and results of operations.

***We do not anticipate paying any cash dividends on our common stock in the foreseeable future.***

You should not rely on an investment in our common stock to provide dividend income. We have not declared or paid cash dividends on our common stock to date. We currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, the terms of any existing or future debt agreements may preclude us from paying dividends.

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As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Investors seeking cash dividends should not purchase our common stock.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 2. PROPERTIES**

Our corporate headquarters are located at 110 Miller Avenue, Suite 100, Ann Arbor, Michigan, 48104, where we occupy approximately 21,000 square feet of office space under two separate leases. We lease approximately 10,000 square feet of third floor office space pursuant to a lease entered into in October 2018, which began on July 1, 2019 and is set to expire on June 30, 2024. In addition, we lease approximately 11,000 square feet of first floor office space pursuant to a lease entered into in February 2019, which began on April 1, 2019 and is set to expire on March 31, 2024.

**ITEM 3. LEGAL PROCEEDINGS**

**Item 3. Legal Proceedings**

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 OvaScience and one current director of the Company (a former director of OvaScience) and OvaScience 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 OvaScience’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 case remains stayed until at least April 30, 2021, when the parties are due to file a further 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 OvaScience and certain former officers of OvaScience 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. The Company believes that the amended complaint and the second amended complaint are without merit. On August 17, 2020, the court granted the parties’ joint motion to stay all proceedings in the case pending mediation. The parties agreed to participate in a second mediation session on November 10, 2020. 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. 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.

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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 OvaScience and one current director of the Company (a former director of OvaScience) 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 OvaScience’s January 2015 follow-on public offering and other public statements concerning OvaScience’s AUGMENT treatment. 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, 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 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.

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.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

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**PART II**

**ITEM 5. MARKET FOR REGISTRANT’S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASE OF EQUITY SECURITIES**

**Market Information**

Our common stock has been traded on the Nasdaq Capital Market under the symbol “MLND” since the closing of the OvaScience Merger on December 7, 2018.

**Stockholders**

As of March 15, 2021, we had 19,043,034 shares of common stock outstanding held by 76 holders of record. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

**Recent Sales of Unregistered Securities**

None.

**Purchases of Equity Securities by the Issuer and Affiliated Parties**

None.

**ITEM 6. SELECTED FINANCIAL DATA**

Not required for smaller reporting companies.

**ITEM 7. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the financial statements and the related notes to those statements included later in this Annual Report. 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 Annual Report, 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

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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%, with the majority of the reduction in personnel expected to be completed by April 15, 2021. We initiated this reduction in force in January 2021 and expect to 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, substantially all of which will be cash expenditures.

We had also been investigating nevanimibe (ATR-101) as a potential treatment for patients with endogenous Cushing’s syndrome (“CS”), a rare endocrine disease characterized by excessive cortisol production from the adrenal glands. As a result of slower than anticipated enrollment in our CS Phase 2 clinical trial, we elected to discontinue the trial in August 2019 and are no longer developing nevanimibe for the treatment of CS.

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.

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**Historical Business and Programs**

Since our inception in January 2012, our operations have focused on conducting preclinical studies and clinical trials, acquiring technology and assets, organization and staffing, business planning, and raising capital. We have devoted substantial effort and resources to acquiring our previous four product candidates, livoletide, nevanimibe, and MLE-301, as well as MLE4901, which we ceased developing in 2017. We acquired livoletide in connection with our acquisition of Alizé Pharma SAS, or Alizé, in December 2017. We in-licensed nevanimibe from the Regents of the University of Michigan, or the University of Michigan, in June 2013. We licensed MLE-301 from F. Hoffmann-La Roche Ltd and Hoffman-La Roche Inc. (collectively, “Roche”), in October 2018. We do not have any product candidates approved for sale and have not generated any revenue from product sales. We have funded our operations primarily through the sale and issuance of common stock, preferred stock and convertible promissory notes, proceeds received from the OvaScience Merger as well as borrowings under term loans.

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 $36.4 million and $44.6 million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had an accumulated deficit of $245.1 million. We expect to continue to incur significant expenses and 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

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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.

***Financing***

In December 2019, we sold 4,791,667 shares of our common stock pursuant to an underwriting agreement (the “Underwriting Agreement”) with Citigroup Global Markets Inc. and SVB Leerink LLC, as representatives of the several underwriters named therein (the “Underwriters”), for net proceeds to us of approximately $26.5 million, after deducting underwriting discounts and commissions and other offering expenses payable by us. The price to the public in this offering was $6.00 per share and resulted in the sale of 4,166,667 shares of our common stock for net proceeds to us of approximately $23.0 million, after deducting underwriting discounts and commissions and other offering expenses. In addition, the Underwriters purchased an

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additional 625,000 shares of our common stock at the public offering price of $6.00 per share pursuant to a purchase option granted to them under the Underwriting Agreement, resulting in net proceeds to us of approximately $3.5 million, after deducting underwriting discounts and commissions.

The offering was 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, and a prospectus supplement thereunder.

***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 fourth quarter of 2020, 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 fourth quarter of 2020, 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.

***OvaScience Merger***

On December 7, 2018, OvaScience, Inc., or OvaScience, now known as Millendo Therapeutics, Inc. completed its reverse merger or, the OvaScience Merger, with what was then known as “Millendo Therapeutics, Inc.,” or Private Millendo, in accordance with the terms of the Agreement and Plan of Merger and Reorganization dated as of August 8, 2018, as amended on September 25, 2018 and November 1, 2018, or the OvaScience Merger Agreement.  OvaScience’s shares of common stock listed on The Nasdaq Capital Market, previously trading through the close of business on Friday, December 7, 2018 under the ticker symbol “OVAS,” commenced trading on The Nasdaq Capital Market, under the ticker symbol “MLND,” on Monday, December 10, 2018.

In August 2018, Private Millendo issued convertible promissory notes, or the Notes, to several of its existing investors and received cash proceeds of $8.0 million. The Notes accrued simple interest of 6.0% per annum.  Additionally, immediately prior to the OvaScience Merger, Private Millendo issued and sold an aggregate of 1,320,129 shares of Private Millendo common stock for total net proceeds of approximately $20.1 million, or the Pre-Closing Financing, to certain existing stockholders of Private Millendo.

In connection with the OvaScience Merger, each outstanding share of Private Millendo capital stock converted into shares of OvaScience’s common stock, and each outstanding option or warrant to purchase Private Millendo capital stock converted into the right to receive shares of OvaScience’s common stock.  At the Closing of the OvaScience Merger, Private Millendo stockholders received an aggregate of 8,789,628 shares of OvaScience common stock, which includes 1,320,129 shares of common stock issued to the investors in the Pre-Closing Financing, Private Millendo option holders received options to purchase 1,874,158 shares of OvaScience common stock and Private Millendo warrant holders received warrants to purchase 17,125 shares of OvaScience common stock.  In addition, upon the Closing of the OvaScience Merger, all principal and interest underlying the Notes converted into 499,504 shares of OvaScience common stock.

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Immediately following the OvaScience Merger, Private Millendo became a wholly-owned subsidiary of OvaScience.  Upon consummation of the OvaScience Merger, or the Closing, OvaScience adopted the business plan of Private Millendo and discontinued the pursuit of OvaScience’s business plan pre-Closing.  The OvaScience Merger was accounted for as a reverse recapitalization with Private Millendo as the accounting acquirer. On the OvaScience Merger date, the primary pre-combination assets of OvaScience was cash, cash equivalents and marketable securities.  At the time of the OvaScience Merger, OvaScience had net assets of $38.0 million, which was comprised primarily of cash, cash equivalents and marketable securities.

Following the Closing of the OvaScience Merger, on December 7, 2018, we issued and sold an aggregate of 1,230,158 shares of common stock to an institutional investor for $16.258065 per share, for total net proceeds of approximately $18.7 million.

***Integration of OvaScience***

Leading up to the closing date of the OvaScience Merger, OvaScience had agreed to terminate, assign or otherwise fully discharge substantially all obligations under all contracts to which OvaScience or its subsidiaries were a party, wind-down the operations, and dissolve certain subsidiaries. OvaScience has closed their offices and all employees were terminated or resigned prior to or at the closing. All operations are drawing to a close that were not already wound down prior to closing.

***Acquisition of Alizé***

In December 2017, Private Millendo entered into agreements to acquire 100% of the outstanding ownership interests of Alizé, a privately held biotechnology company based in Lyon, France focused on the development of a treatment for patients with PWS, through its lead product candidate, livoletide.

In December 2017, we acquired 83.6% of the issued and outstanding share capital of Alizé pursuant to a Share Sale and Contribution Agreement. The consideration included an upfront payment of $1.0 million, and the issuance of Private Millendo's Series A-1 preferred stock, Series B-1 preferred stock, and common-1 stock, which upon consummation of the OvaScience Merger were converted to shares of our common stock. In December 2018, we acquired the remaining 16.4% of Alizé's issued and outstanding share capital from Otonnale SAS, or Otonnale. The consideration included a cash payment of $0.8 million and the issuance of the 442,470 shares of our common stock.

The Share and Contribution Agreement with Alizé was accounted for as an asset acquisition as substantially all of the fair value of the gross assets acquired was concentrated in the livoletide development program. The $63.8 million in estimated fair value allocated to livoletide was expensed, as we determined the asset has no alternative future use. The total consideration given, net of cash acquired was $63.1 million. The assets acquired and liabilities assumed as of the acquisition date were $65.3 million and $2.2 million, respectively, for net assets acquired of $63.1 million.

**Components of 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.

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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 years ended December 31, 2020 and 2019, respectively:

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  | | | **Year Ended**  **December 31,** | | | | | | | | |
|  | | | **2020** | | |  | | | **2019** | | |
|  | | | **(in thousands)** | | | | | | | | |
| Livoletide expenses | | | $ | 8,086 |  |  | | | $ | 14,702 |  |
| Nevanimibe expenses | | | 965 | |  |  | | | 2,899 | |  |
| MLE-301 expenses | | | 5,211 | |  |  | | | 2,723 | |  |
| Personnel expenses | | | 5,501 | |  |  | | | 6,559 | |  |
| Other expenses | | | 611 | |  |  | | | 960 | |  |
| Total | | | $ | 20,374 |  |  | | | $ | 27,843 |  |

Our research and development costs related to livoletide and nevanimibe have decreased significantly due to our decision to discontinue the livoletide 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 December 31, 2020. 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 increased significantly due to preclinical studies and clinical trials during 2020, however, we expect future costs to decrease significantly 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.

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

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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. We expect our general and administrative expenses to increase during the first half of 2021 due to our corporate restructuring plan and the proposed Merger.

***Interest income, net***

Interest income represents amounts earned on our cash, cash equivalents and restricted cash balances.

***Results of operations***

***Comparison of the years ended December 31, 2020 and 2019***

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  | | | **Year Ended**  **December 31,** | | | | | | | | |
|  | | | **2020** | | |  | | | **2019** | | |
|  | | | **(in thousands)** | | | | | | | | |
| Operating expenses: | | |  | | |  | | |  | | |
| Research and development | | | $ | 20,374 |  |  | | | $ | 27,843 |  |
| General and administrative | | | 15,598 | |  |  | | | 17,556 | |  |
|  | | |  | | |  | | |  | | |
| Loss from operations | | | 35,972 | |  |  | | | 45,399 | |  |
| Other expenses: | | |  | | |  | | |  | | |
| Interest income, net | | | (155) | |  |  | | | (1,038) | |  |
| Other loss | | | 589 | |  |  | | | 207 | |  |
| Net loss | | | $ | 36,406 |  |  | | | $ | 44,568 |  |

***Research and development expense***

Research and development expense decreased by $7.5 million to $20.4 million for the year ended December 31, 2020 from $27.8 million for the year ended December 31, 2019. The following table summarizes our research and development expenses for the years ended December 31, 2020 and 2019:

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  | | | **Year Ended**  **December 31,** | | | | | | | | |
|  | | | **2020** | | |  | | | **2019** | | |
|  | | | **(in thousands)** | | | | | | | | |
| Preclinical and clinical development expense | | | $ | 14,262 |  |  | | | $ | 20,324 |  |
| Compensation expense, other than stock-based compensation | | | 4,524 | |  |  | | | 5,260 | |  |
| Stock-based compensation expense | | | 977 | |  |  | | | 1,299 | |  |
| Other expenses | | | 611 | |  |  | | | 960 | |  |
| Total research and development expense | | | $ | 20,374 |  |  | | | $ | 27,843 |  |

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

•a $6.1 million decrease in preclinical and clinical development expense primarily related to decrease spend due to discontinuing our development of the livoletide and nevanimibe programs offset by increased spend on MLE-301;

•a $1.1 million decrease in compensation and stock-based compensation expenses primarily due to the reduction in force completed in the second quarter of 2020, as a result of the discontinuance of our livoletide program; and

•a $0.3 million decrease in other expenses mainly related to a reduction in travel in connection with the COVID-19 pandemic and allocated overhead due to fewer research and development personnel.

***General and administrative expense***

General and administrative expense decreased by $2.0 million to $15.6 million for the year ended December 31, 2020 from $17.6 million for the year ended December 31, 2019. The decrease was primarily due to lower professional fees and travel costs. Professional fees decreased $2.9 million mainly as a result of lower legal, accounting and consulting fees incurred as compared to the prior period. The decrease in these fees was due to lower expenditures on preparations for certain public

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reporting requirements in 2020 as compared to 2019, as well as lower consulting fees incurred related to assessing market opportunities for previous product candidates. Travel costs decreased $0.3 million as a result of a reduction in business travel in connection with the COVID-19 pandemic. These decreases were partially offset by increases in compensation expenses, including stock-based compensation, as well as increases in insurance, rent and facility related expenses. Compensation and stock-based compensation increased by $0.8 million as a result of termination benefits paid in connection with our reduction in force in the second quarter of 2020 and additional options granted in 2020. Insurance, rent and facility related expenses increased $0.4 million. These increases were due to higher insurance premiums and costs for additional leased office space compared to the prior period.

***Interest income, net***

Interest income, net decreased by $0.9 million to $0.2 million net interest income for the year ended December 31, 2020 from $1.0 million net interest income for the year ended December 31, 2019. The change was primarily due to lower interest income received as a result of lower cash, cash equivalent and restricted cash balances and lower interest rates.

***Other loss***

Other loss increased by $0.4 million to $0.6 million for the year ended December 31, 2020 from $0.2 million for the year ended December 31, 2019. The increase was due to higher 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**

The following table sets forth the primary uses of cash and cash equivalents for each year set forth below:

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  | | | **Year Ended**  **December 31,** | | | | | | | | |
|  | | | **2020** | | |  | | | **2019** | | |
|  | | | **(in thousands)** | | | | | | | | |
| Net cash used in operating activities | | | $ | (30,435) |  |  | | | $ | (41,222) |  |
| Net cash (used in) provided by investing activities | | | (26) | |  |  | | | 3,988 | |  |
| Net cash provided by financing activities | | | 5,386 | |  |  | | | 26,943 | |  |
| Effect of foreign currency exchange rate changes on cash | | | 221 | |  |  | | | 33 | |  |
| Net decrease in cash, cash equivalents and restricted cash | | | $ | (24,854) |  |  | | | $ | (10,258) |  |

***Uses of funds***

*Operating activities*

During the year ended December 31, 2020, we used $30.4 million of cash to fund operating activities. During the year ended December 31, 2020, cash used in operating activities reflected our net loss of $36.4 million offset by non-cash charges of $5.7 million, principally related to stock-based compensation, amortization of our right-of-use assets and the foreign currency remeasurement loss and a net change in operating assets and liabilities of $0.3 million.

During the year ended December 31, 2019, we used $41.2 million of cash to fund operating activities. During the year ended December 31, 2019, cash used in operating activities reflected our net loss of $44.6 million and a net change in operating assets and liabilities of $2.0 million, offset by non-cash charges of $5.4 million, principally related to stock-based compensation.

*Investing activities*

During the year ended December 31 2020, we paid $26,000 in purchases of property and equipment. During the year ended December 31, 2019, we received $4.4 million in net proceeds from the sale of marketable securities offset by $0.4 million in purchases of property and equipment.

*Financing activities*

During the year ended December 31, 2020, we received proceeds of $5.5 million received from the issuance of common stock, net of issuance costs paid. See Note 1 of our Consolidated Financial Statements for additional information related to the issuance of common stock.

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During the year ended December 31, 2019, we received proceeds of $0.5 million from the exercise of options and warrants, and $26.7 million in proceeds received from the issuance of common stock, net of issuance costs paid. See Note 1 of our Consolidated Financial Statements for additional information related to the issuance of common stock. These proceeds were offset by $0.2 million for the repayment of debt.

***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 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.

As of December 31, 2020, we had cash, cash equivalents and restricted cash of $38.7 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 any future preclinical studies and clinical trials;

•the scope, prioritization and number of any future research and development programs;

•the costs, timing and outcome of regulatory review of any future product candidates;

•our ability to establish and maintain any future 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 future collaboration agreements, if any;

•the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing any future 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 any future 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

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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**

The following table summarizes our commitments to settle contractual obligations at December 31, 2020:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | | | **Year Ended December 31 2020,** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | **Less than 1**  **Year** | | |  | | | **1 to 3**  **Years** | | |  | | | **3 to 5**  **Years** | | |  | | | **More than**  **5 Years** | | |  | | | **Total** | | |  | | |
|  | | | **(in thousands)** | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | |
| Operating leases (1) | | | $ | 760 |  |  | | | $ | 1,589 |  |  | | | $ | 302 |  |  | | | $ | — |  |  | | | $ | 2,651 |  |  | | |
| Long-term debt (2) | | | 239 | |  |  | | | 61 | |  |  | | | — | |  |  | | | — | |  |  | | | 300 | |  |  | | |
| Licensing arrangements (3) | | | 20 | |  |  | | | — | |  |  | | | — | |  |  | | | — | |  |  | | | 20 | |  | (4) | | |
| Total | | | $ | 1,019 |  |  | | | $ | 1,650 |  |  | | | $ | 302 |  |  | | | $ | — |  |  | | | $ | 2,971 |  | (4) | | |

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

(1)Reflects obligations pursuant to our office leases in Ann Arbor, Michigan.

(2)Reflects obligations pursuant to our advance agreement with Bpifrance Financing. In December 2017, in connection with our acquisition of Alizé, we assumed €0.7 million of debt that Alizé had outstanding with Bpifrance Financing. No interest is charged or accrued with respect to the debt. We are required to make quarterly principal payments between €17,500 to €50,000 per quarter through maturity. In addition to the quarterly payments, we could be obligated to pay, if applicable, no later than March 31 of each year starting from January 1, 2016, a reimbursement annuity equal to 20% of the proceeds generated by us from license, assignment or revenue-generating use of the livoletide program. We are permitted to repay the debt at any time.

(3)Reflects obligations pursuant to our license agreements with the University of Michigan, other than contingent obligations to make milestone and royalty payments where the amount, likelihood and timing of such payments are not fixed or determinable. Contingent payments pursuant to our license agreements with Erasmus University Medical Center and Roche are also excluded from the above table.

(4)We are obligated to pay the University of Michigan minimum royalties of $20,000 per year from 2020 to 2023 and $0.2 million per year beginning in 2024 through expiration of the term of the license agreement. All such amounts due after December 31, 2023 are excluded from the table above because the duration of the license agreement is not determinable. On March 5, 2021, we notified the University of Michigan of our decision to terminate the UM License Agreement, which termination shall be effective as of April 30, 2021, as agreed with the University of Michigan. As a result, we expect our expenditures under this agreement to decrease in the year ending December 31, 2021.

The commitment amounts in the table above are associated with contracts that are enforceable and legally binding and that specify all significant terms, including fixed or minimum services to be used, fixed, minimum or variable price provisions, and the approximate timing of the actions under the contracts. The table does not include obligations under agreements that we can cancel without a significant penalty.

**Off-Balance Sheet Arrangements**

We do not have any relationships with unconsolidated entities or financial partnerships, including entities sometimes referred to as structured finance or special purpose entities that were established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. We do not engage in off-balance sheet financing arrangements. In addition, we do not engage in trading activities involving non-exchange traded contracts. We therefore believe that we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

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**Critical Accounting Policies**

Our Consolidated Financial Statements are prepared in accordance with U.S. GAAP. The preparation of our Consolidated Financial Statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the Consolidated Financial Statements and the reported amounts of expenses during the reported period. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions and conditions.

***Research and development expenses***

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.

At the end of each reporting period, we compare payments made to third-party service providers to the estimated progress toward completion of the applicable research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the progress that we estimate has been made as a result of the service provided, we may record net prepaid or accrued expense relating to these costs. As of December 31, 2020, we had not made any material adjustments to our prior estimates of accrued research and development expenses.

***Stock-based compensation***

We measure expense for all stock options based on the estimated fair market value of the award on the grant date. We use the Black-Scholes option pricing model to value our stock option awards. We recognize compensation expense on a straight-line basis over the requisite service period, which is generally the vesting period of the award. We have issued awards where vesting is subject to a performance condition and the recognition is based on the derived service period. Expense for awards with performance conditions would be estimated and adjusted on a quarterly basis based upon our assessment of the probability that the performance condition will be met. We have not issued awards where vesting is subject to a market condition. The fair market value of our common stock is determined based on the closing price of our common stock on the Nasdaq Capital Market.

**Recent Accounting Pronouncements**

See Note 2 to our Consolidated Financial Statements for a description of recent accounting pronouncements applicable to its Consolidated Financial Statements.

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Not required for smaller reporting companies.

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**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

**MILLENDO THERAPEUTICS, INC.**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

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| [Consolidated Balance Sheets](#i1e5d551bc54544d38669f82744b9ba4b_82) | | | [55](#i1e5d551bc54544d38669f82744b9ba4b_82) | | |
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**Report of Independent Registered Public Accounting Firm**

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

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Millendo Therapeutics, Inc. (the Company) as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, stockholders’ equity (deficit) and cash flows for each of the two years in the period ended December 31, 2020, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

**Basis for Opinion**

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

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

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

**Critical Audit Matter**

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

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|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |
|  | | | ***Accrued preclinical and clinical costs*** | | |
| *Description of the Matter* | | | As described in Note 2 to the consolidated financial statements under the caption “Research and development expenses”, and within Note 6, the Company records the cost of research and development activities as they are incurred. These include, among others, costs of funding research performed by third parties, amounts due under agreements with contract manufacturing organizations and outsourced professional scientific development services. The amounts recorded include an estimate of progress toward the completion of the applicable research or development objectives. The Company compares payments made to third-party service providers to the estimated progress toward completion of the applicable research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the progress that the Company estimates has been made as a result of the service provided, the Company may record net prepaid or accrued expense relating to these costs. As of December 31, 2020, the Company’s accrual for preclinical and clinical costs was $1 million. | | |
|  | | |
| Auditing the Company’s accrual for preclinical and clinical costs was challenging because information necessary to estimate the accruals was accumulated from multiple sources. In addition, in certain circumstances, the determination of the nature and level of services that have been received during the reporting period requires judgment because the timing and pattern of vendor invoicing did not correspond to the level of services provided and invoicing from clinical study sites and other vendors may not yet be available to management. | | |
|  | | |  | | |
| *How We Addressed the Matter in Our Audit* | | | To test the accrued preclinical and clinical costs, our audit procedures included, among others, testing the completeness and accuracy of the underlying data used in the estimate, including, but not limited to, estimated project duration, research and manufacturing services incurred to date and terms of contractual arrangements. To assess the reasonableness of the data, we corroborated the progress of the clinical trials with Company research and development personnel and obtained third-party evidence supporting the activities performed to date. We recalculated the accrual based on executed contracts with the clinical research organizations, contract manufacturing organizations and clinical study sites. We also tested subsequent invoicing received from third parties and any pending change orders to assess the impact to the accrual through the balance sheet date and compared that to the Company’s estimates. | | |

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2016.

Grand Rapids, Michigan

March 29, 2021

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**Millendo Therapeutics, Inc.**

**Consolidated Balance Sheets**

**(in thousands except share and per share amounts)**

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  | | | **December 31,** | | | | | | | | |
|  | | | **2020** | | |  | | | **2019** | | |
| **Assets** | | |  | | |  | | |  | | |
| Current assets: | | |  | | |  | | |  | | |
| Cash and cash equivalents | | | $ | 38,174 |  |  | | | $ | 62,478 |  |
| Short-term restricted cash | | | 484 | |  |  | | | 1,034 | |  |
|  | | |  | | |  | | |  | | |
| Prepaid expenses and other current assets | | | 1,929 | |  |  | | | 6,344 | |  |
| Refundable tax credit | | | 314 | |  |  | | | 1,276 | |  |
| Total current assets | | | 40,901 | |  |  | | | 71,132 | |  |
|  | | |  | | |  | | |  | | |
| Operating lease right-of-use assets | | | 2,157 | |  |  | | | 3,331 | |  |
| Other assets | | | 351 | |  |  | | | 507 | |  |
| Total assets | | | $ | 43,409 |  |  | | | $ | 74,970 |  |
| **Liabilities and stockholders’ equity** | | |  | | |  | | |  | | |
| Current liabilities: | | |  | | |  | | |  | | |
| Current portion of debt | | | $ | 239 |  |  | | | $ | 208 |  |
| Accounts payable | | | 1,486 | |  |  | | | 1,495 | |  |
| Accrued expenses | | | 5,525 | |  |  | | | 9,066 | |  |
| Operating lease liabilities - current | | | 737 | |  |  | | | 1,751 | |  |
| Total current liabilities | | | 7,987 | |  |  | | | 12,520 | |  |
| Debt, net of current portion | | | 61 | |  |  | | | 168 | |  |
| Operating lease liabilities | | | 1,635 | |  |  | | | 2,395 | |  |
|  | | |  | | |  | | |  | | |
| Other liabilities | | | — | |  |  | | | 16 | |  |
| Total liabilities | | | 9,683 | |  |  | | | 15,099 | |  |
| Commitments and contingencies (Note 7) | | |  | | |  | | |  | | |
| 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; 18,999,701 shares and 18,266,545 shares issued and outstanding at December 31, 2020 and 2019, respectively | | | 19 | |  |  | | | 18 | |  |
| Additional paid-in capital | | | 277,647 | |  |  | | | 267,018 | |  |
| Accumulated deficit | | | (245,060) | |  |  | | | (208,654) | |  |
| Accumulated other comprehensive income | | | 452 | |  |  | | | 165 | |  |
| Total stockholders’ equity attributable to Millendo Therapeutics, Inc. | | | 33,058 | |  |  | | | 58,547 | |  |
| Equity attributable to noncontrolling interests | | | 668 | |  |  | | | 1,324 | |  |
| Total stockholders’ equity | | | 33,726 | |  |  | | | 59,871 | |  |
| Total liabilities and stockholders’ equity | | | $ | 43,409 |  |  | | | $ | 74,970 |  |

See accompanying Notes to Consolidated Financial Statements

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**Millendo Therapeutics, Inc.**

**Consolidated Statements of Operations and Comprehensive Loss**

**(in thousands except share and per share amounts)**

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  | | | **Year Ended December 31,** | | | | | | | | |
|  | | | **2020** | | |  | | | **2019** | | |
| Operating expenses: | | |  | | |  | | |  | | |
| Research and development | | | $ | 20,374 |  |  | | | $ | 27,843 |  |
| General and administrative | | | 15,598 | |  |  | | | 17,556 | |  |
|  | | |  | | |  | | |  | | |
| Loss from operations | | | 35,972 | |  |  | | | 45,399 | |  |
| Other expenses: | | |  | | |  | | |  | | |
| Interest income, net | | | (155) | |  |  | | | (1,038) | |  |
|  | | |  | | |  | | |  | | |
| Other loss | | | 589 | |  |  | | | 207 | |  |
| Net loss | | | (36,406) | |  |  | | | (44,568) | |  |
|  | | |  | | |  | | |  | | |
|  | | |  | | |  | | |  | | |
| Net loss per share of common stock, basic and diluted | | | $ | (1.93) |  |  | | | $ | (3.25) |  |
| Weighted-average shares of common stock outstanding, basic and diluted | | | 18,862,537 | |  |  | | | 13,706,744 | |  |
| Other comprehensive income (loss): | | |  | | |  | | |  | | |
| Foreign currency translation adjustment | | | $ | 287 |  |  | | | $ | 17 |  |
| Comprehensive loss | | | $ | (36,119) |  |  | | | $ | (44,551) |  |

See accompanying Notes to Consolidated Financial Statements

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**Millendo Therapeutics, Inc.**

**Consolidated Statements of Stockholders’ Equity (Deficit)**

**(in thousands except share amounts)**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | | |  | | |  | | |  | | |  | | |  | | |  | | |  | | |  | | |  | | |  | | |  | | |  | | |  | | |  | | |  | | |
|  | | | **Common Stock** | | | | | | | | |  | | | **Additional Paid-in Capital** | | |  | | | **Accumulated Deficit** | | |  | | | **Accumulated Other Comprehensive Income** | | |  | | | **Total Stockholders’ (Deficit) attributable to Millendo Therapeutics, Inc.** | | |  | | | **Total Equity Attributable to Noncontrolling Interests** | | |  | | | **Total Stockholders’ (Deficit) Equity** | | |
|  | | | **Shares** | | |  | | | **Amount** | | |  | | |  | | |  | | |  | | |  | | |  | | |
| Balance at January 1, 2019 | | | 13,357,999 | |  |  | | | $ | 13 |  |  | | | $ | 234,876 |  |  | | | $ | (164,086) |  |  | | | $ | 148 |  |  | | | $ | 70,951 |  |  | | | $ | 2,171 |  |  | | | $ | 73,122 |  |
| Exercise of stock options | | | 97,225 | |  |  | | | — | |  |  | | | 361 | |  |  | | | — | |  |  | | | — | |  |  | | | 361 | |  |  | | | — | |  |  | | | 361 | |  |
| Issuance of common stock to board of directors | | | 1,941 | |  |  | | | — | |  |  | | | 20 | |  |  | | | — | |  |  | | | — | |  |  | | | 20 | |  |  | | | — | |  |  | | | 20 | |  |
| Issuance of common stock, net of issuance costs | | | 4,791,667 | |  |  | | | 5 | |  |  | | | 26,486 | |  |  | | | — | |  |  | | | — | |  |  | | | 26,491 | |  |  | | | — | |  |  | | | 26,491 | |  |
| Exercise/forfeiture of BSPCE warrants | | | 17,713 | |  |  | | | — | |  |  | | | 958 | |  |  | | | — | |  |  | | | — | |  |  | | | 958 | |  |  | | | (847) | |  |  | | | 111 | |  |
| Stock-based compensation expense | | | — | |  |  | | | — | |  |  | | | 4,317 | |  |  | | | — | |  |  | | | — | |  |  | | | 4,317 | |  |  | | | — | |  |  | | | 4,317 | |  |
| Foreign currency translation adjustment | | | — | |  |  | | | — | |  |  | | | — | |  |  | | | — | |  |  | | | 17 | |  |  | | | 17 | |  |  | | | — | |  |  | | | 17 | |  |
| Net income (loss) | | | — | |  |  | | | — | |  |  | | | — | |  |  | | | (44,568) | |  |  | | | — | |  |  | | | (44,568) | |  |  | | | — | |  |  | | | (44,568) | |  |
| Balance at December 31, 2019 | | | 18,266,545 | |  |  | | | $ | 18 |  |  | | | $ | 267,018 |  |  | | | $ | (208,654) |  |  | | | $ | 165 |  |  | | | $ | 58,547 |  |  | | | $ | 1,324 |  |  | | | $ | 59,871 |  |
| Exercise of stock options | | | 1,449 | |  |  | | | — | |  |  | | | 2 | |  |  | | | — | |  |  | | | — | |  |  | | | 2 | |  |  | | | — | |  |  | | | 2 | |  |
| Issuance of common stock, net of issuance costs | | | 719,400 | |  |  | | | 1 | |  |  | | | 5,649 | |  |  | | | — | |  |  | | | — | |  |  | | | 5,650 | |  |  | | | — | |  |  | | | 5,650 | |  |
| Exercise/forfeiture of BSPCE warrants | | | 12,307 | |  |  | | | — | |  |  | | | 734 | |  |  | | | — | |  |  | | | — | |  |  | | | 734 | |  |  | | | (656) | |  |  | | | 78 | |  |
| Stock-based compensation expense | | | — | |  |  | | | — | |  |  | | | 4,244 | |  |  | | | — | |  |  | | | — | |  |  | | | 4,244 | |  |  | | | — | |  |  | | | 4,244 | |  |
| Foreign currency translation adjustment | | | — | |  |  | | | — | |  |  | | | — | |  |  | | | — | |  |  | | | 287 | |  |  | | | 287 | |  |  | | | — | |  |  | | | 287 | |  |
| Net income (loss) | | | — | |  |  | | | — | |  |  | | | — | |  |  | | | (36,406) | |  |  | | | — | |  |  | | | (36,406) | |  |  | | | — | |  |  | | | (36,406) | |  |
| Balance at December 31, 2020 | | | 18,999,701 | |  |  | | | $ | 19 |  |  | | | $ | 277,647 |  |  | | | $ | (245,060) |  |  | | | $ | 452 |  |  | | | $ | 33,058 |  |  | | | $ | 668 |  |  | | | $ | 33,726 |  |

See accompanying Notes to Consolidated Financial Statements

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**Millendo Therapeutics, Inc.**

**Consolidated Statements of Cash Flows**

**(in thousands)**

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  | | | **Year Ended December 31,** | | | | | | | | |
|  | | | **2020** | | |  | | | **2019** | | |
| **Operating activities:** | | |  | | |  | | |  | | |
| Net loss | | | $ | (36,406) |  |  | | | $ | (44,568) |  |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |  | | |  | | |  | | |
| Depreciation | | | 152 | |  |  | | | 97 | |  |
|  | | |  | | |  | | |  | | |
| Stock-based compensation expense | | | 4,244 | |  |  | | | 4,317 | |  |
| Foreign currency remeasurement loss | | | 321 | |  |  | | | — | |  |
|  | | |  | | |  | | |  | | |
|  | | |  | | |  | | |  | | |
| Amortization of right-of-use asset | | | 952 | |  |  | | | 955 | |  |
|  | | |  | | |  | | |  | | |
|  | | |  | | |  | | |  | | |
| Other non-cash items | | | 6 | |  |  | | | 30 | |  |
| Changes in operating assets and liabilities: | | |  | | |  | | |  | | |
| Prepaid expenses and other current assets | | | 5,361 | |  |  | | | (698) | |  |
| Other assets | | | 21 | |  |  | | | 66 | |  |
| Accounts payable | | | 25 | |  |  | | | (469) | |  |
| Accrued expenses and other liabilities | | | (3,559) | |  |  | | | 281 | |  |
| Operating lease liabilities | | | (1,552) | |  |  | | | (1,233) | |  |
| Cash used in operating activities | | | (30,435) | |  |  | | | (41,222) | |  |
| **Investing activities:** | | |  | | |  | | |  | | |
| Purchase of property and equipment | | | (26) | |  |  | | | (397) | |  |
| Proceeds from sale of marketable securities | | | — | |  |  | | | 4,385 | |  |
|  | | |  | | |  | | |  | | |
| Cash (used in) provided by investing activities | | | (26) | |  |  | | | 3,988 | |  |
| **Financing activities:** | | |  | | |  | | |  | | |
|  | | |  | | |  | | |  | | |
|  | | |  | | |  | | |  | | |
|  | | |  | | |  | | |  | | |
| Repayment of debt | | | (108) | |  |  | | | (184) | |  |
| Proceeds from the issuance of common stock, net of issuance costs | | | 5,453 | |  |  | | | 26,688 | |  |
| Proceeds from sale of private placement, net of issuance costs | | | — | |  |  | | | (15) | |  |
|  | | |  | | |  | | |  | | |
|  | | |  | | |  | | |  | | |
| Repayment of principal on finance lease | | | (37) | |  |  | | | (18) | |  |
| Proceeds from option and BSPCE warrant exercises | | | 78 | |  |  | | | 472 | |  |
| Cash provided by financing activities | | | 5,386 | |  |  | | | 26,943 | |  |
| Effect of foreign currency exchange rate changes on cash | | | 221 | |  |  | | | 33 | |  |
| Net decrease in cash, cash equivalents and restricted cash | | | (24,854) | |  |  | | | (10,258) | |  |
| Cash, cash equivalents and restricted cash at beginning of period | | | 63,512 | |  |  | | | 73,770 | |  |
| Cash, cash equivalents and restricted cash at end of period | | | $ | 38,658 |  |  | | | $ | 63,512 |  |
|  | | |  | | |  | | |  | | |
|  | | |  | | |  | | |  | | |
|  | | |  | | |  | | |  | | |
| **Supplemental schedule of non-cash investing and financing activities:** | | |  | | |  | | |  | | |
|  | | |  | | |  | | |  | | |
|  | | |  | | |  | | |  | | |
|  | | |  | | |  | | |  | | |
|  | | |  | | |  | | |  | | |
|  | | |  | | |  | | |  | | |
|  | | |  | | |  | | |  | | |
| Financing costs in accounts payable and accrued expenses | | | $ | — |  |  | | | $ | 197 |  |
| Right-of-use assets acquired under operating leases | | | $ | — |  |  | | | $ | 3,414 |  |

See accompanying Notes to Consolidated Financial Statements

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**Millendo Therapeutics, Inc.**

**Notes to 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 the second quarter, which resulted in the Company recording $3.1 million in the second quarter of 2020. The Company recorded additional expense in the second half of 2020 related to the livoletide program, which reflects changes to estimated closeout costs. 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 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 the second quarter of 2020. The Company recorded additional expense in the second half of 2020 related to the nevanimibe program, which reflects changes to estimated close out costs. The Company does not expect to incur future material expenses related to its nevanimibe program for the treatment of CAH as it is no longer developing this program

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.

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%, with the majority of the reduction in personnel expected to be completed by April 15, 2021. The Company initiated this reduction in force in January 2021 and expects to 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, substantially all of which 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”). If the Merger is completed, the business of Tempest will continue as the business of the combined company (see Note 12).

The Company had also been investigating nevanimibe (ATR-101) as a potential treatment for patients with endogenous Cushing's syndrome (“CS”), a rare endocrine disease characterized by excessive cortisol production from the adrenal glands. As a result of slower than anticipated enrollment in its CS Phase 2 clinical trial, the Company elected to discontinue this trial in

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August 2019, suspend development of nevanimibe for the treatment of CS, and focus its resources on other programs in its research and development pipeline.

***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 December 31, 2020, the Company had cash, cash equivalents and restricted cash of $38.7 million and an accumulated deficit of $245.1 million.

In December 2019, the Company sold a total of 4,791,667 shares of its common stock pursuant to an underwriting agreement (the “Underwriting Agreement”) with Citigroup Global Markets Inc. and SVB Leerink LLC, as representatives of the several underwriters named therein (the “Underwriters”), for total net proceeds of approximately $26.5 million, after deducting underwriting discounts and commissions and other offering expenses payable by the Company. The price to the public in this offering was $6.00 per share and resulted in the sale of 4,166,667 shares of the Company's common stock for net proceeds of approximately $23.0 million, after deducting underwriting discounts and commissions and other offering expenses payable by the Company. In addition, the Underwriters purchased an additional 625,000 shares of the Company's common stock at the public offering price of $6.00 per share pursuant to a purchase option granted to them under the Underwriting Agreement, resulting in net proceeds of approximately $3.5 million, after deducting underwriting discounts and commissions.

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 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 our 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) pursue another strategic transaction or (iii) may resume research and development activities.

The Company believes its cash, cash equivalents and restricted cash at December 31, 2020 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 Consolidated Financial Statements include the accounts of Millendo Therapeutics, Inc. and its subsidiaries, and all intercompany amounts have been eliminated. The 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 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.

***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. Actual results could differ from those estimates. 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.

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***Significant Risks and Uncertainties***

With the global spread of the ongoing COVID-19 pandemic in 2020, the Company has implemented 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 clinical and preclinical development activities. The extent to which the COVID-19 pandemic impacts the Company’s business, its preclinical and clinical development and regulatory efforts, its corporate development objectives 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.

In addition, the Company is subject to other challenges and risks specific to its business and its ability to execute on its strategy, as well as risks and uncertainties common to companies in the pharmaceutical industry with development operations, including, without limitation, risks and uncertainties associated with: obtaining regulatory approval of its product candidates, loss of single source suppliers or failure to comply with manufacturing regulations, identifying, acquiring or in-licensing additional products or product candidates; pharmaceutical product development and the inherent uncertainty of clinical success; and the challenges of protecting and enhancing its intellectual property rights; complying with applicable regulatory requirements. In addition, to the extent the ongoing COVID-19 pandemic adversely affects its business and results of operations, the Company may also have the effect of heightening many of the other risks and uncertainties discussed above.

***Concentration of credit risk***

Financial instruments that potentially subject the Company to concentrations of credit risk are primarily cash, cash equivalents and restricted cash. The Company generally invests its cash in deposits with high credit quality financial institutions. Deposits at banks may exceed the insurance provided on such deposits. Additionally, the Company performs periodic evaluations of the relative credit standing of these financial institutions.

***Cash and cash equivalents***

The Company considers all highly liquid investments that have maturities of three months or less when acquired to be cash equivalents. Cash equivalents as of December 31, 2020 and 2019 consisted of money market funds.

***Restricted cash***

Restricted cash relates to amounts used to secure the Company’s credit card facility balances held on deposit with major financial institutions, to collateralize a letter of credit in the name of the Company’s landlord pursuant to a certain operating lease agreement, and to fund an escrow arrangement in connection with a sublease agreement also pursuant to that same operating lease agreement. The escrow agreement ended in connection with the expiration of the Company's Waltham, Massachusetts lease agreement in November 2020 (see Note 7). The following table provides a reconciliation of the components of cash, cash equivalents, and restricted cash reported in the Company's consolidated balance sheets to the total of the amount presented in the Consolidated Statements of Cash Flows:

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  | | | **December 31,** | | | | | | | | |
|  | | | **2020** | | |  | | | **2019** | | |
|  | | | **(in thousands)** | | | | | | | | |
| Cash and cash equivalents | | | $ | 38,174 |  |  | | | $ | 62,478 |  |
| Restricted cash | | | 484 | |  |  | | | 1,034 | |  |
|  | | |  | | |  | | |  | | |
| Total cash, cash equivalents, and restricted cash shown in the Consolidated Statements of Cash Flows | | | $ | 38,658 |  |  | | | $ | 63,512 |  |

***Refundable tax credit***

The Company earns French research tax credits (crédit d’impôt recherche) or (“CIR”) in connection with its research efforts through its wholly owned subsidiary in Lyon, France. CIR earned are refundable or they can offset French corporate income tax due. Since the French research tax credit can be recovered in cash, the Company has elected to treat this as a grant. During the year ended December 31, 2020 and 2019, the Company recognized a reduction of research and development expenses of $0.5 million and $1.2 million, respectively, and had a research tax credit receivable of $0.3 million and $1.3 million at December 31, 2020 and 2019, respectively.

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***Leases***

The Company determines if an arrangement is a lease at contract inception. A lease exists when a contract conveys to the customer the right to control the use of identified property, plant, or equipment for a period of time in exchange for consideration. The definition of a lease embodies two conditions: (1) there is an identified asset in the contract that is land or a depreciable asset (i.e., property, plant, and equipment), and (2) the customer has the right to control the use of the identified asset.

The lease liabilities are initially and subsequently measured at the present value of the unpaid lease payments at the lease commencement date. When readily determinable, the Company uses the implicit rate in determining the present value of lease payments. When leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the lease commencement date, including the lease term.

The ROU asset is initially measured at cost, which comprises the initial amount of the lease liability adjusted for lease payments made at or before the lease commencement date, plus any initial direct costs incurred less any lease incentives received. For operating leases, the ROU asset is subsequently measured throughout the lease term at the carrying amount of the lease liability, plus initial direct costs, plus (minus) any prepaid (accrued) lease payments, less the unamortized balance of lease incentives received. Lease expense for lease payments is recognized on a straight-line basis over the lease term. Refer to Note 7 for further details.

***Fair value of financial instruments***

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

•Level 1—Quoted prices in active markets for identical assets or liabilities.

•Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

•Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The asset’s or liability’s fair value measurement level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The carrying value of the Company’s debt approximates fair value as of December 31, 2020 and 2019.

***Other assets***

Other assets includes property and equipment and other assets. Property and equipment, less accumulated depreciation, are recorded at cost and are depreciated on a straight-line basis over their estimated useful lives which range from three to five years except for leasehold improvements which are amortized over the shorter of the asset life or lease term. Repairs and maintenance costs are expensed as incurred. Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The Company has not recognized any impairment of long-lived assets through December 31, 2020.

***Research and development expenses***

Research and development costs are expensed as incurred and consist primarily of personnel expenses, costs of funding research performed by third-parties, expenses incurred under agreements with contract manufacturing organizations, payments under third-party licensing agreements, consultant fees and expenses associated with outsourced professional scientific development services, expenses related to regulatory activities and allocated expense for facility costs. Milestone payment obligations incurred prior to regulatory approval of the product, which are accrued when the event requiring payment of the

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milestone occurs, are included in research and development expenses. Upfront milestone payments made to third-parties who perform research and development services on the Company’s behalf are expensed as services are rendered.

At the end of each reporting period, the Company compares payments made to third-party service providers to the estimated progress toward completion of the applicable research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the progress that the Company estimates has been made as a result of the service provided, the Company may record net prepaid or accrued expense relating to these costs. As of December 31, 2020 and 2019, the Company has not made any material adjustments to its prior estimates of accrued research and development expenses.

***Stock-based compensation***

The Company measures and recognizes compensation expense for all stock options awarded to employees and nonemployees based on the estimated fair market value of the award on the grant date. The Company uses the Black-Scholes option pricing model to value its stock option awards. The Company recognizes compensation expense on a straight-line basis over the requisite service period, which is generally the vesting period of the award. The Company accounts for forfeitures of stock options as they occur.

Estimating the fair market value of options requires the input of subjective assumptions, including the estimated fair value of the Company’s common stock, the expected life of the options, stock price volatility, the risk-free interest rate and expected dividends. The assumptions used in the Company’s Black-Scholes option-pricing model represent management’s best estimates and involve a number of variables, uncertainties and assumptions and the application of management’s judgment, as they are inherently subjective.

***Income taxes***

The Company recognizes deferred tax assets and liabilities for temporary differences between the financial reporting basis and the tax basis of the Company’s assets and liabilities and the expected benefits of net operating loss carryforwards. The impact of changes in tax rates and laws on deferred taxes, if any, applied during the period in which temporary differences are expected to be settled, is reflected in the Company’s financial statements in the period of enactment. The measurement of deferred tax assets is reduced, if necessary, if, based on weight of the evidence, it is more likely than not that some, or all, of the deferred tax assets will not be realized. As of December 31, 2020 and 2019, the Company has concluded that a full valuation allowance is necessary for all of its net deferred tax assets. The Company had no material amounts recorded for uncertain tax positions, interest or penalties in the accompanying Consolidated Financial Statements.

***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):

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  | | | **Year ended December 31,** | | | | | | | | |
|  | | | **2020** | | |  | | | **2019** | | |
| Stock options | | | 3,749,102 | |  |  | | | 2,498,606 | |  |
|  | | |  | | |  | | |  | | |
| Common stock warrants | | | 17,125 | |  |  | | | 17,125 | |  |
|  | | |  | | |  | | |  | | |
| BSA and BSPCE warrants | | | 48,265 | |  |  | | | 95,567 | |  |
|  | | | 3,814,492 | |  |  | | | 2,611,298 | |  |

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***Segment information***

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one segment.

***Foreign currency***

Results of foreign operations are translated from their functional currency into U.S. dollars (reporting currency) using average exchange rates in effect during the year, while assets and liabilities are translated into U.S. dollars using exchange rates in effect at the balance sheet date. The resulting translation adjustments are recorded in accumulated other comprehensive loss. Transaction gains and losses resulting from exchange rate changes on transactions denominated in currencies other than the functional currency are included in income in the period in which the change occurs and reported within other expenses in the consolidated statements of operations and comprehensive loss.

***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. Early adoption is permitted. 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 intraperiod 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. Early adoption is permitted. 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. The 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 ASU 2018-13 did not have a material impact on the Company's 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.

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***Subsequent events***

Subsequent events were evaluated through the filing date of this Annual Report.

**3. Fair Value Measurements**

The following table presents the Company’s assets and liabilities that are measured at fair value on a recurring basis (amounts in thousands):

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | | | **December 31, 2020** | | | | | | | | | | | | | | |
|  | | | **(Level 1)** | | |  | | | **(Level 2)** | | |  | | | **(Level 3)** | | |
| Assets | | |  | | |  | | |  | | |  | | |  | | |
| Money market funds (included in cash and cash equivalents) | | | $ | 33,636 |  |  | | | $ | — |  |  | | | $ | — |  |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | | | **December 31, 2019** | | | | | | | | | | | | | | |
|  | | | **(Level 1)** | | |  | | | **(Level 2)** | | |  | | | **(Level 3)** | | |
| Assets | | |  | | |  | | |  | | |  | | |  | | |
| Money market funds (included in cash and cash equivalents) | | | $ | 59,382 |  |  | | | $ | — |  |  | | | $ | — |  |
|  | | |  | | |  | | |  | | |  | | |  | | |
|  | | |  | | |  | | |  | | |  | | |  | | |
|  | | |  | | |  | | |  | | |  | | |  | | |

**4. Accrued Expenses**

Accrued expenses consist of (amounts in thousands):

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  | | | **December 31,** | | | | | | | | |
|  | | | **2020** | | |  | | | **2019** | | |
| Compensation and related benefits | | | $ | 1,978 |  |  | | | $ | 2,042 |  |
| Professional fees | | | 719 | |  |  | | | 2,929 | |  |
| Preclinical and clinical costs | | | 1,002 | |  |  | | | 1,820 | |  |
|  | | |  | | |  | | |  | | |
| Insurance premiums | | | 1,476 | |  |  | | | 1,423 | |  |
| Other | | | 350 | |  |  | | | 852 | |  |
| Total | | | $ | 5,525 |  |  | | | $ | 9,066 |  |

**5. Debt**

***Bpifrance Reimbursable Advance***

In December 2017, in connection with its acquisition of Alizé, a privately held biotechnology company based in Lyon, France, 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.

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For the year ending December 31, 2020 the Company made $0.1 million in 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. During the third quarter the Company resumed normal principal payments under the Bpifrance Advance agreement. For the year ending December 31, 2019, the Company made principal payments of $0.2 million. At December 31, 2020, the balance outstanding was $0.3 million (€0.2 million).

**6. License Agreements**

***University of Michigan License Agreement***

In June 2013, the Company entered into a license agreement with the Regents of the University of Michigan (the “University of Michigan”) for a worldwide, exclusive, sublicensable license to the University of Michigan’s interest in certain patent rights jointly owned with the Company, covering the use of ATR-101 for the treatment of certain indications (the “UM License Agreement”). Due to the Company's decision to cease investing in the nevanimibe program, effective on March 5, 2021, the Company notified the University of Michigan of its decision to terminate the UM License Agreement, which termination shall be effective April 30, 2021, as agreed to by the University of Michigan.

The Company would have been obligated to make payments to the University of Michigan totaling up to $2.5 million upon the achievement of certain development and commercial milestones. No amounts were paid in 2018 or 2019 related to the achievement of development or commercial milestones. During the year ended December 31, 2019, $0.1 million was paid in order to extend the milestone achievement date of certain development milestones. The Company would have also been required to pay the University of Michigan a low-single digit royalty percentage on net sales of applicable products, if any.

In addition, $20,000 in annual minimum royalties would have been due under the UM License Agreement for each of 2021 through 2023. Further, beginning in 2024, the Company would have been required to pay an annual fee of $0.2 million which would have been creditable against royalties due, if any, until the expiration or termination of the UM License Agreement.

***Assignment agreement with Erasmus University Medical Center and the University of Turin***

In connection with its acquisition of Alizé, the Company assumed Alizé’s obligations under an assignment agreement with Erasmus University Medical Center, the University of Turin and certain individuals (collectively “the Assignors”), for certain patents and patent applications relating to livoletide. In March 2021, the Company notified the assignors that it had discontinued its PWS program.

In connection with the assignment, the Company agreed to pay the Assignors a flat, low single digit royalty on net commercial sales of products containing livoletide that are covered by the claims of the assigned intellectual property. Further, upon approval of livoletide by the FDA or EMA, the Company would have been required to pay the Assignors CDN $100,000, which amount would have been deducted from any future royalty payments due to the Assignors. The Company also agreed to pay the Assignors a low single digit percentage of any amounts received in connection with its license of the assigned intellectual property or products containing livoletide that are covered by the claims of the assigned intellectual property.

***License Agreement with Roche***

On October 16, 2018, the Company entered into a license agreement with F. Hoffmann-La Roche Ltd and Hoffman-La Roche Inc. (collectively, “Roche”), for a worldwide, exclusive license to Roche's interest in certain patent rights and know-how covering, among other things, the use of a neurokinin 3 receptor antagonist (the "Roche License Agreement"). Due to the Company's decision to discontinue developing the MLE-301 program, in March 2021, the Company notified Roche that it was terminating the Roche License Agreement effective three months from the date of such notice.

As consideration for the rights granted to the Company under the Roche License Agreement, the Company agreed to pay Roche an up-front payment. Under the terms of the Roche License Agreement, the Company would have also been obligated to make significant milestone and royalty payments in connection with the attainment of certain development steps and the sale of resulting products with respect to the neurokinin 3 receptor antagonist. In addition, the Company would have been required to share a portion of any net proceeds received in connection with certain agreements that it may enter into with third-parties to develop and commercialize the neurokinin 3 receptor antagonist.

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**7. Commitments and Contingencies**

***Operating leases***

The Company has noncancelable operating leases for office space which have remaining lease terms of approximately 3.5 years. In connection with the OvaScience Merger, the Company assumed 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 noncancelable 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 December 31, 2020, the operating lease ROU asset and the operating lease liabilities were $2.2 million and $2.4 million, respectively. The weighted average discount rate used to account for the Company's operating leases 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 year ended December 31, 2020. The weighted average remaining term of the Company's noncancelable operating leases is 3.38 years.

Rent expense related to the Company's operating leases was approximately $0.9 million and $0.7 million for the years ended December 31, 2020 and 2019, respectively. The Company recognizes rent expense on a straight-line basis over the lease period. Cash paid for amounts included in the measurement of the lease liabilities was approximately $1.8 million and $1.5 million during the years ended December 31, 2020 and 2019, respectively. The Company received approximately $0.3 million in sublease payments related to its Waltham, Massachusetts lease during each of the years ended December 31, 2020 and 2019. Future minimum rental payments under the Company’s noncancelable operating leases at December 31, 2020 is as follows (amounts in thousands):

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |
| Year Ending December 31, | | |  | | |
| 2021 | | | $ | 760 |  |
| 2022 | | | 783 | |  |
| 2023 | | | 806 | |  |
| 2024 | | | 302 | |  |
| 2025 | | | — | |  |
| Thereafter | | | — | |  |
| **Total** | | | $ | 2,651 |  |
| Present Value Adjustment | | | (279) | |  |
| **Lease liability at December 31, 2020** | | | $ | 2,372 |  |

***Employment benefit plan***

The Company maintains a defined contribution 401(k) plan in which employees may contribute up to 100% of their salary and bonus, subject to statutory maximum contribution amounts. The Company contributes a safe harbor minimum contribution equivalent to 3% of employees’ compensation. The Company generally assumes all administrative costs of the plan. For the years ended December 31, 2020 and 2019, the expense relating to the contributions made was $0.2 million and $0.2 million, respectively.

***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.

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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 OvaScience and one current director of the Company (a former director of OvaScience) and OvaScience 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 OvaScience’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 case remains stayed until at least April 30, 2021, when the parties are due to file a further 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 OvaScience and certain former officers of OvaScience 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. The Company believes that the amended complaint and the second amended complaint are without merit. On August 17, 2020, the court granted the parties’ joint motion to stay all proceedings in the case pending mediation. The parties agreed to participate in a second mediation session on November 10, 2020. 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. 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 OvaScience and one current director of the Company (a former director of OvaScience) 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 OvaScience’s January 2015 follow-on public offering and other public statements concerning OvaScience’s AUGMENT treatment. 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, 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 complaint is without merit and intends to defend against the litigation.

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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.

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.

**8. Common Stock and Convertible Preferred Stock**

***Common stock***

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company’s stockholders. Subject to preferences that may apply to any outstanding preferred stock, holders of common stock are entitled to receive ratably any dividends that the Company’s board of directors may declare out of funds legally available for that purpose on a non-cumulative basis. No dividends had been declared through December 31, 2020.

***Common stock warrants***

As of December 31, 2020, there were 17,125 common stock warrants outstanding with a weighted average exercise price of $16.93 per share.

**9. 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 “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 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, 2019 were added to the number of available shares effective January 1, 2020.

The term "Prior Plans' 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; or (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 (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

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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 1% of the total number of shares of the Company's common stock outstanding on December 31 of the preceding calendar year, (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, 2020.

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 years ended December 31, 2020 and 2019 (amounts in thousands):

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  | | | **Year Ended December 31,** | | | | | | | | |
|  | | | **2020** | | |  | | | **2019** | | |
| Research and development | | | $ | 977 |  |  | | | $ | 1,299 |  |
| General and administrative | | | 3,267 | |  |  | | | 3,018 | |  |
| Total | | | $ | 4,244 |  |  | | | $ | 4,317 |  |

***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 was 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.

The following table summarizes the activity related to stock option grants to employees and nonemployees for the years ended December 31, 2020 and 2019:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | | | **Shares** | | |  | | | **Weighted-average exercise price share** | | |  | | | **Weighted-average remaining contractual life (years)** | | |
| Outstanding at January 1, 2019 | | | 1,764,287 | |  |  | | | $ | 26.81 |  |  | | | 8.0 | | |
|  | | |  | | |  | | |  | | |  | | |  | | |
| Granted | | | 1,225,901 | |  |  | | | 9.73 | |  |  | | |  | | |
| Exercised | | | (97,225) | |  |  | | | 3.71 | |  |  | | |  | | |
| Forfeited | | | (394,357) | |  |  | | | 40.42 | |  |  | | |  | | |
| Outstanding at December 31, 2019 | | | 2,498,606 | |  |  | | | 17.18 | |  |  | | | 7.7 | | |
| Granted | | | 1,864,375 | |  |  | | | 4.71 | |  |  | | |  | | |
| Exercised | | | (1,449) | |  |  | | | 1.08 | |  |  | | |  | | |
| Forfeited | | | (612,430) | |  |  | | | 13.39 | |  |  | | |  | | |
| Outstanding at December 31, 2020 | | | 3,749,102 | |  |  | | | $ | 11.60 |  |  | | | 7.9 | | |
| Vested and exercisable at December 31, 2020 | | | 1,819,399 | |  |  | | | $ | 16.34 |  |  | | | 6.8 | | |
| Vested and expected to vest at December 31, 2020 | | | 3,749,102 | |  |  | | | $ | 11.60 |  |  | | | 7.9 | | |

As of December 31, 2020, the unrecognized compensation cost related to 1,929,703 unvested stock options expected to vest was $8.1 million. This unrecognized compensation will be recognized over an estimated weighted-average amortization period of 2.3 years. The aggregate intrinsic value of options exercised during the year ended December 31, 2020 was $1,000. The aggregate intrinsic value of options exercised during the year ended December 31, 2019 was $0.7 million. The aggregate intrinsic value of options outstanding and options exercisable as of December 31, 2020 was $0.2 million and $0.1 million,

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respectively. The options granted during the years ended December 31, 2020 and 2019, had an estimated weighted average grant date fair value of $3.13 and $6.74, respectively.

The fair value of options is estimated using the Black-Scholes option pricing model, which takes into account inputs such as the exercise price, the value of the underlying common stock at the grant date, expected term, expected volatility, risk-free interest rate and dividend yield. The fair value of each grant of options during the years ended December 31, 2020 and 2019 was determined using the methods and assumptions discussed below.

•The expected term of employee options with service-based vesting is determined using the “simplified” method, as prescribed in SEC’s Staff Accounting Bulletin (“SAB”) No. 107, whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option due to the Company’s lack of sufficient historical data. The expected term of nonemployee options is equal to the contractual term.

•The expected volatility is based on historical volatilities of similar entities within the Company’s industry which were commensurate with the expected term assumption as described in SAB No. 107.

•The risk-free interest rate is based on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected term.

•The expected dividend yield is 0% because the Company has not historically paid, and does not expect for the foreseeable future to pay, a dividend on its common stock.

•Prior to the OvaScience Merger, the Company’s common stock was not publicly traded. The Company’s board of directors periodically estimated the fair value of the Company’s common stock considering, among other things, contemporaneous valuations of its common stock prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants 2013 Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation.* Following the OvaScience Merger, the fair market value of the Company’s common stock is determined based on the closing price of its common stock on the Nasdaq Capital Market.

The grant date fair value of each option grant was estimated throughout the year using the Black-Scholes option-pricing model using the following assumptions for the Plan:

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  | | | **Year Ended, December 31,** | | |  | | | **Year Ended, December 31,** | | |
|  | | | **2020** | | |  | | | **2019** | | |
| Expected term (in years) | | | 5.74 | | |  | | | 6.02 | | |
| Expected volatility | | | 77 | | % |  | | | 80 | | % |
| Risk-free interest rate | | | 0.86 | | % |  | | | 2.22 | | % |
| Expected dividend yield | | | 0 | | % |  | | | 0 | | % |
| Fair market value of common stock | | | $ | 4.71 |  |  | | | $ | 9.73 |  |

At the time of the Alizé acquisition, Alizé had 6,219 non-employee (BSA) warrants and 5,360 employee (BSPCE) warrants outstanding, which have weighted-average exercise prices of €80.06 and €83.40, respectively. As of December 31, 2020, all BSAs and BSPCEs were vested. During the year ended December 31, 2020, 910 BSPCE warrants were exercised resulting in the issuance of 12,307 shares of the Company's common stock. In addition, during the year ended December 31, 2020, a total of 2,586 BSA and BSPCE warrants were forfeited. As of December 31, 2020, there were an aggregate of 48,265 shares of common stock issuable upon the exercise of the warrants with a weighted-average exercise price of $7.85 per share. These instruments are included in the equity attributable to noncontrolling interests.

**10. Income Taxes**

As of December 31, 2020, the Company had approximately $330.8 million and $280.9 million of federal and state net operating loss carryforwards, respectively, which begin to expire in 2031. As of December 31, 2020, the Company had approximately $5.3 million and $1.1 million of federal and state research and development tax credit carryforwards, respectively, that begin to expire in 2031 and 2029, respectively. As of December 31, 2020, the Company had approximately $7.4 million of federal orphan drug tax credit carryforwards that begin to expire in 2032. As of December 31, 2020, the Company had foreign net operating loss carryforwards of approximately $20.7 million which can be carried forward indefinitely.

Section 382 of the Internal Revenue Code of 1986, as amended (the “Code”) provides for limitation on the use of net operating loss and research and development tax credit carryforwards following certain ownership changes (as defined in Code) that

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could limit the Company's ability to utilize these carryforwards. Pursuant to Section 382 of the Code, an ownership change occurs when the stock ownership of a 5% stockholder increases by more than 50% over a three-year testing period. The Company may have experienced various ownership changes, as defined by the Code, as a result of past financing and may in the future experience an ownership change. Accordingly, the Company's ability to utilize the aforementioned carryforwards may be limited. Additionally, U.S. tax laws limit the time during which these carryforwards may be applied against future taxes.

The components of the net deferred income tax asset as of December 31, 2020 and 2019 are as follows (amounts in thousands):

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  | | | **December 31,** | | | | | | | | |
|  | | | **2020** | | |  | | | **2019** | | |
| Deferred taxes: | | |  | | |  | | |  | | |
| Net operating loss carryforwards | | | $ | 90,842 |  |  | | | $ | 96,378 |  |
| Research and development credit carryforwards | | | 13,603 | |  |  | | | 13,404 | |  |
|  | | |  | | |  | | |  | | |
| Stock-based compensation | | | 4,071 | |  |  | | | 4,107 | |  |
| Accruals | | | 352 | |  |  | | | 414 | |  |
| Right-of-use asset | | | (508) | |  |  | | | (742) | |  |
| Lease liability | | | 559 | |  |  | | | 934 | |  |
| Capitalized start-up costs | | | 775 | |  |  | | | 855 | |  |
| Other | | | 20 | |  |  | | | 10 | |  |
| Gross deferred tax asset | | | 109,714 | |  |  | | | 115,360 | |  |
| Less: valuation allowance | | | (109,714) | |  |  | | | (115,360) | |  |
| Net deferred tax asset | | | $ | — |  |  | | | $ | — |  |

In assessing the realizability of deferred tax assets, the Company considers whether it is more-likely-than-not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which the temporary differences representing net future deductible amounts become deductible. After consideration of all the evidence, both positive and negative, the Company has recorded a full valuation allowance against its net deferred tax assets as of December 31, 2020 because the Company has determined that is it more likely than not that these assets will not be fully realized due to historic net operating losses incurred. The valuation allowance decreased by $5.6 million during the year ended December 31, 2020, primarily due to the write-off of net operating loss carryforwards related to a wholly owned foreign subsidiary that filed for liquidation during the year ended December 31, 2020, offset by the generation of net operating losses and credit carryforwards during 2020. In addition to the deferred taxes listed in the above table, an income tax reduction of $83.4 million (tax-effected $19.5 million deferred tax asset with a full valuation allowance) resulting from the foreign subsidiary liquidation may be available as capital loss carryforwards, net operating loss carryforwards or a combination of both in the U.S., however, a detailed analysis of these losses is required to make this determination and has not yet been initiated.

On December 31, 2020 and 2019, the Company had no unrecognized tax benefits. The Company’s policy is to record interest and penalties related to income taxes as a component of income tax expense. As of December 31, 2020 and 2019, the Company had no accrued interest or penalties related to income taxes and no amounts have been recognized in the Company’s statement of operations.

A reconciliation of income tax expense (benefit) at the statutory federal income tax rate and income taxes as reflected in the financial statements is as follows:

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  | | | **December 31,** | | | | | | | | |
|  | | | **2020** | | |  | | | **2019** | | |
| Federal income tax benefit at statutory rate | | | 21.0 | | % |  | | | 21.0 | | % |
| State income tax, net of federal benefit | | | 2.2 | | % |  | | | 2.4 | | % |
| Permanent differences | | | (2.4) | | % |  | | | (1.0) | | % |
| Rate change | | | — | | % |  | | | (8.7) | | % |
| Research and development credit benefit | | | 1.7 | | % |  | | | 2.7 | | % |
| Change in valuation allowance | | | (22.5) | | % |  | | | (16.4) | | % |
| Effective income tax rate | | | — | | % |  | | | — | | % |

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The Company files income tax returns in the U.S. Federal, various state, and foreign jurisdictions. The statute of limitations for assessment by the Internal Revenue Service (IRS) and state tax authorities is open for the Company’s tax years from 2017 to present. Federal and state carryforward attributes that were generated prior to the tax year ended December 31, 2017 may still be adjusted upon examination by the IRS or state tax authorities if they either have been or will be used in a period for which the statute of limitations remains open. The statute of limitations for assessment by the authorities in the various foreign jurisdictions in which the Company files ranges from one to three years and is open for the Company’s tax years from 2017 to present. There are currently no federal, state or foreign income tax audits in progress.

**11. Related Party Transactions**

As discussed in Note 1, the Company sold shares of its common stock in December 2019. Roche invested in the Company's December 2019 financing. One of the Company's Board members is affiliated with Roche.

**12. Subsequent Events**

Following an extensive process of evaluating strategic alternatives and identifying and reviewing potential candidates for a strategic acquisition or other transaction, on March 29, 2021, the Company entered into a Merger Agreement with Tempest. If the Merger is completed, the business of Tempest will continue as the business of the combined organization.

At the closing of the Merger, (a) each then 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 in the Merger Agreement) 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) calculated in accordance with the Merger Agreement 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.

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.

**ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

**ITEM 9A. CONTROLS AND PROCEDURES**

*Disclosure Controls and Procedures*

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to the company’s management, including its chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our management, with the participation of our chief executive officer and our chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2020. Based on the evaluation of our disclosure controls and procedures as of December 31, 2020, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

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*Management’s Report on Internal Control over Financial Reporting*

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. Our management, under the supervision and with the participation of our chief executive officer and our chief financial officer, conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2020 based on the framework in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on the results of its evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2020.

Under SEC rules, because we are a non-accelerated filer, we are not required to provide an auditor attestation report on internal control over financial reporting, nor did we engage our independent registered public account firm to perform an audit of our internal control over financial reporting.

*Changes in Internal Control over Financial Reporting*

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the quarter ended December 31, 2020 which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

*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.

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**ITEM 9B. OTHER INFORMATION**

Not applicable.

**PART III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

The information required by this item is incorporated by reference to our Proxy Statement for our 2021 Annual Meeting of Shareholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2020.

As part of our system of corporate governance, our board of directors has adopted a code of business and ethics. The code applies to all of our employees, officers (including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions), agents and representatives, including our independent directors and consultants, who are not employees of ours, with regard to their Company-related activities. Our code of business conduct and ethics is available on our website at www.millendo.com. We intend to post on this section of our website any amendment to our code of business conduct and ethics, as well as any waivers of our code of business conduct and ethics, that are required to be disclosed by the rules of the SEC or the Nasdaq Stock Market.

**ITEM 11. EXECUTIVE COMPENSATION**

The information required by this item is incorporated by reference to our Proxy Statement for our 2021 Annual Meeting of Shareholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2020.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The information required by this item is incorporated by reference to our Proxy Statement for our 2021 Annual Meeting of Shareholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2020.

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

The information required by this item is incorporated by reference to our Proxy Statement for our 2021 Annual Meeting of Shareholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2020.

**ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

The information required by this item is incorporated by reference to our Proxy Statement for our 2021 Annual Meeting of Shareholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2020.

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**PART IV**

**ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

We have filed the following documents as part of this Annual Report:

**(a)(1)     Financial Statements**

The financial statements are included in Item 8. “Financial Statements and Supplementary Data.”

**(a)(2)     Financial Statement Schedules**

All schedules are omitted as information required is inapplicable or the information is presented in the financial statements and the related notes.

**(a)(3)     Exhibits**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **Exhibit**  **Number** | | |  | | | **Description of Exhibit** | | |  | | |
|  | | |  | | |  | | |  | | |
| 2.1 | | |  | | | [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)](https://www.sec.gov/Archives/edgar/data/1544227/000110465921042769/tm2111026d1_ex2-1.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 3.1 | | |  | | | [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)](http://www.sec.gov/Archives/edgar/data/1544227/000155837019005038/mlnd-20190331ex31b53fa83.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 3.2 | | |  | | | [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)](http://www.sec.gov/Archives/edgar/data/1544227/000110465918050995/a18-18482_1ex3d1.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 4.1 | | |  | | | [Specimen Stock Certificate evidencing shares of Common Stock of the Registrant (incorporated by reference from Exhibit 4.1 to the Registration Statement on Form S-1 filed on August 29, 2012, File No. 333-183602)](http://www.sec.gov/Archives/edgar/data/1544227/000104746912008575/a2210793zex-4_1.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 4.6 | | |  | | | [Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934](https://www.sec.gov/Archives/edgar/data/1544227/000154422720000004/mlnd-20191231xex46.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 10.1+ | | |  | | | [OvaScience, Inc. 2011 Stock Incentive Plan (incorporated by reference from Exhibit 10.1 to the Registration Statement on Form 10 filed on April 11, 2012, File No. 000-54647)](http://www.sec.gov/Archives/edgar/data/1544227/000104746912004129/a2208487zex-10_1.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 10.2+ | | |  | | | [Form of Incentive Stock Option Agreement under the OvaScience, Inc. 2011 Stock Incentive Plan (incorporated by reference from Exhibit 10.2 to the Registration Statement on Form 10 filed on May 17, 2012, File No. 000-54647)](http://www.sec.gov/Archives/edgar/data/1544227/000104746912006137/a2209465zex-10_2.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 10.3+ | | |  | | | [Form of Nonstatutory Stock Option Agreement under the OvaScience, Inc. 2011 Stock Incentive Plan (incorporated by reference from Exhibit 10.3 to the Registration Statement on Form 10 filed on May 17, 2012, File No.000-54647)](http://www.sec.gov/Archives/edgar/data/1544227/000104746912006137/a2209465zex-10_3.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 10.4+ | | |  | | | [Form of Restricted Stock Agreement under the OvaScience, Inc. 2011 Stock Incentive Plan (incorporated by reference from Exhibit 10.4 to the Registration Statement on Form 10 filed on April 11, 2012, File No. 000-54647)](http://www.sec.gov/Archives/edgar/data/1544227/000104746912004129/a2208487zex-10_4.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 10.5+ | | |  | | | [OvaScience, Inc. 2012 Stock Incentive Plan (incorporated by reference from Exhibit 10.5 to the Registration Statement on Form 10 filed on April 11, 2012, File No. 000-54647)](http://www.sec.gov/Archives/edgar/data/1544227/000104746912004129/a2208487zex-10_5.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 10.6+ | | |  | | | [Form of Incentive Stock Option Agreement under the OvaScience, Inc. 2012 Stock Incentive Plan (incorporated by reference from Exhibit 10.6 to the Annual Report on Form 10-K filed on March 16, 2015, File No. 001-35890)](http://www.sec.gov/Archives/edgar/data/1544227/000104746915002286/a2223498zex-10_6.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 10.7+ | | |  | | | [Form of Nonstatutory Stock Option Agreement under the OvaScience, Inc. 2012 Stock Incentive Plan (incorporated by reference from Exhibit 10.7 to the Annual Report on Form 10-K filed on March 16, 2015, File No. 001-35890)](http://www.sec.gov/Archives/edgar/data/1544227/000104746915002286/a2223498zex-10_7.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 10.8+ | | |  | | | [Form of Inducement Nonqualified Stock Option Agreement subject to the terms of the OvaScience 2012 Stock Incentive Plan](https://www.sec.gov/Archives/edgar/data/1544227/000154422720000004/mlnd-20191231xex108.htm) | | |  | | |
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| 10.9+ | | |  | | | [Millendo Therapeutics, Inc. 2012 Stock Incentive Plan, as amended (incorporated by reference from Exhibit 10.8 to the Annual Report on Form 10-K filed on April 1, 2019, File No. 001-35890)](http://www.sec.gov/Archives/edgar/data/1544227/000155837019002660/mind-20181231ex108b324f4.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 10.10+ | | |  | | | [Form of Stock Option Agreement under the Millendo Therapeutics, Inc. 2012 Stock Incentive Plan (incorporated by reference from Exhibit 10.9 to the Annual Report on Form 10-K filed on April 1, 2019, File No. 001-35890)](http://www.sec.gov/Archives/edgar/data/1544227/000155837019002660/mind-20181231ex109fae545.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 10.11+ | | |  | | | [Sub Plan for French Residents to the Millendo Therapeutics, Inc. 2012 Stock Plan, as amended (incorporated by reference from Exhibit 10.5 to the Current Report on Form 8-K, as filed with the Securities and Exchange Commission on December 13, 2018, File No. 001-35890)](http://www.sec.gov/Archives/edgar/data/1544227/000110465918072810/a18-38204_8ex10d5.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 10.12+ | | |  | | | [Form of Stock Option Agreement under the Sub Plan for French Residents to the Millendo Therapeutics, Inc. 2012 Stock Plan, as amended (incorporated by reference from Exhibit 10.11 to the Annual Report on Form 10-K filed on April 1, 2019, File No. 001-35890)](http://www.sec.gov/Archives/edgar/data/1544227/000155837019002660/mind-20181231ex10117780b.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 10.13+ | | |  | | | [2019 Equity Incentive Plan (incorporated by reference from Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on June 13, 2019, File No. 001-35890)](http://www.sec.gov/Archives/edgar/data/1544227/000110465919035378/a19-11518_1ex10d1.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 10.14+ | | |  | | | [Form of Option Grant Package under 2019 Equity Incentive Plan (incorporated by reference from Exhibit 10.7 to the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 12, 2019, File No. 001-35890)](http://www.sec.gov/Archives/edgar/data/1544227/000155837019007932/mlnd-20190630ex107cfce16.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 10.15+ | | |  | | | [Form of RSU Grant Package under 2019 Equity Incentive Plan (incorporated by reference from Exhibit 10.8 to the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 12, 2019, File No. 001-35890)](http://www.sec.gov/Archives/edgar/data/1544227/000155837019007932/mlnd-20190630ex108da3c00.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 10.16+ | | |  | | | [Form of Stock Option Agreement under the Sub Plan for French Residents under 2019 Equity Incentive Plan (incorporated by reference from Exhibit 10.16 to the Annual Report on Form 10-K filed on March 11, 2020, File No. 001-35890)](https://www.sec.gov/Archives/edgar/data/1544227/000154422720000004/mlnd-20191231xex1016.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 10.17+ | | |  | | | [Form of Inducement Nonqualified Stock Option Agreement subject to the terms of the 2019 Equity Incentive Plan (incorporated by reference from Exhibit 10.17 to the Annual Report on Form 10-K filed on March 11, 2020, File No. 001-35890)](https://www.sec.gov/Archives/edgar/data/1544227/000154422720000004/mlnd-201912x31xex1017.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 10.18+ | | |  | | | [2019 Employee Stock Purchase Plan (incorporated by reference from Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on June 13, 2019, File No. 001-35890)](http://www.sec.gov/Archives/edgar/data/1544227/000110465919035378/a19-11518_1ex10d2.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 10.19+ | | |  | | | [Form of Indemnity Agreement between Millendo Therapeutics, Inc. and each of its directors and executive officers (incorporated by reference from Exhibit 10.1 to the Current Report on Form 8-K, as filed with the Securities and Exchange Commission on December 13, 2018, File No. 001-35890)](http://www.sec.gov/Archives/edgar/data/1544227/000110465918072810/a18-38204_8ex10d1.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 10.20 | | |  | | | [Stock Purchase Agreement, by and among OvaScience, Inc., the purchasers set forth on Schedule I thereto and Millendo Therapeutics, Inc., dated November 1, 2018 (incorporated by reference from Exhibit 10.45 to the Registration Statement on Form S-4 filed on November 2, 2018, File No. 333-227547)](http://www.sec.gov/Archives/edgar/data/1544227/000104746918006980/a2236886zex-10_45.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 10.21 | | |  | | | [First Amendment to Shareholders and Option Agreement, dated September 28, 2018 (incorporated by reference from Exhibit 4.9 to the Registration Statement on Form S-3, as filed with the Securities and Exchange Commission on November 6, 2018, File No. 333-228209)](http://www.sec.gov/Archives/edgar/data/1544227/000104746918007084/a2237017zex-4_9.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 10.22 | | |  | | | [Registration Rights Agreement, by and among OvaScience, Inc. and the persons listed on Schedule A thereto, dated November 1, 2018 (incorporated by reference from Exhibit 10.46 to the Registration Statement on Form S-4 filed on November 2, 2018, File No. 333-227547)](http://www.sec.gov/Archives/edgar/data/1544227/000104746918006980/a2236886zex-10_46.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 10.23 | | |  | | | [Second Amended and Restated Investor Rights Agreement by and among Millendo Therapeutics, Inc. and certain of its stockholders, dated December 19, 2017 (incorporated by reference from Exhibit 4.6 to the Registration Statement on Form S-3, as filed with the Securities and Exchange Commission on November 6, 2018, File No. 333-228209)](http://www.sec.gov/Archives/edgar/data/1544227/000104746918007084/a2237017zex-4_6.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 10.24 | | |  | | | [First Amendment to Second Amended and Restated Investor Rights Agreement, dated October 24, 2018 (incorporated by reference from Exhibit 4.7 to the Registration Statement on Form S-3, as filed with the Securities and Exchange Commission on November 6, 2018, File No. 333-228209)](http://www.sec.gov/Archives/edgar/data/1544227/000104746918007084/a2237017zex-4_7.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 10.25 | | |  | | | [Shareholders and Option Agreement, by and between Millendo Therapeutics, Inc. and Otonnale SAS, dated December 19, 2017 (incorporated by reference from Exhibit 4.8 to the Registration Statement on Form S-3, as filed with the Securities and Exchange Commission on November 6, 2018, File No. 333-228209)](http://www.sec.gov/Archives/edgar/data/1544227/000104746918007084/a2237017zex-4_8.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 10.26 | | |  | | | [Amended and Restated Equity Distribution Agreement dated March 4, 2020, between Millendo Therapeutics, Inc., Citigroup Global Markets Inc. and SVB Leerink LLC (incorporated by reference from Exhibit 1.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on March 4, 2020, File No. 333-230749)](http://www.sec.gov/Archives/edgar/data/1544227/000110465920028925/tm2011597d1_ex1-1.htm) | | |  | | |
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| 10.27 | | |  | | | [Lease Agreement, by and between Millendo Therapeutics, Inc. and Ann Arbor Real Estate Group, L.L.C., dated October 22, 2018 (incorporated by reference from Exhibit 10.29 to the Annual Report on Form 10-K, Filed on March 11, 2020, File No. 001-35890).](https://www.sec.gov/Archives/edgar/data/1544227/000154422720000004/mlnd-20191231xex1029.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 10.28 | | |  | | | [Lease Agreement by and between Millendo Therapeutics, Inc. and Ann Arbor Real Estate Group, L.L.C., dated February 1, 2019 (incorporated by reference from Exhibit 10.1 to the Current Report on Form 8-K, as filed with the Securities and Exchange Commission on February 7, 2019, File No. 001-35890).](https://www.sec.gov/Archives/edgar/data/1544227/000110465919006384/a19-4137_1ex10d1.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 10.29+ | | |  | | | [Executive Chair Agreement, by and between Millendo Therapeutics US, Inc. and Julia C. Owens, Ph.D., dated January 27, 2021.](mlnd-20201231xex1029.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 10.30+ | | |  | | | [Separation from Employment, by and between Millendo Therapeutics US, Inc. and Julia C. Owens, Ph.D., dated January 27, 2021.](mlnd-20201231xex1030.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 10.31+ | | |  | | | [Amended and Restated Employment Agreement between Louis Arcudi III and Millendo Therapeutics US, Inc., dated as of January 27, 2021.](mlnd-20201231xex1031.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 10.32+ | | |  | | | [Amended and Restated Employment Agreement between Jennifer Minai-Azary and Millendo Therapeutics US, Inc., dated of January 27, 2021.](mlnd-20201231xex1032.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 21.1 | | |  | | | [Subsidiaries of the Registrant.](mlnd-20201231xex211.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 23.1 | | |  | | | [Consent of Ernst & Young LLP, independent registered public accounting firm](mlnd-20201231xex231.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 24.1 | | |  | | | [Power of Attorney (included on signature page)](mlnd-20201231.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 31.1 | | |  | | | [Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002](mlnd-20201231xex311.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 31.2 | | |  | | | [Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as adopted pursuant to section 302 of the Sarbanes-Oxley Act of 2002](mlnd-20201231xex312.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 32.1^ | | |  | | | [Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rules 13a-14(b) and 15d-14(b) promulgated under the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, as adopted pursuant to section 906 of The Sarbanes-Oxley Act of 2002](mlnd-20201231xex321.htm) | | |  | | |
|  | | |  | | |  | | |  | | |
| 101.INS | | |  | | | XBRL Instance Document | | |  | | |
|  | | |  | | |  | | |  | | |
| 101.SCH | | |  | | | XBRL Taxonomy Extension Schema Document | | |  | | |
|  | | |  | | |  | | |  | | |
| 101.CAL | | |  | | | XBRL Taxonomy Extension Calculation Linkbase Document | | |  | | |
|  | | |  | | |  | | |  | | |
| 101.DEF | | |  | | | XBRL Taxonomy Extension Definition Linkbase Document | | |  | | |
|  | | |  | | |  | | |  | | |
| 101.LAB | | |  | | | XBRL Taxonomy Extension Label Linkbase Document | | |  | | |
|  | | |  | | |  | | |  | | |
| 101.PRE | | |  | | | XBRL Taxonomy Extension Presentation Linkbase Document | | |  | | |

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+     Indicates management contract or compensatory plan.

#     Confidential treatment has been granted with respect to portions of this exhibit (indicated by asterisks) and those portions have been separately filed with the Securities and Exchange Commission.

^     These certifications are being furnished solely to accompany this Annual Report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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**ITEM 16. FORM 10-K SUMMARY**

Not applicable.

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**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) 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* | | |
| March 29, 2021 | | |  | | | Louis Arcudi III  *President and Chief Executive Officer* | | |

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Louis Arcudi III and Jennifer Minai-Azary, jointly and severally, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign this Annual Report on Form 10-K of Millendo Therapeutics, Inc., and any or all amendments thereto, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises hereby ratifying and confirming all that said attorneys-in-fact and agents, or his, her or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **Signature** | | |  | | | **Title** | | | **Date** | | |
| */s/ Louis Arcudi III* | | |  | | | President, Chief Executive Officer and Director *(Principal Executive Officer)* | | | March 29, 2021 | | |
| Louis Arcudi III | | |  | | |  | | |
|  | | |  | | |  | | |  | | |
| */s/ Jennifer Minai-Azary* | | |  | | | Chief Financial Officer  *(Principal Financial Officer and Principal Accounting Officer)* | | | March 29, 2021 | | |
| Jennifer Minai-Azary | | |  | | |  | | |
|  | | |  | | |  | | |  | | |
| */s/ Julia C. Owens, Ph.D.* | | |  | | | Chairperson of the Board of Directors | | | March 29, 2021 | | |
| Julia C. Owens, Ph.D. | | |  | | |  | | |  | | |
|  | | |  | | |  | | |  | | |
| */s/ Carol Gallagher, Pharm.D.* | | |  | | | Director | | | March 29, 2021 | | |
| Carol Gallagher, Pharm.D. | | |  | | |  | | |  | | |
|  | | |  | | |  | | |  | | |
| */s/ James Hindman* | | |  | | | Director | | | March 29, 2021 | | |
| James Hindman | | |  | | |  | | |  | | |
|  | | |  | | |  | | |  | | |
| */s/ John P. Howe, III, M.D.* | | |  | | | Director | | | March 29, 2021 | | |
| John P. Howe, III, M.D. | | |  | | |  | | |  | | |
|  | | |  | | |  | | |  | | |
| */s/ Geoff Nichol, M.B., Ch.B., M.B.A.* | | |  | | | Director | | | March 29, 2021 | | |
| Geoff Nichol, M.B., Ch.B., M.B.A. | | |  | | |  | | |  | | |
|  | | |  | | |  | | |  | | |
| */s/ Carole Nuechterlein, J.D.* | | |  | | | Director | | | March 29, 2021 | | |
| Carole Nuechterlein, J.D. | | |  | | |  | | |  | | |

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